Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K121248

510(k) Summary

DEC 13 2013

Submitter Information: Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

Establishment Registration Number: 3006611221

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Name of Device:

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF System pump and LiquoGuard CSF System tube set

Classification: Shunt, Central Nervous System and Components, Class II, 21 CFR § 882.5550

Product Code: JXG

Device Description:

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The dynamic range of this system is from -15mmHg to +75 mmHg. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Use:

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure using pressure sensors and a pump, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure up to 75 mmHg and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Substantial Equivalence:

The Möller Medical LiquoGuard CSF System is substantially equivalent to the CSF drainage systems listed below with regard to intended use, design, operating principles, and materials.

Integra NeuroSciences Corporation	K030289, K032817
Codman & Shurtleff, Inc.	K061568

The Möller Medical LiquoGuard CSF System shares features with, the intracranial pressure monitor listed below (the shared features include CSF pressure monitoring, semiconductor sensor principle, display, alarm functions and data recording).

Camino NeuroCare.™ Inc.	K962928

By using the LiquoGuard CSF System, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement.

Additional details for comparing these CSF Systems are contained in Table 8 and Table 9.

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Table 8: System Comparison

Product / Component	Dipping chamber systems		ICP Monitor system	Combination
	Hermetic Plus External CSF Drainage System	CODMAN EDS 3 CSF	Multi-Parameter Monitor (MPM)	LiquoGuard CSF System
Tube set disposable	•	•		•
CSF drainage bag	•	•		•
Pressure transducer			•	•
Micro controller			•	•
Software operated			•	•
Data storage			•	•
Button / Foil keypad			•	•
Screen			•	•
Ports			•	•
Casing			•	•
Power supply			•	•

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Table 9: Device Comparison

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Reference Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure and measurement of CSF pressure.	Externally draining of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients.	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and patient.	Measurement of intracranial pressure in the ventricles and during the cerebrospinal fluid (CSF) drainage.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.	**Tubing material:** Not applicable. **Pressure sensor:** Single transducer. **CSF Collection Bag:** Not applicable.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on pressure equivalence (Pascal's law of fluid statics) inside the head.
Height alignment of patient and	Device can be positioned arbitrarily, only the pressure	Alignment is critical because it controls the	Alignment is critical because it controls the	Device can be positioned arbitrarily; the pressure sensors need to be

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Reference Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
device	sensor needs to be aligned.	target pressure.	target pressure.	incorporated.
Device adjusting fluid flow	LiquoGuard CSF System peristaltic pump controlled by pressure at sensor location.	None - fluid flow is not controlled or limited.	None - fluid flow is not controlled or limited.	No drainage.
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF System.	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.	Pressure, pressure curve and temperature are monitored and recorded.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high. * Pressure too low. * Physiological pressure pulsation lost. * Pressure remains constant for too long. * Dual sensors deviate in readings (defective sensor). * Watchdog or main controller does not respond to each other's requests (device or software malfunction). * Battery low.	No integrated alarm functions.	No alarm functions.	Few integrated alarm functions: * Pressure too high. * Battery low.

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	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Reference Device
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Measured pressure range	-15mmHg to +75mmHg.	No measurement.	No measurement.	-10mmHg to +250mmHg.
Physical dimensions	315mm x 210 mm x 280 mm (H x W x D). 4.8 kg.	-	-	274 mm x 216 mm x 89 mm (H x W x D). 4.3 kg.
Displayed parameters	Actual ICP value, ICP waveform, ICP trend. Display resolution of 1 mmHg.	No display.	No display.	Actual ICP value, ICP waveform, ICP trend, intracranial temperature, Cerebral Perfusion Pressure. Display resolution of 1 mmHg.
Sensor type	Dual transducer.	Single transducer.	No sensor.	Fiber-optic single pressure transducer.
Scheduled preventive maintenance	Every 12 months	No	No	Every 18 months
Battery	Rechargeable sealed lead acid. Charge time: 8h. Operation time: 3h.	No battery.	No battery.	Rechargeable sealed lead acid. Charge time: 8-10h. Operation time: 1-2h.

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Summary of substantial equivalence discussion

Many if not all risks leading to accidental, cerebral herniation in both systems (traditional drainage and ICP monitors) can be reduced or even eliminated by the LiquoGuard CSF System.

The LiquoGuard CSF System is working equivalently to a drip chamber, with the additional safety that, using LiquoGuard CSF System, a partial or intermittent catheter occlusion may be detected in many cases: In difference to the dripping chamber which must be an open system during drainage the LiquoGuard CSF System can measure the hydrostatic pressure inside the tube (drainage system) during drainage because the drainage system is closed, combined with a CSF pressure monitor and its features like displaying pressure values, curves and trends and enabling alarm functionality. The principles of measurement are comparable to the ICP monitor and its pressure transducer as both systems measure the pressure of the surrounding liquid. The only difference is the position of the transducers, and the fact that LiquoGuard uses dual transducers for redundancy.

The LiquoGuard CSF System behaves comparable to a traditional drainage system even in the case of a clotted catheter or collapsed ventricles. It is able to sound and display alarms to operators, is portable, can be used while not connected to the mains, records and stores data and can be connected to bedside monitor systems, same as the Multi Parameter Monitor.

By combining the functionality of dripping chambers with the features of a computer operated device (ICP monitor) and adding a peristaltic pump the LiquoGuard CSF System benefit is potentiated as some major problems are solved (elimination of sensor drift problematic, protection of accidental over and / or under drainage, pressure measurement simultaneously with CSF drainage, etc.).

Summary and Conclusion of the Performance Testing:

The LiquoGuard CSF System has the same indication for use as the predicate devices (measurement and drainage of CSF). In addition, the LiquoGuard CSF System tubing set is made from the same materials as the predicate devices, and because the risks associated with the surgical insertion of a CSF drain are not dependent on the CSF drainage system chosen, no new safety or effectiveness concerns are introduced over the predicate devices. Please refer to Table 10 for the list of bench tests – there you find a list of all bench tests that have been performed.

The test series exhibits a very wide range of performance tests and all necessary and required tests for the LiquoGuard were appropriate performed and all tests passed according to the predetermined pass/fail criteria. Particularly highlighting are tests which serve to check the pressure and alarm systems. For this purpose, a plurality of measurements has been carried out to verify the critical components.

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Table 10: List of bench test

Pressure measurement	✓ Absence of sensor drift during packaging / sterilization ✓ Absence of sensor drift during ageing ✓ Precision of displayed pressure at various pump rates and pressure loads
Pressure regulation	✓ Endurance test with in-vitro simulated patient ✓ Performance comparison with drip chamber ✓ Reliability of pump shut-off with negative pressures ✓ Device functions independent of positioning
Volume and flow measurement	✓ Precision of total volume and flow (pump rate) measurement
Alarm functions related to patient condition	✓ Pressure alarms ✓ Pulsation alarm (indication for events like: catheter occlusion collapsed ventricles and disconnected catheter) ✓ Pressure too constant (indication for events like: catheter occlusion collapsed ventricles and disconnected catheter) ✓ Influence of pressure on catheter walls ✓ Detection of clogged catheter
Alarm functions related to device functions	✓ Defective/disconnected sensors ✓ Disconnected/leaking tube set ✓ Battery low ✓ Main controller/watchdog cross-check ✓ Double safety ✓ Tube set too old ✓ Battery defective
Mechanical handling and operation	✓ Disposable check for single-use ✓ Wrong tube set insertion ✓ Opening of front panel ✓ Disposable check for age
Endurance	✓ Automatic switch to battery upon power failure ✓ Tube set durability
Other	✓ External connectivity

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Summary and Conclusion of the Clinical Study:

Drawing on the user base and combining similar, independent studies from several hospitals into one data basis, we collected 413 patient records on treatments using the LiquoGuard (LG) as well as the predicate devices (drip chambers). We identified a number of "adverse events" and compared their rate of incidence for both cases (LG vs. predicate) for the total patient population as well as certain patient categories, e.g. medical indication.

Since the two CSF drainage methods (LiquoGuard and drip chamber) apply the same therapy (drainage) to the patients, we expected to obtain similar results. Indeed, the data show a great similarity. E.g., total rates of incidence of adverse events are for each type of event very close, with most small variations in favor of the LiquoGuard.

The findings support the equivalence of LiquoGuard and the listed predicate devices.

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JXG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 13, 2013

Möller Medical GmbH
c/o Mr. Grant Geckeler
1612 Jenks Drive
Corona, CA 92880

Re: K121248
Trade/Device Name: LiquoGuard CSF System
Regulation Number: 21 CFR 882.5550
Regulation Name: Shunt, Central Nervous System and Components
Regulatory Class: Class II
Product Code: JXG
Dated: May 13, 2013
Received: September 16, 2013

Dear Mr. Geckeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number: **K121248**

Device Name: **LiquoGuard CSF System**

Indications for Use:

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure using pressure sensors and a pump, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure up to 75 mmHg and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH

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Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

April 16, 2012

FDA CDRH DMC
AUG 22 2013
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Traditional 510(k) Premarket Notification for LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**.

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis.

The **LiquoGuard CSF System** is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The **LiquoGuard CSF System** controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The **LiquoGuard CSF System** also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

The **LiquoGuard CSF System** consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Common Name:	External CSF Drainage System
Proprietary Name:	LiquoGuard CSF System
	Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification and Product Code:
21 CFR § 882.5550, "Shunt, Central Nervous System and Components", Class II, JXG

The Möller Medical **LiquoGuard CSF System** is substantially equivalent to the Central Nervous System devices "Integra NeuroSciences corporation (K030289, K032817)" and "Codman & Shurtleff, Inc. (K061568)" in terms of intended use, design, operating principles, and materials.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH

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MöllerMedical

Design and Use of the Device **LiquoGuard CSF System:**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002 _004
MM Cover Letter GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K121248/B2 A1

Möller Medical GmbH

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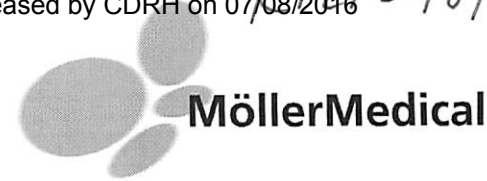

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

August 9, 2013

Food and Drug Administration
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The **LiquoGuard CSF System** consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

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Proprietary Name:	LiquoGuard CSF System
	Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

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MöllerMedical

Design and Use of the Device **LiquoGuard CSF System:**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002 _004
MM 2012-04_Cover_Letter
GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K121248/~~32~~ A1

Möller Medical GmbH

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Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

FDA CDRH DMC
AUG 08 2013
Received

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

April 16, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Traditional 510(k) Premarket Notification for LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**.

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis.

The **LiquoGuard CSF System** is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The **LiquoGuard CSF System** controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The **LiquoGuard CSF System** also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

The **LiquoGuard CSF System** consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Common Name:	External CSF Drainage System
Proprietary Name:	LiquoGuard CSF System
	Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification and Product Code:
21 CFR § 882.5550, "Shunt, Central Nervous System and Components", Class II, JXG

The Möller Medical **LiquoGuard CSF System** is substantially equivalent to the Central Nervous System devices "Integra NeuroSciences corporation (K030289, K032817)" and "Codman & Shurtleff, Inc. (K061568)" in terms of intended use, design, operating principles, and materials.

FB_002_004
MM Cover Letter GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

33

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-90
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

Design and Use of the Device **LiquoGuard CSF System:**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002_004
MM Cover Letter GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K121248-32 A1

Möller Medical GmbH

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MöllerMedical

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

FDA CDRH DMC
JUN 0 5 2013
Received

April 16, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Traditional 510(k) Premarket Notification for LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**.

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis.

The **LiquoGuard CSF System** is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The **LiquoGuard CSF System** controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The **LiquoGuard CSF System** also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

The **LiquoGuard CSF System** consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification and Product Code:
21 CFR § 882.5550, "Shunt, Central Nervous System and Components", Class II, JXG

The Möller Medical **LiquoGuard CSF System** is substantially equivalent to the Central Nervous System devices "Integra NeuroSciences corporation (K030289, K032817)" and "Codman & Shurtleff, Inc. (K061568)" in terms of intended use, design, operating principles, and materials.

FB_002_004
MM Cover Letter GWG

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MöllerMedical

Design and Use of the Device **LiquoGuard CSF System:**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002 _004
MM Cover Letter GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MöllerMedical

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

June 13, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Additional Information for Traditional 510(k) Premarket Notification K121248 LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed **Additional Information for Traditional 510(k) Premarket Notification K121248** regarding the **LiquoGuard CSF System** in response to FDA correspondence dated Mai 21, 2012. The original 510(k) Premarket Notification for the **LiquoGuard CSF System** was submitted as Traditional 510(k) on April 25, 2012.

With this amendment, Möller Medical is providing a revised Traditional 510(k) (revision 001) with citation to a second predicate device, the intracranial pressure monitor.

The revised Traditional 510(k) K121248 including all attachments is submitted in duplicate (as required) with an electronic (CD-ROM) copy serving as the second copy of the documentation.

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at +1 714 283 1683, by fax +1 714 637 2460, or by email: ggeckeler@geoinc.org.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002_004
Cover Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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Möller Medical GmbH

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MöllerMedical

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

June 13, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
MAY 29 2013
Received

Additional Information for Traditional 510(k) Premarket Notification K121248 LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed **Additional Information for Traditional 510(k) Premarket Notification K121248** regarding the **LiquoGuard CSF System** in response to FDA correspondence dated Mai 21, 2012. The original 510(k) Premarket Notification for the **LiquoGuard CSF System** was submitted as Traditional 510(k) on April 25, 2012.

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The revised Traditional 510(k) K121248 including all attachments is submitted in duplicate (as required) with an electronic (CD-ROM) copy serving as the second copy of the documentation.

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

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Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002_004
Cover_Letter_2012-06_001

25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

FDA CDRH DMC
MAY 29 2013
Received

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

April 16, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Traditional 510(k) Premarket Notification for LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**.

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis.

The **LiquoGuard CSF System** is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The **LiquoGuard CSF System** controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The **LiquoGuard CSF System** also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

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Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification and Product Code:
21 CFR § 882.5550, "Shunt, Central Nervous System and Components", Class II, JXG

The Möller Medical **LiquoGuard CSF System** is substantially equivalent to the Central Nervous System devices "Integra NeuroSciences corporation (K030289, K032817)" and "Codman & Shurtleff, Inc. (K061568)" in terms of intended use, design, operating principles, and materials.

FB_002_004
MM 2012-04_Cover_Letter
GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MöllerMedical

Design and Use of the Device **LiquoGuard CSF System:**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002 _004
MM 2012-04_Cover_Letter
GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Möller Medical GmbH
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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

MöllerMedical

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Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

May 13, 2013

FDA CDRH DMC
MAY 15 2013
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Additional Information for Traditional 510(k) Premarket Notification K121248 LiquoGuard CSF System

To Whom It May Concern:

Möller Medical submits the enclosed **Additional Information for Traditional 510(k) Premarket Notification K121248** regarding the **LiquoGuard CSF System** in response to FDA correspondence dated November 20, 2012. The original 510(k) Premarket Notification for the **LiquoGuard CSF System** was submitted as Traditional 510(k) on April 25, 2012.

With this amendment, Möller Medical is providing additional information in order for FDA to complete their review of the **LiquoGuard CSF System**. Möller Medical believes that the enclosed information provides sufficient information to allow FDA to review and provide clearance for the **LiquoGuard CSF System**.

The enclosed additional information for K121248 is submitted in duplicate with an electronic (CD-ROM) copy serving as the second copy of the documentation. Additionally, the additional information for K121248 is submitted per Email.

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the US Agent of Möller Medical GmbH Grant Geckeler at +1 714 283 1683, by fax +1 714 637 2460, or by email: ggeckeler@geoinc.org or the undersigned at +49 661 941 95 0, by fax +49 661 941 95 850, or by email: info@moeller-medical.com.

Sincerely,

Dr. Christoph Traxler
General Manager

Juliane Dragon
Regulatory Affairs Manager

23

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002_004
Cover_Letter_2013-05_000

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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MöllerMedical

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

August 9,2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Additional Information for Traditional 510(k) Premarket Notification K121248 LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed **Additional Information for Traditional 510(k) Premarket Notification K121248** regarding the **LiquoGuard CSF System** in response to FDA correspondence dated Mai 21, 2012. The original 510(k) Premarket Notification for the **LiquoGuard CSF System** was submitted as Traditional 510(k) on April 25, 2012.

With this amendment, Möller Medical is providing a revised Traditional 510(k) (revision 001) with citation to a second predicate device, the intracranial pressure monitor.

The revised Traditional 510(k) K121248 including all attachments is submitted in duplicate (as required) with an electronic (CD-ROM) copy serving as the second copy of the documentation.

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at +1 714 283 1683, by fax +1 714 637 2460, or by email: ggeckeler@geoinc.org.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002_004
Cover Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04.04.2012		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

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City: Fulda	State / Province:	ZIP/Postal Code: 36043	Country: Germany
Contact Name: Juliane Dragon			
Contact Title: Regulatory Affairs Manager	Contact E-mail Address: jdragon@moeller-medical.com		

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Contact Title:	Contact E-mail Address: ggeckeler@geoinc.org		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
PSC Publishing Services (301) 443-6740 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [x] New Device
- [x] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [x] Software/Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other*(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [x] Process change:
  - [x] Manufacturing
  - [x] Packaging
  - [ ] Sterilization
  - [ ] Other*(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other*(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason*(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent/Applicant
  - [ ] Design/Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason*(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason*(specify)*:

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JXG	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K030289	1	Hermetic Plus External CSF Drainage System	1	Integra Life Sciences Corporation
2	K032817	2	External Drainage Set	2	Integra NeuroSciences Implants S.A.
3	K061568	3	CODMAN EDS 3 CSF External Drainage System	3	Codman & Shurtleff, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

External CSF Drainage System

	Trade or Proprietary or Model Name for This Device		Model Number
1	LiquoGuard CSF	1	00002563
2	LiquoGuard CSF Tubing Set (1500mm)	2	00002650, REF. 92007836
3	LiquoGuard CSF Tubing Set (2000mm)	3	00002911, REF. 92008568
4	Safety Cushion for Tubing Set	4	00002701
5	Attachment Clamp	5	00002672

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K070099	2 K082222	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
JXG	21 CFR 882.5550	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

882 - Shunt, Central Nervous System and Components

Indications *(from labeling)*

Continous measurement of CSF pressure and CSF drainage

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Note:Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number*(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Möller Medical GmbH		Establishment Registration Number: 3006611221
Division Name*(if applicable)*		Phone Number*(including area code)*: +49 661 941 95 0
Street Address: Wasserkuppenstraße 29-31		FAX Number*(including area code)*: +49 661 941 95 850
City: Fulda	State / Province	ZIP Code: 36043 / Country: Germany
Contact Name: Juliane Dragon	Contact Title: Regulatory Affairs Manager	Contact E-mail Address: jdragon@moeller-medical.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name*(if applicable)*		Phone Number*(including area code)*
Street Address		FAX Number*(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name*(if applicable)*		Phone Number*(including area code)*
Street Address		FAX Number*(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11135-1	ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development process for medical devices	2007	04/04/2012
2	10993-7	ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008	04/04/2012
3	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2003	04/04/2012
4	60601-1-2	EN	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2002	04/04/2012
5					
6					
7					

Please include any additional standards to be cited on a separate page.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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MöllerMedical

TRADITIONAL PREMARKET NOTIFICATION [510(K)] SUBMISSION

LIQUOGUARD CSF SYSTEM

Legal Manufacturer:
Möller Medical GmbH
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

Table of revision

Revision	Description	Date
000	Issue of the 510(k)	2012-04
001	Including "Table of revision". Including secondary predicate device "Intracranial pressure monitor (ICP)".	2012-06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1. Medical Device User Fee Cover Sheet (From FDA 3601)

The MDUFMA Cover Sheet is provided in front of the 510(k).

2. CDRH Premarket Review Submission Voluntary Cover Sheet

The CDRH Premarket Review Submission Cover Sheet is provided in front of the 510(k).

3. 510(k) Cover Letter

The 510(k) Cover Letter is provided in front of the 510(k).

4. Indication for Use Statement

The Indication for Use Statement is provided **Appendix 1**.

5. 510(k) Summary

Submitter Information: Möller Medical GmbH
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36043 Fulda, Germany

Establishment Registration Number: 3006611221

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E-mail: ggeckeler@geoinc.org

Name of Device:

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF System pump and LiquoGuard CSF System tube set

Classification: Shunt, Central Nervous System and Components, Class II, 21 CFR § 82.5550

Product Code: JXG

Substantial Equivalence:

The Möller Medical LiquoGuard CSF System is substantially equivalent to the CSF drainage systems listed below with regard to intended use, design, operating principles, and materials.

Integra NeuroSciences Corporation	K030289, K032817
Codman & Shurtleff, Inc.	K061568

The Möller Medical LiquoGuard CSF System shares features with, and is substantially equivalent with regard to these features, to the intracranial pressure monitor listed below (the shared features include CSF pressure monitoring, semiconductor sensor principle, display, alarm functions and data recording).

Camino NeuroCare.™ Inc.	K962928

Device Description:

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the “gold standard” for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during

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vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Intended Use:

The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The device also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides alarm functions similar to those of intracranial pressure monitors.

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6. Truthful and Accuracy Statement

The Truthful and Accuracy Statement is provided in **Appendix 2**.

7. Class III Summary and Certification

Not Applicable.

8. Financial Certification or Disclosure Statement

Not Applicable (clinical study is conducted in Europe with a CE marked device).

9. Declarations of Conformity and Summary Reports

Not Applicable.

10. Executive Summary

10.1 Registration History

The LiquoGuard CSF System is CE marked since 2006. All over 200 devices are successfully placed on the European market, in South America, Russia, etc. without any incident.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device (see **Section 10.7**) and was extended by a secondary predicate device, the ICP monitor, to establish the substantial equivalence with regard to some of the technologies used (display, semiconductor sensor, alarm functions).

10.2 Indications for use

The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (primary predicate devices).

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The LiquoGuard CSF System also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions similar to those offered by intracranial pressure monitors (secondary predicate device).

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

10.3 Device description

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

10.4 Predicate devices with same indication

The Möller Medical LiquoGuard CSF System and the Integra LifeSciences (K030289, K032817) and Codman & Shrutleff (K061568) "primary" predicate devices listed in this application have the same indication.

10.5 Predicate device with same technological characteristics

The Möller Medical LiquoGuard CSF System and the Multi-Parameter Monitor (K962928) "secondary" predicate device listed in this application have the same technological characteristics.

10.6 Summary of substantial equivalence discussion

The LiquoGuard CSF System is a tube system with integrated redundantly designed pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CSF drainage. The intrathecal CSF drain is used independent of the LiquoGuard CSF System, and the products approved for intrathecal CSF drainage can be connected to the LiquoGuard CSF System (but are not

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part of the system). The indication for insertion of intrathecal drainage will not be affected by using the LiquoGuard CSF System.

The control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing dripping chamber systems and the LiquoGuard CSF System. The effective mechanism and the function of the CSF extraction by means of a target value-controlled rotor pump in the LiquoGuard CSF System is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard CSF System offers comparable effectiveness to existing CSF drainage systems.

The measuring sensors are comparable to the ones used in ICP monitors (Multi Parameter Monitor), as well as many functions (ICP value display, trend analysis, etc.), alarm settings (e.g. high pressure) and components (e.g. battery, display, microcontroller, etc.).

10.7 Performance Testing - Clinical

On April 8, 2009 representatives of Möller Medical and of the FDA met in Rockville to discuss the need of clinical data and the realization of a clinical trial.

After consulting the FDA the following points were defined as guideline for the planed clinical trial:

- The clinical question is one of safety – efficacy is assumed based on the fact that the CSF draining is already a gold standard in trauma and neurosurgery.
- Clinical data is requested to answer the issue of whether or not the action of the LiquoGuard CSF System pump results in a significant increase in adverse events compared to the drip chamber (predicate device).
- The clinical trial can be done by an observational study, as a control group historical data can be used.
- No scientific study will be necessary. To avoid any bias, it is sufficient to include all patients treated with the LiquoGuard CSF System in a facility over some period of time the data collection.
- The data can be collected in Europe.

On the basis of this guideline Möller Medical defined a study protocol and started the clinical trial in 2009 (please refer to **Section 20** for detailed information).

11. Device Description

11.1 Definition of drainage system

Cerebrospinal fluid (CSF) is drained from a patient using (i) a catheter placed in the third or lateral ventricle or lumbar subarachnoidal space, and (ii) a "drainage system" that removes any excessive CSF coming out of the catheter, and disposes of the fluid into a collection

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bag. Conventionally, the drainage system is a dripping chamber which works like a siphon or spill: any excessive CSF pressure leads to dripping inside the dripping chamber.

11.2 Product idea of the LiquoGuard CSF System

The key disadvantages of the conventional drainage systems are that they have no integrated alarm functions, that they are error-prone and they cannot measure ICP and drain at the same time with only one access to the patent. A wrong cock position or a clogged/disconnected catheter can lead to under- or overdrainage. This problem is solved by the LiquoGuard CSF System that replaces the drainage systems above. It consists of (a) a tube set that is connected to the catheter just like the conventional dripping chamber. The tube set contains a dual pressure sensor measuring the pressure inside the tube at the end of the catheter. The other component (b) is an electronically controlled pump removing CSF as long as the measured pressure is excessive. The LiquoGuard CSF System detects many typically occurring and dangerous situations not caught by dripping chambers and / or ICP monitors, e.g. a sudden pressure drop by an accidentally extracted catheter, or a pressure staying constant for an extended period of time (which is unphysiological and may indicate a clogged/disconnected catheter or an accidentally opened 4-way stop cock).

11.3 Components of the LiquoGuard CSF System

The LiquoGuard CSF System consists of the LiquoGuard CSF System pump and the LiquoGuard CSF System tube set.

11.3.1 LiquoGuard CSF System pump

The LiquoGuard CSF System main (see **Figure 1**) unit contains a peristaltic pump in which the tube set is inserted and connected for operation. It has a blue turning knob and three touch keys for user operation, a card slot to insert a memory card and a display to show pressure and flow values as well as a pressure and flow history. There are 5 light emitting diodes and a speaker for the audible alarms.

The main unit is software operated by a micro controller and energy supplied by mains or battery.

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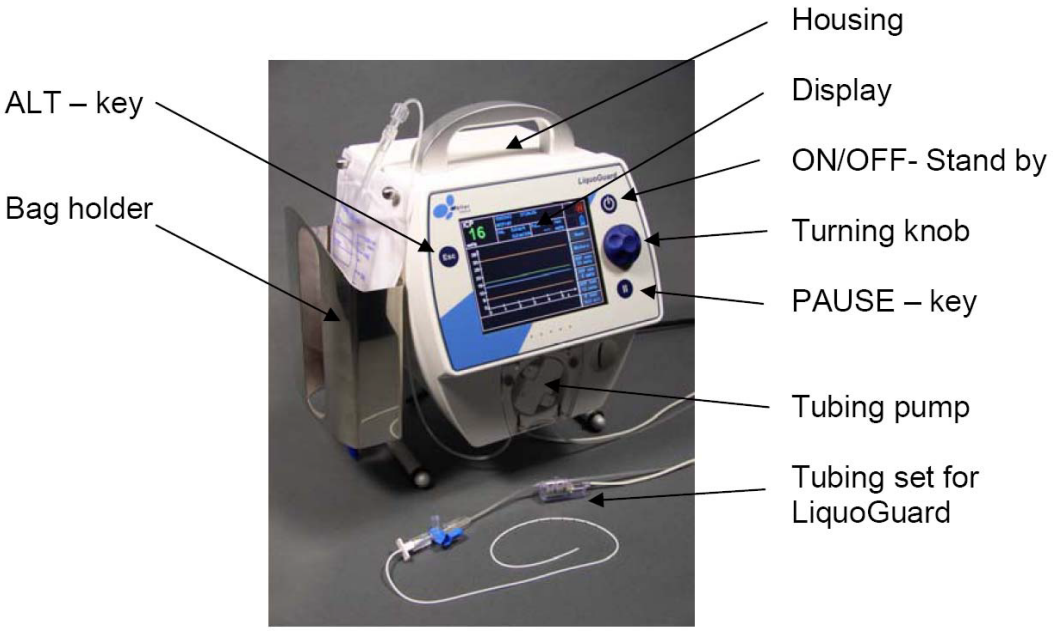

Figure 1: Front view of LiquoGuard CSF System

11.3.2 LiquoGuard CSF System tube set (disposable)

The LiquoGuard CSF System tube set consists of a polyvinyl chloride (PVC) tubing, luer locks, stop cocks, a drainage bag with a reflux valve, specially shaped plastic pieces to ensure correct insertion into the pump, and a pressure sensor housing with two piezo-resistant pressure transducers, a cable for connection to the pump and a sticker to attach the sensor housing to the patient's skin. The tube set is only for use with the LiquoGuard CSF System. Please refer to **Appendix 3** for the product materials and **Appendix 4** the packing contents.

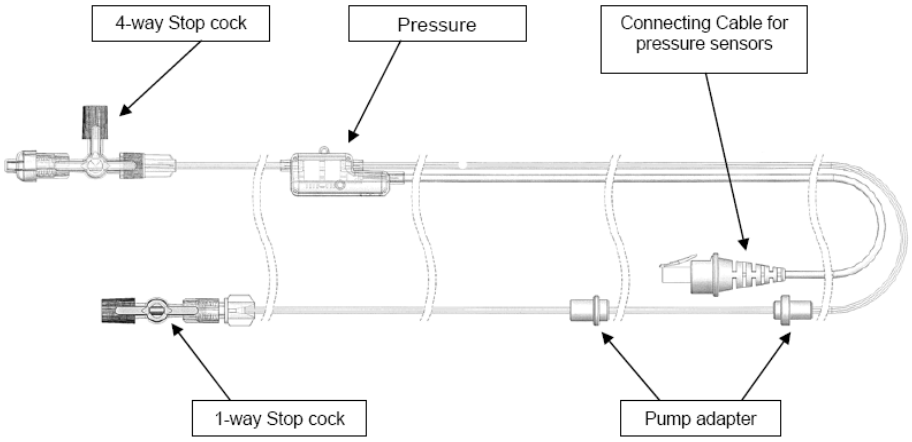

Figure 2: LiquoGuard CSF System tube set as schematic picture with its individual parts

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The tube set exists in two variants which only differ in the length of the PVC tubing (1500mm and 2000mm). All components are exactly the same. The tube set is supplied as disposable sterile product.

11.4 Principle of the LiquoGuard CSF System

The normal operation of the pump works as follows:

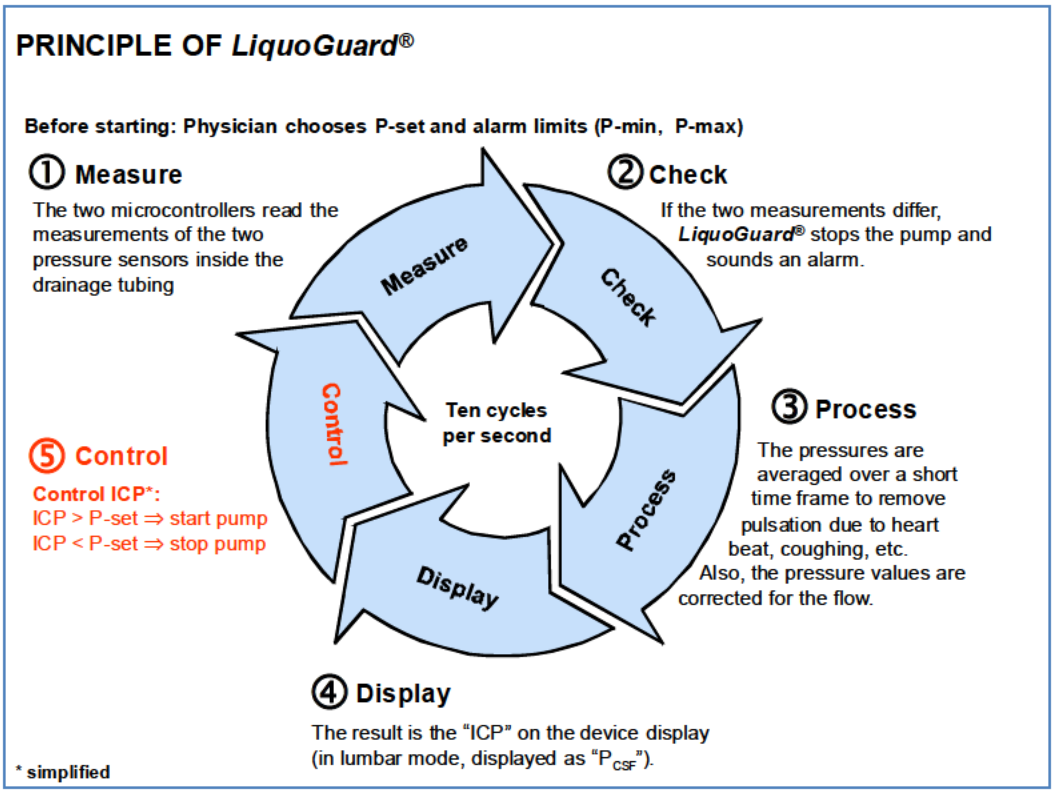

Figure 3: Principle of LiquoGuard CSF System

- Every 0.1s, read the measurements of two pressure transducers inside the tubing.
- Compare the two pressure values using the two microcontrollers of the LiquoGuard CSF System. If the resulting values differ by more than the combined tolerance of both sensors, assume that at least one of the sensors is malfunctioning: in this case, ignore all settings and all measured values, stop the pump, and sound an alarm.
- Otherwise, average the measured pressure value over the two pressure transducers and over a short time frame (configurable, standard setting 1s). The result is the CSF pressure shown on the device display – we call it simply ICP (intracranial pressure) in the following. The goal of this averaging is to remove the physiological pressure pulsations caused indirectly by the heart beat from the measurement.
- If <u>ICP is higher than P-set</u> (desired pressure, ordered by physician) by some small margin, operate the pump.
- If <u>ICP is lower than P-set</u> by some small margin, stop the pump.

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- Independently from P-set: if the measured pressure value (before averaging) is lower than the lower alarm limit, stop the pump.
- Independently from all settings: If measured pressure value (inside the tubing) is lower than 2 mmHg, stop the pump.

11.5 Details regarding the principle

11.5.1 Two microcontrollers

There are two microcontrollers. Each one has an analogue to digital converter and calculates the actual pressure inside the tube system. These values are communicated between the two controllers.

The system always displays the arithmetic average of the two measured values (the diagram shows the master controller's pressure signal). If both values differ by more than 4 mmHg, an alarm is generated, as the system can't determine which value is the correct one. If the two values are within the valid range the average of the two sensors is used to control the pump.

A comment on the “small margin” mentioned above: this is needed to prevent the pump from starting/stopping too frequently. This small margin is called the “hysteresis”; it is a standard tool in all regulating devices that use only “on” and “off”-states, like switching a pump on or off. In the case of LiquoGuard CSF System, the hysteresis value is configurable and defaults to 0.5 mmHg.

A comment on the “lower alarm limit” mentioned above: The default value of the lower alarm setting is 0 mmHg. This setting can be changed by an order of a physician, however the allowed values are restricted to be above or equal to a minimum of -15 mmHg, which is a small negative value, far too small to tear off and aspirate brain tissue. To put this into perspective, note that negative ICPs of -50 mmHg and more occur physiologically in a healthy human being.

Detailing the difference between ICP and pressure in the drainage tubing: The pressure inside the tubing is equal to the ICP by the laws of hydrostatics, if there is a non-occluded liquid column between the ventricle and the pressure sensors. As this normally is the case the measured pressure is displayed as "ICP" on the devices display. However, in the cases of catheter occlusion or collapsed ventricles (=closing of the catheter holes by brain tissue), the ICP can rise above the pressure inside the tubing. A drip chamber, working on hydrostatics alone, drains CSF depending on the pressure inside the tubing. The LiquoGuard CSF System does the same – it requires an excess pressure inside the tubing for pump operation. In the case of collapsed ventricles, the ICP may be high and yet no drainage will occur with both the drip chamber and the LiquoGuard CSF System. The effects of the two systems are thus substantially equivalent.

11.5.2 LiquoGuard CSF System alarm system

The main safety advantage of the LiquoGuard CSF System over the passive dripping chambers and solely pressure measuring ICP monitors is the combination of both systems in one device and the sophisticated alarm system: there are many potentially hazardous

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situations in which LiquoGuard CSF System will call a nurse or doctor by audible and visible alarm signals. The following is a summary of all alarms offered:

Pulsation alarm:

- LiquoGuard CSF System continuously monitors the physiological pressure pulsations caused by the heartbeat.
- LiquoGuard CSF System will sound an alarm if this pulsation is not present.
- This is a check if the liquid column between the ventricle and the pressure sensors is present.
- Possible reasons for this include catheter occlusion and collapsed ventricles (catheter holes covered by brain tissue).

Pressure alarms:

- LiquoGuard CSF System will sound an alarm if the pressure is higher or lower than the respective pre-selected alarm limits
- LiquoGuard CSF System will sound an alarm if the pressure remains constant for an extended period of time (Possible reasons include catheter problems with lumbar drainage)

Sensor cross-checking:

- LiquoGuard CSF System dual pressure sensor technology measures the pressure inside the tube with two completely independent transducers.
- Even the cables are duplicate.
- If there is any discrepancy between the two sensor readings, LiquoGuard CSF System will sound an alarm and shut the pump off as security measure.

Watchdog functionality:

- The sensor information is processed by two completely independent microcontrollers (that have been programmed by two different software engineers).
- These controllers read out the two pressure sensors and exchange their results via interprocessor communication.
- LiquoGuard CSF System will sound an audible and visible alarm and shut the pump off as security measure if there is any significant discrepancy of the data, or failure of the other controller to answer. The alarms are independent as well (different speakers and LEDs for each microcontroller).
- This technology is similar to the safety concepts of avionics in airplanes or the redundancy of powerplants.

Battery alarm:

- In mobile application, LiquoGuard CSF System monitors the remaining battery time.
- LiquoGuard CSF System will sound an alarm if the battery is low.

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11.5.3 Battery back-up

A rechargeable lead-gel battery is used as backup to ensure the system functionality for up to 3 hours while there is no mains power. The device has a charging symbol which goes down as the battery discharges. Before the battery is entirely depleted, an alarm will sound and the display will read “Battery empty, connect to AC”. After the battery alarm sounds, there is still 5-10 minutes of battery power remaining until the display goes off, at which time the alarm continues to sound for a few more minutes until the device deactivates.

Complete charging of an empty battery is approximately 8 hours.

Discharging time is getting shorter. For security reasons the rechargeable battery is replaced once a year during security checks. The device has to go into service every 12 months for checks on the security system, dual processor system, communication with pressure sensors, and battery.

11.6 Key Questions & Answers of previous 510(k) application

11.6.1 Over-drainage

In patients with elevated ICP but small/slit-like ventricles, the active removal of CSF may lead to further ventricular collapse and catheter occlusion with brain tissue or debris, necessitating catheter removal/revision with significant potential morbidity/mortality.

“The LiquoGuard CSF System does not work by “active removal of CSF”; over-drainage/aspiration is not possible. In contrast, this danger is present with the predicate device (drip chamber).

To clarify the principle of LiquoGuard CSF System: Although LiquoGuard CSF System is an “active” (electrical) device, it does not “aspirate”, meaning it never generates negative pressure. The pump only operates if the pressure inside the tube is excessive, i.e. necessarily positive (no “suction” or “aspiration”). This is equivalent to the drip chamber which drains only when the pressure inside the tube suffices to drive CSF up to the height of the drip chamber. Therefore, LiquoGuard CSF System drains CSF exactly when the properly adjusted drip chamber would, and LiquoGuard CSF System does not remove CSF under the types of conditions that a properly adjusted drip chamber would not. An “active” aspiration of tissue or debris is not possible by design, because the preset target pressure is always positive.

In contrast to the LiquoGuard CSF System, a drip chamber can aspirate tissue and debris if it is adjusted at a level lower than the patient or if it falls to the ground. In these cases, the drip chamber can generate a negative pressure inside the catheter equal to the weight of the CSF column inside the tubing, reaching from the patient to the drip chamber. For example, with a CSF density of water (1 g/ml) and a drip chamber on the ground (1 m = 3 ft below the patient), this corresponds to a negative pressure of –10 kPa = –75 mmHg, clearly dangerous for the patient.

In practice, medical personnel can be very hesitant to report such incidents, but an example can be found in MAUDE report # 1221649-1996-00006. In the case cited there, the drip chamber fell to the floor, subarachnoidal bleeding and death of the patient followed. Another example is MAUDE report # 2648988-2003-00009, where a malfunctioning

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stopcock led to over-drainage of 200 cc. Many MAUDE reports mention leakages of drip chamber-based drainage sets, which may lead to accidental and unnoticed over-drainage.

With LiquoGuard CSF System, a leaking tube set, (or disconnected catheter, malfunctioning stop cock etc.) will be detected as soon as it lowers the patient's CSF pressure level below the pre-set alarm level. Please see **Section 18** test reports 41 and 52, where the reliability of pressure alarms and the detection of disconnections are confirmed.

In small/slit-like ventricles, the catheter holes may be covered by brain tissue which prevents drainage by any gravity-fed CSF drainage system. In this case, a drip chamber fails to drain and fails to notify medical personnel. LiquoGuard CSF System, lacking an excessive pressure in the tubing, fails to drain just like the predicate device. However, LiquoGuard CSF System will most likely either sound the "pulsation invalid" alarm or the "pressure too constant" alarm in this case. Please see **Section 18** test reports 42, 43 and 44, where we confirmed the reliability of these alarms as well as the alarm consequences of a catheter occlusion.

To explain the above mentioned alarms: Normally, the pressure pulsations caused by the heart beat are detected by LiquoGuard CSF System and can be seen on LiquoGuard's display, as long as the liquid column between ventricle and pressure sensor is complete. When the catheter holes are covered by brain tissue (or the catheter is occluded, etc.), this liquid column is interrupted and the measured pulsation is lost inside the tubing, where the sensors are positioned. As soon as LiquoGuard CSF System registers no pulsations, it sounds an alarm.

To summarize, LiquoGuard CSF System places no additional risks on a patient with small/slit-like ventricles. In contrast, drip chambers – when unattended – may well place such risks.

LiquoGuard CSF System does help to detect potentially deleterious situations because of its alarm features, whereas with a drip chamber, medical personnel are not alerted to potential problems by the device."

11.6.2 Under-drainage

Patients with elevated ICP may need 5-10 cc of CSF removal quickly to avert cerebral herniation, and a fixed setting of drainage may not allow this.

"We agree that there is a risk of under-drainage, but if this happens, it will not go unnoticed. As soon as the ICP (and with it the pressure inside the tubing) raises above the pre-set alarm level of LiquoGuard CSF System, the device will sound an alarm and thus call the attention of medical personnel to the patient's condition. (No such safety feature is present with the drip chambers.) Please see **Section 18** test report 41.

The drainage rate of LiquoGuard CSF System is pre-selected and can be set as high as 50 ml/h. It can be further adjusted up to 150 ml/h using a password-protected hidden menu. Should that not be sufficient – which can be noticed by a continued alarm – the three-way stopcock of the tubing set can be connected to another drainage bag to quickly allow removal of excessive fluid.

With drip chambers, a significant risk of accidental and unnoticed under-drainage exists; causes include catheter clogging, clogging of air vents, anti-reflux valves and other kinds of blockages. In this context, refer to MAUDE # 1226348-2007-00216 where a blocked anti-

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reflux-valve was followed by patient's death. An under-drainage situation cannot go unnoticed when using the LiquoGuard CSF System (see above)."

In patients requiring lumbar intrathecal catheterization for CSF diversion (which is usually performed to allow dural healing after surgery to prevent/fix CSF leak), under-drainage may prevent sufficient CSF removal that is needed for dural closure. This would put the patient at increased risk for wound infection/meningitis.

"Especially in the cases of CSF leaks after surgery, LiquoGuard CSF System allows a very smooth and continuous drainage as the flow rate can be set to a certain rate and the device will continuously drain with this rate as long as the pressure is above a certain pre-set level.

In contrast, lumbar drainage with the predicate devices (drip chambers) is done via a very thin catheter, that can easily be occluded or squeezed and therefore lead to unnoticed under-drainage or via a nurse opening and closing the stopcock in order to get out the right amount of fluid drainage – which is difficult to control and can lead to pressure fluctuations which often cause headaches, nausea and vomiting for the patients.

Once the need for drainage is addressed, LiquoGuard CSF System offers the possibility of slowly and precisely adjusting the flow rate. This is difficult (if not impossible) with the drip chambers.

An under-drainage situation cannot go unnoticed when using LiquoGuard CSF System. Should the pressure rise above the pre-set alarm limit, LiquoGuard CSF System will sound an alarm; personnel will become aware of the problem; and adjustments to the flow rate (flush the catheter, etc.) can be made accordingly. Please see test report 41.

12. Substantial Equivalence Discussion

Primary predicate device: Dripping chamber

The LiquoGuard CSF System shares indications and essential design principles with the following predicate devices, which have been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created and the LiquoGuard CSF System is substantially equivalent to the predicate devices. Please refer to **Appendix 5** for copies of the 510(k) summaries for these substantially equivalent devices and **Appendix 6** for the clinical evaluation according to MEDDEV 2.7.1.

Table 1: Substantial Equivalence Devices – Dripping Chamber

Trade Name	510(k) Submitter/Holder	510(k) Number
Hermetic Plus External CSF Drainage System External Drainage Set	Integra LifeSciences Corp	K030289, K032817
CODMAN EDS 3 CSF External Drainage System	Codman & Shrutleff, Inc.	K061568

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Secondary predicate device: Intracranial pressure monitor

The LiquoGuard CSF System shares some technological and functional aspects with the following predicate device, which has been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created and the LiquoGuard CSF System is substantially equivalent to the predicate device. Please refer to **Appendix 5** for copies of the 510(k) summaries for these substantially equivalent devices.

Table 2: Substantial Equivalence Devices – Intracranial pressure monitor

Trade Name	510(k) Submitter/Holder	510(k) Number
Multi-Parameter Monitor (MPM) Intracranial Pressure Monitoring System	Camino NeuroCara, ™ Inc.	K962928

12.1 Indications for use

The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices).

The LiquoGuard CSF System also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions similar to those offered by intracranial pressure monitors (secondary predicate device).

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

12.2 Device design and working principle

12.2.1 Primary predicate device: Dripping chamber

A dripping chamber is a gravity-driven siphoning device. It basically functions as a spill, disposing of all fluid that rises higher in the tubing than the nozzle inside the chamber. In CSF drainage, this principle is being used to maintain a desired target pressure in the patient. Referring to **Figure 4**, the desired target pressure is defined at the Foramen of Monro (marked as a white F inside a red circle). Aligning the dripping chamber at a height Δh relative to the patient's Foramen of Monro, the fluid column inside the tubing creates, by Pascal's law, a pressure of

$$(1) \qquad P_{target} = \rho\, g\, \Delta h$$

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at the Foramen of Monro. Here, ρ is the mass density of the fluid (CSF), and g is the gravitational acceleration (9.81 m/s^2). Equation (1) is a general law of fluid statics and correct unless the catheter or tubing is clogged or not completely filled between the ventricle and the dripping chamber.

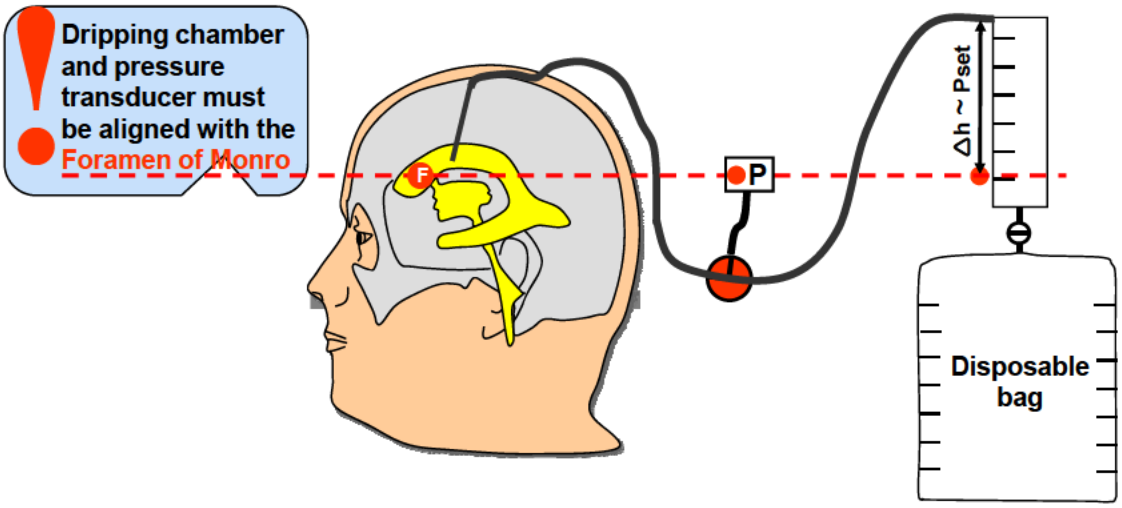

Figure 4: CSF drainage using predicate device (dripping chamber)

In the case of CSF drainage using the LiquoGuard CSF System (Figure 5), exactly the same Pascal's law states that the pressure at the Foramen of Monro must be *equal* to the pressure sensed by the dual electronic pressure sensors (box marked P in Figure 5) that are fixed outside on the patient's head at the height of the Foramen of Monro. This is again generally correct unless the catheter or tubing is clogged or not completely filled between the ventricle and the pressure sensors. LiquoGuard CSF System uses its tube pump to reduce excessive pressure sensed at the pressure sensors, using the algorithm

If sensed pressure > P_{target}, then switch pump ON.

If sensed pressure < P_{target}, then switch pump OFF.

(slightly simplified).

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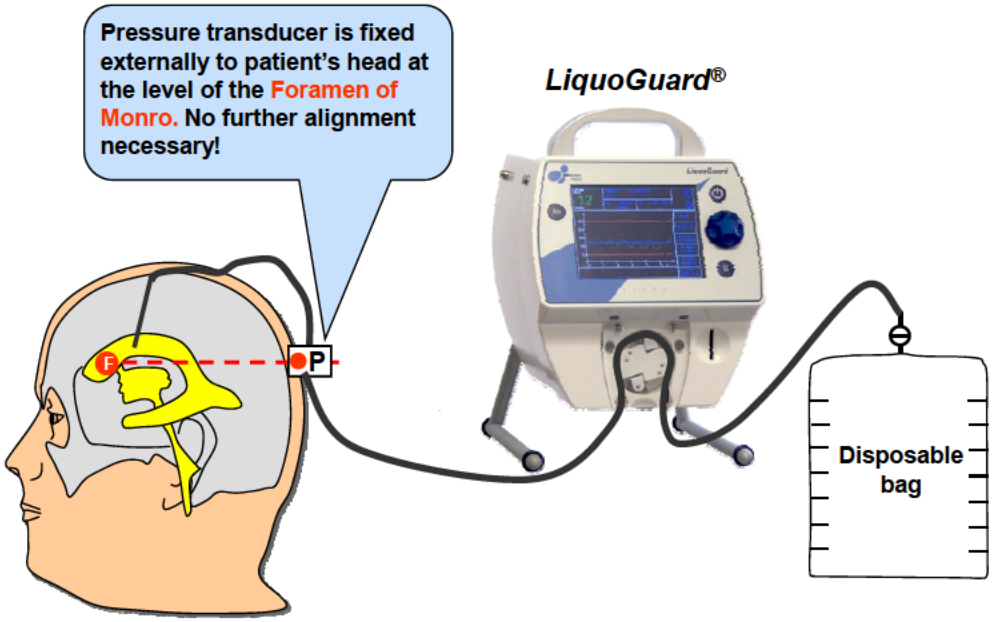

Figure 5: CSF drainage using LiquoGuard CSF System

Note the similarity between the LiquoGuard CSF System and the predicate device (dripping chamber):

- Both devices function completely ignorant of the medical indication, the protein/blood content of the drained CSF (unless that content leads to clogging), or the attached catheter.
- Both devices make use of Pascal's law and thus depend on a completely filled, unblocked fluid column in the catheter and the tubing. However, while in the case of the dripping chamber the whole tubing (1000-2000mm length) has to be filled and unblocked, for LiquoGuard CSF System only the small initial part of the tubing up to the pressure sensors (100mm) is relevant.

Note the key advantages of LiquoGuard CSF System:

- The pressure is electronically sensed and documented.
- The pressure is used by the device to monitor the drainage process.
- The device does not have to be aligned in height, only the sensor.

These advantages translate into lower risks:

- Underdrainage can happen with the dripping chamber, e.g. when the air vent or tubing is clogged, or the height alignment of the chamber is lost by a repositioning of the patient. In this context, refer to MAUDE # 1226348-2007-00216 where a blocked valve was followed by patient's death. With LiquoGuard CSF System, there is no air vent in the system, the relevant part of the tubing is much shorter (only the first 100mm to the pressure sensors are relevant), and no alignment is needed.

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Additionally, the pressure is constantly being monitored, and an alarm is signaled when the pressure leaves the pre-set safety boundaries.

- Overdrainage can happen with the dripping chamber, e.g. in the case of an accidental disconnection, or when the dripping chamber drops to the floor. In practice, medical personnel can be very hesitant to report such incidents, but an example can be found in MAUDE report # 1221649-1996-00006. In the case cited there, the drip chamber fell to the floor, subarachnoidal bleeding and death of the patient followed. Another example is MAUDE report # 2648988-2003-00009, where a malfunctioning stopcock led to over-drainage of 200 cc. Many MAUDE reports mention leakages of drip chamber-based drainage sets, which may lead to accidental and unnoticed over-drainage.

  With LiquoGuard CSF System, overdrainage because of a leaking tube set, disconnected catheter, or malfunctioning stop cock, etc. is simply impossible because the pump will stop whenever low pressure is sensed. Additionally, an alarm is signaled when the pressure leaves the pre-set safety boundaries. Please see **Section 18** test reports 41 and 52, where the reliability of pressure alarms and the detection of disconnections are confirmed.

- Catheter or tube clogging: The required fluid column has to be complete and unblocked starting from the ventricle only up to the sensors, which is only the catheter plus about 100mm of the LiquoGuard CSF System tubing. In the case of the dripping chamber, the fluid column has to be complete and unblocked all the way from the catheter to the dripping chamber (1000-2000mm). Obviously, the chances of tube clogging increase with the length of the tubing. Additionally, LiquoGuard CSF System monitors the physiological CSF pressure pulsations of the patient, and when these pulsations are lost, it sounds an alarm, indicating that something is wrong – possibly a clogged catheter.

LiquoGuard's pulsation alarm catches some of the dangerous situations not determined when using a drip chamber: As described above LiquoGuard CSF System offers an additional safety feature which is unmatched by the drip chamber. The LiquoGuard CSF System continuously monitors the physiological pressure pulsations caused by the heartbeat. With suitable settings, the LiquoGuard CSF System will sound an alarm as soon as this pressure pulsation is not present. This will in many cases detect if the liquid column between the ventricle and the pressure sensors is indeed present, i.e. if catheter is not occluded or its holes covered by brain tissue in the case of collapsed ventricles. However, although the bench test results indicate that this alarm reliably detects catheter occlusions and collapsed ventricles, Möller does **not** claim that the pulsation alarm of the LiquoGuard CSF System will determine all the aforementioned medical situations and thus sound an alarm in all these conditions. It is merely a safety feature not matched by the drip chamber. The operation of the pump is in all cases equivalent to the drip chamber, the described pulsation monitoring and alarm function is just an additional safety feature.

LiquoGuard CSF System cannot accidentally aspirate brain tissue: The pump measures the pressure **inside the tubing** and drains if **that** pressure is too high. In most cases, the pressure inside the tubing will be equal to the ICP by the laws of hydrostatics. The crucial point to note is that, if catheter occlusion occurs or the ventricles are collapsed such that brain tissue covers the catheter holes, the two pressures may be different. The LiquoGuard CSF System measures **inside the tubing** and will operate the pump only if it

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determines the pressure **inside the tubing** as excessive. The drip chamber does exactly the same – it drains if there is excessive pressure inside the tubing. Therefore, the two drainage methods are substantially equivalent. To aspirate brain tissue (which would be dangerous for the patient), a negative pressure **inside the tubing** would have to be induced by pump activity. The LiquoGuard CSF System never does that, because it is using exactly that crucial pressure **inside the tubing** to control the pump.

Patients with collapsed ventricles can drain less than 100ml/24 hours, no matter if a traditional drainage system or the LiquoGuard CSF System is being used. Therefore, a patient who has either system is at equal risk for intraventricular catheter occlusion. Since the LiquoGuard CSF System pump starts to drain CSF only in a positive pressure range, the system only drains excess pressure. This is comparable to a passive pressure valve system, such as the highly abundant implanted shunting systems which open in a positive pressure range. The LiquoGuard CSF System does not “suck out CSF”; “sucking” implies the generation of negative pressure in the tubing, which the LiquoGuard CSF System by design never allows to occur. Therefore, the LiquoGuard CSF System is equivalent to a drip chamber draining excess pressure by the principle of hydrostatics. All safety aspects of the drainage operation are therefore comparable to the predicate device of a traditional drip chamber mounted over the zero level of the patient (positive pressure).

In **traditional lumbar CSF drainage**, the volume of drained CSF is dependent on more than the pressure head of CSF and the level of drip chamber. It is dependent on:

a. Level of the head of the patient (positioning).

b. Level of the dripping chamber.

c. Diameter of lumbar drainage tube (small tube = less drainage).

d. Consistence of CSF (viscosity).

e. Passage of CSF.

f. Adaptation of dripping chamber to movement of the patient (e.g. patient stands up during drainage).

g. Intermitted occlusion of lumbar drainage due to compression e.g. by processi spinosi during retroflexion of the patient.

h. Absence of nurse during CSF drainage (system open).

i. Unnoticed disconnection of the lumbar drainage leading to high CSF outflow (which drains mostly into the bed).

This means that in several situations, uncontrolled CSF outflow can occur with traditional lumbar CSF drainage with high risks for the patient.

Patients with continued lumbar CSF drainage to a pressure of 0 mmHg may be at risk for cerebral herniation. Exactly this condition can easily and accidentally occur when using a conventional dripping chamber. This applies in particular to conditions f, h, i of the list above. In all these conditions, the traditional lumbar drainage offers **zero** safety against these risks. In contrast, the LiquoGuard CSF System safeguards against all three critical conditions:

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If the patient stands up, pressure increases, but the sampling flow of the LiquoGuard CSF System (e.g. 10 ml/h or whatever the chosen value is) will remain unchanged. Contrast this to the drip chamber, which allows in this situation an unlimited (!) outflow of CSF, e.g. more than 200 ml within a few minutes depending on parameters a-e in the list above.

The LiquoGuard CSF System is able to drain CSF continuously over an extended period of time. With the drip chamber, however, a nurse has to count the drops and adjust the level of the dripping chamber. If the nurse leaves the patient even for some minutes, the flow rate can change quickly, endangering the patient.

In this case, the LiquoGuard CSF System will detect a pressure drop to zero immediately due to the disconnection. This will lead to an alarm of the LiquoGuard CSF System. In contrast, the traditional lumbar drainage using a drip chamber does not offer any alarm system.

12.2.2 Secondary predicate device: Intracranial pressure monitor

The Multi Parameter Monitor is to be used for continuously monitoring of intracranial pressure with a pressure measurement range of -10 to 250 mmHg. In addition temperature is measured and displayed.

The Multi Parameter Monitor is compact and portable and displays the ICP value, pressure waveform, records data continuously, stores data in memory and displays trend on command. The Multi Parameter Monitor can be connected to hospital bedside monitor system and is designed for standalone use even when not connected to the mains as built in rechargeable battery permit monitoring during patient transport.

The model 110-4BT is made for use by qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma. The model 110-4HMT is made for use by qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and during the cerebrospinal fluid drainage. Both intend to be used with an external drainage system as indicated by individual manufacturers when CSF drainage is needed.

The pressure transducer generally measures the pressure of the surrounding medium. In this special case the pressure of the surrounding CSF (ventricular use) respectively the brain tissue (parenchymal use).

The pressure signal is converted into a pressure value by the software / micro controller and then displayed to the operator and device internal used for numerous functionality e.g. comparison with user set high pressure alarm value.

Note the similarity between the LiquoGuard CSF System and the secondary predicate device (intracranial pressure monitor):

The Multi Parameter Monitor and the Möller Medical LiquoGuard CSF System consist of the following main components:

- Connection between patient and device
- Data processing unit
- Data storage
- Human interfaces

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    - Screen
    - Buttons
- Connecting ports for data in- and output
- Power supply
- Casing

Both, the Multi Parameter Monitor and the Möller Medical LiquoGuard CSF System consist of all mentioned components. Differences only exist in some details without having effect on the general functionality or comparability. The Multi Parameter Monitor for example uses a fiber optical data transmission between pressure transducer and processing unit while Möller Medicals LiquoGuard CSF System uses wired communication. More differences between Multi Parameter Monitor and Möller Medicals LiquoGuard CSF System are given in **Table 4**.

Beside such minor differences the Integra MPM 1 and the Möller Medical LiquoGuard CSF System consist of the same components and are therefore directly comparable.

Note the key advantages of LiquoGuard CSF System:

- LiquoGuard CSF System stores copies of safety relevant data directly onto the transducer unit (which is connected to the patient) to ensure e.g. abide of maximum usage time. Multi Parameter Monitor has no such safety functionality.
- In various studies sensor drift of ICP sensors has been identified as a major problem during ICP measurement. LiquoGuard CSF System solves this problem as it uses two pressure transducers. Both pressure values are constantly compared by the processing unit. The for device operation used and displayed pressure values can therefore be corrected from sensor drift effect or, when the drift gets too big, the device can refuse values or the whole tube set. The big and meaningful effect of sensor drift was reviewed several times. **Appendix 61** shows two such studies.

  As Multi Parameter Monitor, such as all other ICP monitors, only display ICP values without validation of these data, the physician has no chance to review these ICP values and normally no second and independent ICP value is available, the patient is in risk of maltreatment.
- LiquoGuard CSF System has an enlarged battery running time and can therefore be used during long duration consultations (e.g. x-ray).
- No need to set the zero point anymore because LiquoGuard CSF System tube sets are already zero set when delivered.
- Measurement, recording and display of drained CSF volume.

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

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12.3 Summarizing

Many if not all risks leading to accidental, cerebral herniation in both systems (traditional drainage and ICP monitors) can be reduced or even eliminated by the LiquoGuard CSF System. There is no new risk introduced by the LiquoGuard CSF System.

The LiquoGuard CSF System is working equivalently to a drip chamber, with the additional safety that, using LiquoGuard CSF System, a partial or intermittent catheter occlusion may be detected in many cases: In difference to the dripping chamber which must be an open system during drainage the LiquoGuard CSF System can measure the hydrostatic pressure inside the tube (drainage system) during drainage because the drainage system is closed, combined with a CSF pressure monitor and its features like displaying pressure values, curves and trends and enabling alarm functionality. The principles of measurement are comparable to the ICP monitor and its pressure transducer as both systems measure the pressure of the surrounding liquid. The only difference is the position of the transducers, and the fact that LiquoGuard uses dual transducers for redundancy.

The LiquoGuard CSF System behaves comparable to a traditional drainage system even in the case of a clotted catheter or collapsed ventricles. It is able to sound and display alarms to operators, is portable, can be used while not connected to the mains, records and stores data and can be connected to bedside monitor systems, same as the Multi Parameter Monitor.

By combining the functionality of dripping chambers with the features of a computer operated device (ICP monitor) and adding a peristaltic pump the LiquoGuard CSF System benefit is potentiated as some major problems are solved (elimination of sensor drift problematic, protection of accidental over and / or under drainage, pressure measurement simultaneously with CSF drainage, etc.).

12.4 Common components of LiquoGuard CSF System and predicate devices

The Integra LifeSciences, the Codman & Shrutleff systems and the Camino Multi Parameter Monitor utilize components such as sterile tubing sets, pressure sensors, CSF drainage bags, microcontroller and interfaces that Möller Medical's LiquoGuard CSF System utilizes too. The LiquoGuard CSF System tubing set is made from polyvinyl chloride, the same material that the Integra and Codman external tubing sets are made of, along with numerous marketed I.V. administration tubing sets. The Möller Medical tubing set has two pressure transducers. The Integra tubing set and the Camino Multi Parameter Monitor also incorporate a transducer. Additionally, the Möller Medical, Integra and Codman systems all include CSF drainage bags. The Möller Medical system and the Camino Multi Parameter Monitor display values, curves and trends on a built in monitor, sound alarms via speaker and light emitting LED, are operated by pressing foil keypad buttons and are basically computer and software controlled.

By using the LiquoGuard CSF System, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement. Additional details for comparing these CSF Systems are contained in **Table 3** and **Table 4**.

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Table 3: System Comparison

Product / Component	Dipping chamber systems		ICP Monitor system	Combination
	Hermetic Plus External CSF Drainage System	CODMAN EDS 3 CSF	Multi-Parameter Monitor (MPM)	LiquoGuard CSF System
Tube set disposable	•	•		•
CSF drainage bag	•	•		•
Pressure transducer			•	•
Micro controller			•	•
Software operated			•	•
Data storage			•	•
Button / Foil keypad			•	•
Screen			•	•
Ports			•	•
Casing			•	•
Power supply			•	•

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Table 4: Device Comparison

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Secondary Predicate Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure and measurement of CSF pressure.	Externally draining of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients.	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and patient.	Measurement of intracranial pressure in the ventricles and during the cerebrospinal fluid (CSF) drainage.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.	**Tubing material:** Not applicable. **Pressure sensor:** Single transducer. **CSF Collection Bag:** Not applicable.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on pressure equivalence (Pascal's law of fluid statics) inside the head.
Height alignment	Device can be positioned	Alignment is critical	Alignment is critical	Device can be positioned

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	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Secondary Predicate Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
of patient and device	arbitrarily, only the pressure sensor needs to be aligned.	because it controls the target pressure.	because it controls the target pressure.	arbitrarily; the pressure sensors need to be incorporated.
Device adjusting fluid flow	LiquoGuard CSF System peristaltic pump controlled by pressure at sensor location.	None - fluid flow is not controlled or limited.	None - fluid flow is not controlled or limited.	No drainage.
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF System.	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.	Pressure, pressure curve and temperature are monitored and recorded.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high. * Pressure too low. * Physiological pressure pulsation lost. * Pressure remains constant for too long. * Dual sensors deviate in readings (defective sensor). * Watchdog or main controller does not respond to each other's requests	No integrated alarm functions.	No alarm functions.	Few integrated alarm functions: * Pressure too high. * Battery low.

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	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Secondary Predicate Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
	(device or software malfunction). * Battery low.			
Measured pressure range	-15mmHg to +75mmHg.	No measurement.	No measurement.	-10mmHg to +250mmHg.
Physical dimensions	315mm x 210 mm x 280 mm (H x W x D). 4.8 kg.	-	-	274 mm x 216 mm x 89 mm (H x W x D). 4.3 kg.
Displayed parameters	Actual ICP value, ICP waveform, ICP trend. Display resolution of 1 mmHg.	No display.	No display.	Actual ICP value, ICP waveform, ICP trend, intracranial temperature, Cerebral Perfusion Pressure. Display resolution of 1 mmHg.
Sensor type	Dual transducer.	Single transducer.	No sensor.	Fiber-optic single pressure transducer.
Scheduled preventive maintenance	Every 12 months	No	No	Every 18 months
Battery	Rechargeable sealed lead acid. Charge time: 8h. Operation time: 3h.	No battery.	No battery.	Rechargeable sealed lead acid. Charge time: 8-10h. Operation time: 1-2h.

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13. Proposed Labeling

13.1 Operating Manual

Please refer to Appendix 7 for a copy of the Operating Manual for the LiquoGuard CSF System. This operating manual contains diagrams, dimensions, tolerances and identifies the available accessories.

13.2 Package Labeling

Please refer to Appendix 8 for a copy of the labels for the LiquoGuard CSF System. Please refer to Appendix 9 for a copy of the labels for the sterile LiquoGuard CSF System Tubing Set, 1500mm and Appendix 10 for the copy of the labels for the sterile LiquoGuard CSF System Tubing Set, 2000mm.

Note: All labeling for product to be marketed in the U.S. will meet the U.S. labeling requirements of 21 CFR Part 801.

13.3 Catalog Numbers

The catalog number for the LiquoGuard CSF System is provided below in Table 5.

Table 5: Catalog Number for the LiquoGuard CSF System

Product Names	Catalog Number
LiquoGuard CSF System pump	00002563
LiquoGuard CSF System Tubing Set, 1500mm	00002650
LiquoGuard CSF System Tubing Set, 2000mm	00002911
Safety Cushion for LiquoGuard CSF System Tubing Set	00002701
LiquoGuard CSF System Attachment Clamp	00002672

14. Sterilization and Shelf Life

The LiquoGuard CSF System Tubing Sets are sterilized using the EtO sterilization method at the following facility:

Sterigenics
Kasteler Straße 45
Geb. G525 65203
Wiesbaden – Germany

The EtO sterilization process has been successfully validated in accordance with ISO 11135-1. In addition, the EtO residual analyze was performed according to ISO 10993-7 and all requirements were met.

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The initial sterilization validation was performed in 2006 according to ISO 11135:1994 and ISO 10993-7:1995. To meet all requirements of the revised standards a re-validation of the sterilization was performed in 2010. The validation of 2006 and 2010 together fulfill all requirements of the ISO 11135-1:2007 and the ISO 10993-7:2008.

Please refer to **Appendix 11** and **Appendix 12** for the sterility validation reports of 2006 and 2010 for the LiquoGuard CSF System Tubing Set.

The LiquoGuard CSF System Tubing Set is packaged in a blister of PETG (700µm, medical grade), sealed with a Tyvek foil which is in accordance with ISO 11607-1. Proposed shelf life is 2 years - please refer to **Appendix 13** for the accelerated aging test report.

15. Biocompatibility

Please refer to **Appendix 14** for the biocompatibility testing according to ISO 10993-1 of the LiquoGuard CSF System Tubing Set.

16. Software Validation

The software documentation is in accordance with FDA's May 2005 guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

16.1 Level of concern

The level of concern is, "Major Level of Concern", as failures or latent design flaws that could directly result in major injury or death to the patient or operator.

16.2 Software Description

The software controls the LiquoGuard CSF System pump, which means, the operation with the keys and the display as well as the rotation of the motor are controlled by software.

The LiquoGuard CSF System is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error.

16.3 Device Hazard Analysis

A device hazard analysis has been conducted on the LiquoGuard CSF System pump. To mitigate identified risks, two pressure sensors and two microcontrollers are incorporated as a double check to ensure proper functioning of the pump. Additionally, the pump will give off an audible alarm in the case that the pump is not operating properly.

Please refer to **Appendix 15** for the detailed Device hazard analysis for the LiquoGuard CSF System including the software.

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16.4 Software Requirements Specification

All software has major level of concern. Therefore, all functions are described in the verification and validation testing for the Möller Medical LiquoGuard CSF System. Please refer to Appendix 16.

16.5 Software Architecture Design

The high level software architecture design document which includes a detailed depiction of the functional units and software modules is provided in Appendix 17.

16.6 Software Design Specification

The software design specifications are summarized in the software detailed design documents. The SDS documents are listed in Table 6 below.

Table 6: Software Design Specification Documents

Software Design Specifications (SDS)	Appendix Reference
Serial communication interrupt	Appendix 18
Timer interrupt	Appendix 19
Watchdog communication	Appendix 20
Display	Appendix 21
Operation	Appendix 22
Alarm	Appendix 23
Motor control	Appendix 24
Data logging	Appendix 25
Patient monitor	Appendix 26
Measurement	Appendix 27
SD-Card	Appendix 28

16.7 Traceability Analysis

Traceability between system requirements and subsystem requirements is provided in Appendix 29.

16.8 Software Development Environment

The summary of the software life cycle development plan, including a summary of the configuration management and maintenance activities is provided in Appendix 30.

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16.9 Verification and Validation

Verification and validation of the LiquoGuard CSF System have been conducted. Please refer to Appendix 31 for the list of bench tests that have been conducted.

17. Electromagnetic Compatibility and Electrical Safety

The Möller Medical LiquoGuard CSF System pump has been tested in accordance and meets the following electromagnetic compatibility and safety standards:

Relevant Directives:

93/42/EEC: Directive of 14 June 1993 concerning medical devices.

73/23/EEC: Directive of 19 February 1973 concerning low voltage, with modification of 93/68/EEC.

Electromagnetic Immunity and Emission:

DIN EN 60601-1-2, Publication date: 2002-10: Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility - Requirements and tests.

DIN EN 55011, Publication date: 2003-08: Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement (IEC/CISPR11:1997, modified + A1:1999 + A2:2002); German version EN5501:1998 + A1:1998 + A2:2002.

Copies of the Electromagnetic Compatibility reports for LiquoGuard CSF System are included in Appendix 32.

18. Performance Testing – Bench

The LiquoGuard CSF System has the same indication for use as the predicate devices (measurement and drainage of CSF). In addition, the LiquoGuard CSF System tubing set is made from the same materials as the predicate devices, and because the risks associated with the surgical insertion of a CSF drain are not dependent on the CSF drainage system chosen, no new safety or effectiveness concerns are introduced over the predicate devices. Please refer to Table 7 for the list of bench tests - there you find a summary of all bench tests that have been performed.

Table 7: List of bench test

1. Pressure measurement		
11	**Absence of sensor drift during packaging / sterilization.** **Test Plan:** Check stability of zero-point off-set of finished tube sets before/after packaging and sterilization. **Criterion:** Absolute drift must be <1.0 mmHg.	Appendix 33

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	Test Procedure: Check stability of zero-point off-set of 50 finished tube sets before/after packaging and sterilization. **Result:** Passed.	
12	**Absence of sensor drift during ageing.** **Test Plan:** Check stability of zero-point off-set of finished tube sets before/after accelerated shelf ageing. **Criterion:** Absolute drift must be <1.0 mmHg. **Test Procedure:** Check stability of zero-point off-set of 10 finished tube sets before/after accelerated shelf ageing. **Result:** Passed.	Appendix 34
13	**Precision of displayed pressure at various pump rates and pressure loads.** **Test Plan:** Check displayed pressure with various pump rates and pressure loads. **Criterion:** Display precision ± 2 mmHg. **Test Procedure:** Use wide vessel with water at different heights to generate pressure, Pressure range -10 to +70mmHg, generate flow rate at various pump settings, no flow at pressures <2mmHg. **Result:** Passed.	Appendix 35
2. Pressure regulation		
21	**Endurance test with in-vitro simulated patient.** **Test Plan:** Check longterm stability of the system. **Criterion:** No unexpected events, no malfunction. **Test Procedure:** Use demo patient for an endurance in-vitro test over 31 days (1 month); during this time do tube set changes as foreseen. **Result:** Passed.	Appendix 36
22	**Performance comparison with drip chamber.** **Test Plan:** Verify that LiquoGuard CSF System is reacting like a drip chamber. **Criterion:** Pump is working when the drip chamber is dripping; and pump is stopping when the drip chamber is not dripping. **Test Procedure:** Use a demo set-up with drip chamber and LG (parallel); set drip chamber to certain height, adjust P-Set accordingly. Then generate varying pressure values (Use wide vessel with water at different heights to generate pressure, Pressure range -10 to +70mmHg) and verify that the pump is working when drip chamber is dripping and that the pump is stopping when the drip chamber is not dripping. **Result:** Passed.	Appendix 37
23	**Reliability of pump shut-off with negative pressures.** **Test Plan:** Verify that pump always stops at 2 mmHg.	Appendix 38

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	Criterion: Pump always stops at P-min or at 2 mmHg. **Test Procedure:** Use wide vessel with water at different heights to generate pressure, Pressure range -10 to +70mmHg, generate flow rate by pump settings 1-120 ml/h, flow must stop immediately whenever pressure drops below 2mmHg. **Result:** Passed.	
24	**Device functions independent of positioning.** **Test Plan:** Verify that changing device position has no influence on device functions/pressure readings. **Criterion:** Changing device position has no influence on device functions/pressure readings. **Test Procedure:** Use wide vessel with water at different heights to generate pressure, Pressure range -10 to +70mmHg, generate flow rate by pump settings 1-120 ml/h, flow must stop immediately whenever pressure drops below 2mmHg. Any change in the position of the device or the simulated "patient head" (vessel + sensors) must not influence the functions of the device. **Result:** Passed.	Appendix 39
3. Volume and flow measurement		
31	**Precision of total volume and flow (pump rate) measurement.** **Test Plan:** Check precision of the total volume measurement at different pump rates (flow). **Criterion:** Precision ± 15% max, for different pump rates. Check two things: total volume must be consistent with preselected flow AND displayed total volume on the device. **Test Procedure:** Use demo patient to create pressure. Generate flow rate by different pump settings; verify volume displayed on the screen (comparison with precision scale). **Result:** Passed.	Appendix 40
4. Alarm functions related to patient condition		
41	**Pressure alarms.** **Test Plan:** Check pressure alarms. **Criterion:** Alarm MUST be issued reliably (after intentional delay of 20 seconds). **Test Procedure:** Use demo patient to create high pressure and low pressure alarms. Use different settings of P-min and P-max; e.g. -15 mmHg and +75 mmHg; 0 mmHg and + 50 mmHg, 5 mmHg and +25 mmHg. Verify alarm both in and out of pause mode. **Result:** Passed.	Appendix 41
42	**Pulsation alarm (indication for events like: catheter occlusion collapsed ventricles and disconnected catheter).**	Appendix 42

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	Test Plan: Check pressure alarms. **Criterion:** Alarm MUST be issued reliably (after intentional delay of 20 seconds). **Test Procedure:** Use demo patient to create pulsations (with different amplitudes: very small amplitude, middle-sized amplitude, large amplitude). Whenever pulsation is switched off or too weak to be seen on display, an alarm MUST be triggered. **Result:** Passed.	
43	**Pressure too constant (indication for events like: catheter occlusion collapsed ventricles and disconnected catheter).** **Test Plan:** Check alarm "pressure too constant" at different settings. **Criterion:** Alarm is always issued after pressure remains constant (no changes beyond the pre-set sensitivity) for longer than 12s. **Test Procedure:** Check alarm "pressure too constant" at different settings (0.1, 0.5, 1, 2 mmHg), in and out of pause mode. **Result:** Passed.	Appendix 43
44	**Influence of pressure on catheter walls.** **Test Plan:** Verify that pressure on catheter walls (for clogged catheter) does not change reaction of device. **Criterion:** Influence of pressure on catheter walls is not measurable by the device. **Test Procedure:** Simulate clogged catheter, check influence of pressure on catheter walls. **Result:** Passed.	Appendix 44
45	**Detection of clogged catheter.** **Test Plan:** Check if an alarm is issued when there is a clogged catheter. **Criterion:** Alarm is issued (in standard settings). **Test Procedure:** Use demo patient to simulate an application; simulate a clogged catheter/tube (for lumbar drainage and ventricular drainage). Device must issue a "pressure too constant" and "pulsation" alarm with clogged catheter and standard settings. **Result:** Passed.	Appendix 45
5. Alarm functions related to device functions		
51	**Defective/disconnected sensors.** **Test Plan:** Check alarm for defective/disconnected sensor. **Criterion:** Alarm is issued after delay of 20 seconds. **Test Procedure:** Use demo patient to simulate an application; 1) disconnect sensor and wait for reaction of the device; 2) Use a defective sensor and wait for reaction of the device. **Result:** Passed.	Appendix 46

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52	**Disconnected/leaking tube set.** **Test Plan:** Verify that an alarm is issued when the tube set is pulled out of the patient's head/body or disconnected at the catheter connection. **Criterion:** Alarm is issued independent of pause mode and device settings. **Test Procedure:** Use demo patient to simulate an application; 1) disconnect tube set from catheter and wait for reaction of the device; 2) introduce leakage in tube set before the sensor position, simulating a catheter that has been pulled out of the patient's head/body. Wait for reaction of the device (both: for lumbar and ventricular drainage). **Result:** Passed.	**Appendix 47**
53	**Battery low.** **Test Plan:** Check alarm for low battery. **Criterion:** Alarm is always issued when battery is low, device still functions for some time and gives alarm until it shuts off completely. **Test Procedure:** Use demo patient to simulate an application, run device on battery as long as possible -- until device shuts off. Supervise device and note times of alarms. **Result:** Passed.	**Appendix 48**
54	**Main controller/watchdog cross-check.** **Test Plan:** Check alarm for internal device error. **Criterion:** Alarm is issued after delay of 20 seconds. **Test Procedure:** Use demo patient to simulate an application; simulate defective main controller/defective watch dog by intentionally hard-resetting the respective controller (direct manual grounding of reset line) or similar measure. **Result:** Passed.	**Appendix 49**
55	**Double safety.** **Test Plan:** The pressure signal and alarm path from sensors until speakers/LEDs is designed as two redundant, independent systems. **Criterion:** In all cases, at least one of the alarm systems works. **Test Procedure:** Simulate various malfunctions and check that an alarm is generated. **Result:** Passed.	**Appendix 50**
56	**Tube set too old.** **Test Plan:** Check alarm for old tube set. **Criterion:** After 5 days information is shown on the display that the tube set has to be changed. After 7 days an alarm is generated. **Test Procedure:** Start an application with a tube set; use tube set as long as possbible. Check that alarm is coming up. **Result:** Passed.	**Appendix 51**

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57	**Battery defective.** **Test Plan:** Check alarm for defective battery. **Criterion:** An Alarm is issued when the battery is not present or malfunctioning. **Test Procedure:** Use demo patient to simulate an application, run device on battery, remove the battery during operation. **Result:** Passed.	Appendix 52
6. Mechanical handling and operation		
61	**Disposable check for single-use.** **Test Plan:** Verify that tube set cannot be reused. **Criterion:** Message is displayed that tube set is used and a new tube set has to be used. **Test Procedure:** To trigger the message: 1) Start an application with used tube set. 2) Start an application with a new tube set, but exchange that tube set "accidentally" with a used tube set. **Result:** Passed.	Appendix 53
62	**Wrong tube set insertion.** **Test Plan:** Verify mechanical coding of tube set. **Criterion:** Tube set cannot be inserted in wrong direction. **Test Procedure:** Try to insert tube set in wrong direction -> end pieces must not fit into corresponding cut-outs (cavities) in pump case. **Result:** Passed.	Appendix 54
63	**Opening of front panel.** **Test Plan:** Verify that opening the front panel during an application does not pose a risk. **Criterion:** 1. The pump may not stop or interrupt operation upon opening of the front panel 2. The pump must be too weak to injure the operator's finger when placed into the rotating pump. **Test Procedure:** Start application. Open panel. 1. Check application is still working. 2. Check forces on a finger inserted into the rotating pump. **Result:** Passed.	Appendix 55
64	**Disposable check for age.** **Test Plan:** Verify that tube set is not too old. **Criterion:** Message is displayed that tube set is unusable. **Test Procedure:** To trigger the message: prepare a tube set with an older date but mark it as "unused". Try to start an application with this tube set. **Result:** Passed.	Appendix 56

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7. Endurance		
71	**Automatic switch to battery upon power failure.** **Test Plan:** Verify that pump continues to operate upon a power failure. **Criterion:** Pump has to continue operating without any change upon power failure. **Test Procedure:** Start application. While application is running (1. during and 2. between pump intervals) pull mains.. **Result:** Passed.	Appendix 57
72	**Tube set durability.** **Test Plan:** Check tube set durability. **Criterion:** Tube part within pump may not leak for at least 150 hours of continuous pumping at 50 ml/h speed, equivalent to a total drainage of 7,5 litres of CSF. **Test Procedure:** Start an application with a tube set; use tube set as long as possbible (until tube set leakage). **Result:** Passed.	Appendix 58
8. Other		
81	**External connectivity.** **Test Plan:** Check external connectivity (monitoring system, relay output). **Criterion:** Pressure of LG and monitoring system must be identical (within tolerance: ±2 mmHg around pressure of 0 mmHg;± 3mmHg around pressure of 20 mmHg; ± 6mmHg around pressure of 50 mmHg; relay output: must always react when alarm is issued! **Test Procedure:** Start an application, connect device to patient monitoring sytem, check if pressure on monitoring system and on LG are the same; for relay output: check if relay is acticated by the LiquoGuard CSF System with any occurrence of an alarm. **Result:** Passed.	Appendix 59

19. Performance Testing – Animal

Because the LiquoGuard CSF System has the same indication for use as the primary predicate devices (external cerebral spinal fluid (CSF) drainage) and the same technological characteristics as the secondary predicate device (intracranial pressure measurement), and because all functions can be verified and tested in bench tests, animal performance testing was not deemed necessary based on the products risk assessment.

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20. Performance Testing – Clinical

The LiquoGuard CSF System has the same indication for use as the primary predicate devices (external cerebral spinal fluid (CSF) drainage) and the same technological characteristics as the secondary predicate device (intracranial pressure measurement), and because all functions can be verified and tested in bench tests, formal clinical performance testing was not deemed necessary based on the products risk assessment.

To present the safety of the LiquoGuard CSF System a clinical trial was started in 2009, 75 cases have been collected and are included in the study report. The LiquoGuard CSF System is CE marked in Europe since 2006 where the study was performed. Please refer to **Appendix 60** for the study protocols, the results and the discussion.

21. Others

The LiquoGuard CSF System is CE marked in Europe since 2006. The LiquoGuard CSF System is an innovation in the draining of CSF and some of neurosurgeons who are working with the LiquoGuard CSF System published their experience with the device. Please refer **Appendix 61** for some published reports.

- B.M. Hoelper "Clinical study report of a new pressure and volume controlled CSF drainage system (LiquoGuard)".
- N. Klemz, B. Luther, P. Köster, T. Nowak, E. Berendes "Continuous Controlled Lumbar Spinal Fluid Drainage for Prevention of Spinal Ischemia during Thoracoabdominal Surgery of the Aorta".
- Manfred Kudernatsch, Suleyman Nauros, Peter A. Winkler (Poster) "Automatical Pressure- and Flow-Controlled Ventricular CSF Drainage LiquoGuard®: Two Years of Experience with over 50 Children in Pediatric Neurosurgery and Epilepsy Surgery".

The mentioned publications for the comparison of the LiquoGuard CSF System with the secondary predicate device "intracranial pressure monitore" are submitted in **Appendix 61**.

- M. Gelabert-Gonzáles, V. Ginesta-Galan, R. Sernamito-Gareín, A.G. Allut, J. Bandin-Diéguez and R.M. Rumbo "The Camino intracranial pressure device in clinical practice. Assessment in a 1000 cases".
- Giuseppe Citerio, M.D., Ian Piper, Ph.D., Iain R. Chambers, Ph.D., Davide Gallo, M.D., Per Enblad, M.D., Karl Kiening, M.D., Arminas Ragauska, Ph.D., Juan Sahuquillo, M.D., Barbara Gregson, Ph.D. "Multicenter Clinical Assessment of the Raumedic Neurovent-P Intracranial Pressere Sensor: A Report by the BrainIT Group.".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 1

INDICATION FOR USE STATEMENT

Back to **List of Appendices**
Back to **Chapter 4. Indication for use Statement**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com Web: www.moeller-medical.com

March 26, 2012

Indications for Use

510(k) Number (if known): TBD

Device Name: LiquoGuard CSF System

Indications for Use:
The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 2

TRUTHFUL AND ACCURACY STATEMENT

Back to **List of Appendices**

Back to **Chapter 6. Thruthful and Accuracy Statement**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH

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Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

April 04, 2012

Premarket Notification
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as general manager of Möller Medical GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Dr. Christoph Traxler, General Manager
(Typed Name)

4 APRIL 2012
(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 3

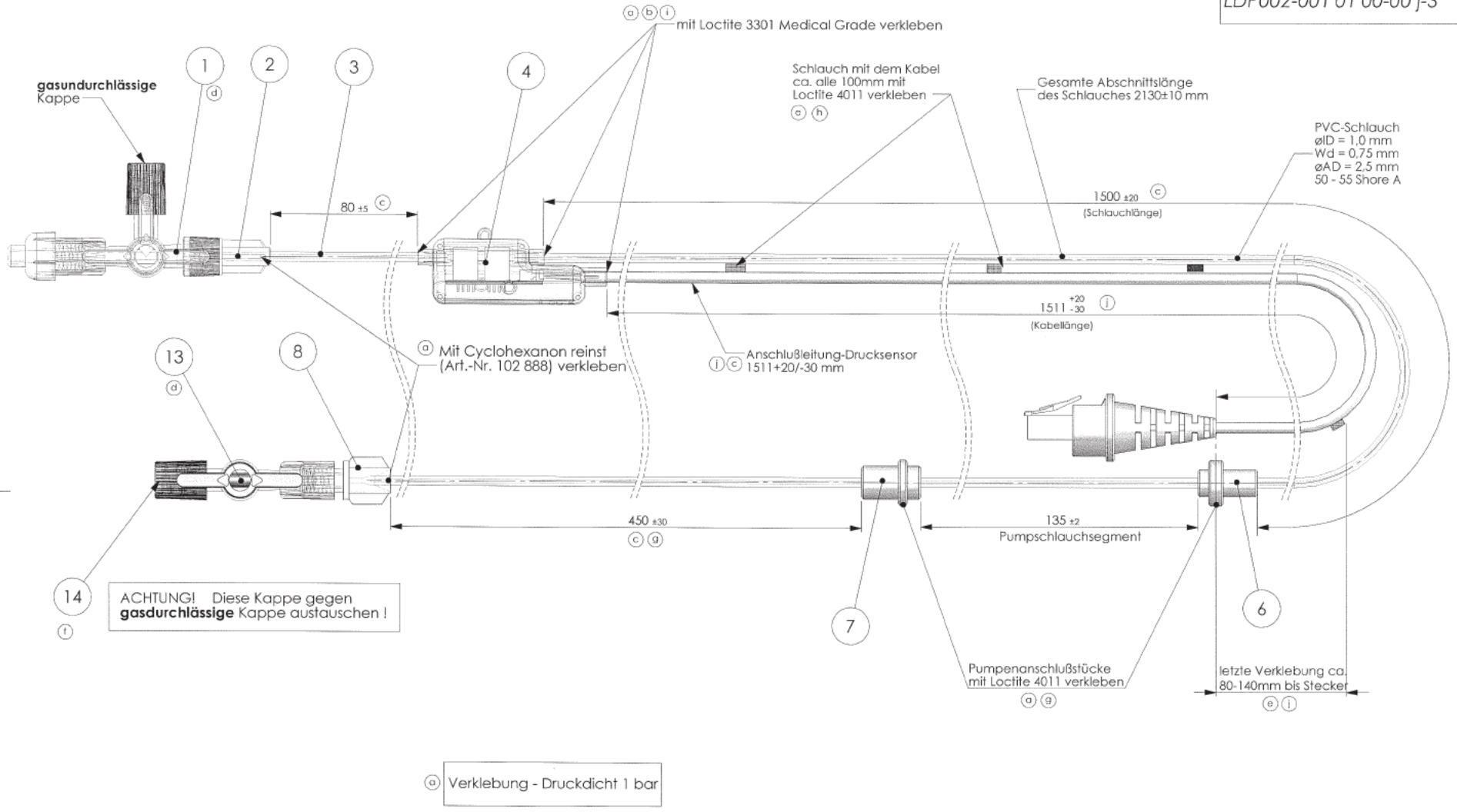
PRODUCT MATERIALS
LIQUOGUARD CSF TUBING SET

Back to **List of Appendices**
Back to **Chapter 11. Device Description**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-001 01 00-00 j-3



MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 007 836	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1
							Gewicht: Volumen:
							Werkstoff: Werkstoff-Nr.:
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i	Kleber geändert	KO 268	19.06.07	LW			
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-001 01 00-00 0-3		Ers. für: LDP002-001 01 00-00 i-3

Schlauchset 1500 mm "LiquoGuard"

LDP002-001 01 00-00 j-3

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com Web: www.moeller-medical.com

MöllerMedical

Material of the LiquoGuard CSF Tubing Set (LDP002-001 01 00-00 j-3):

No.	Part	Material
1	4-way-cock (neutral)	Polycarbonate
2	Luer-Lock (male)	Glued with cyclohexanon
3	Tubing (2,5mm x 1,0mm)	PVC 50-55 Shore A
4	Housing of pressure sensors, including the pressure sensor and the connecting cable	Makrolon glued with Loctite 3301 Medical Grade, Freescale MPX2011DT1 for medical application, Polyurethane
6	Pump adapter (broad)	Makrolon glued with Loctite 4011
7	Pump adapter (small)	Makrolon glued with Loctite 4011
8	Luer-Lock (female)	Glued with cyclohexanon
13	1-way-cock (blue)	Polycarbonate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 4

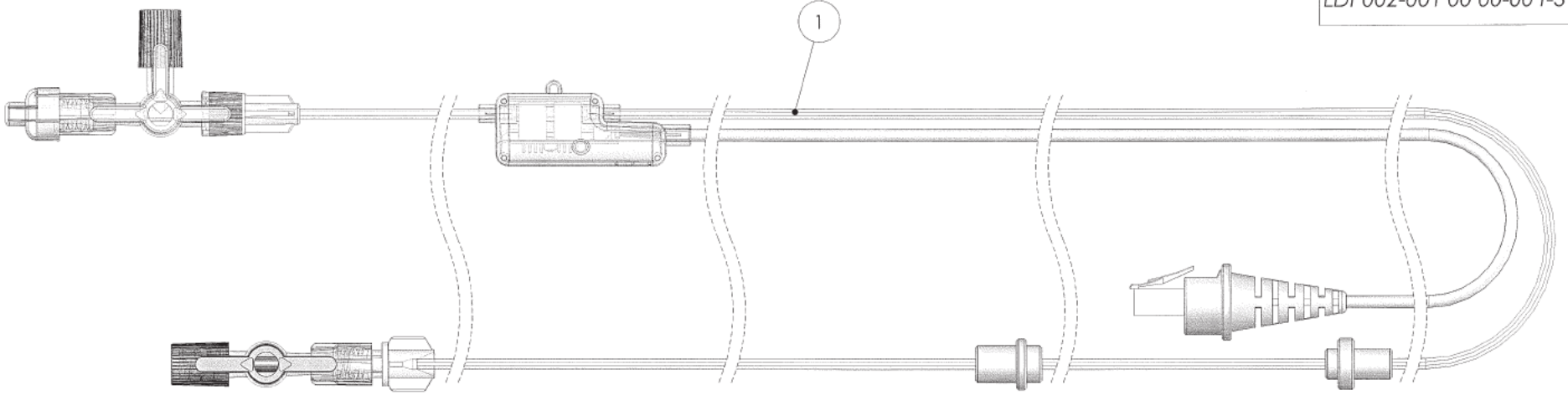
PACKAGING CONTENTS OF THE LIQUOGUARD CSF TUBING SET

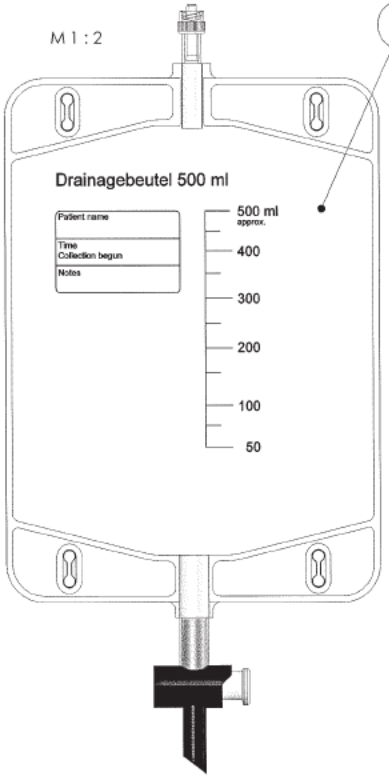
Back to **List of Appendices**
Back to **Chapter 11. Device Description**

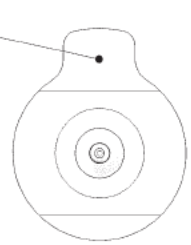
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

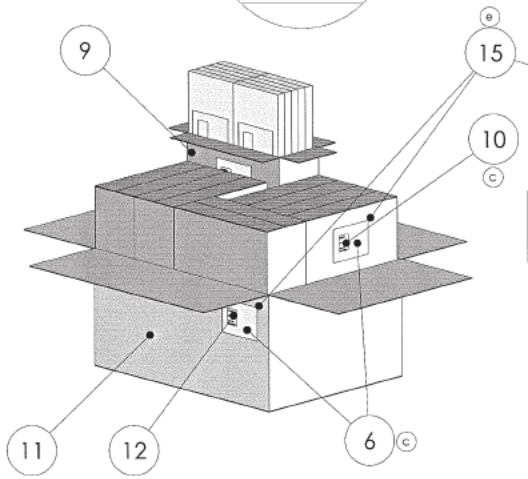
Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

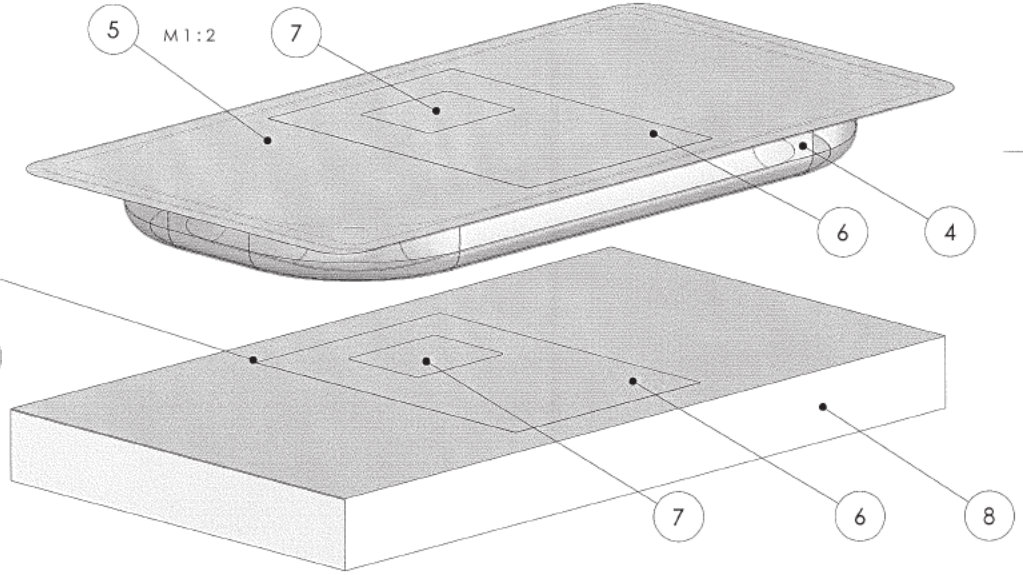
LDP002-001 00 00-00 f-3











d 13 Patientenaufkleber

d 14 Gebrauchsanweisung - Heft, mehrsprachig

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 00 002 650	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1 Werkstoff: Halbzeug:	Gewicht:	Volumen: Werkstoff-Nr.:
						Datum	Name	Schlauchset 1500 mm (VPE = 1 Stck.) "LiquoGuard" mit Zubehör / kpl. verp.	
					Bearb.	27.04.06	LW		
f	Pos. 6 geändert	KO3262	03.03.10	MÜ-De	Gepr.	03.03.10			
e	hinzu	KO 2694	19.07.07	LW	Norm				
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c	Aufkleber geändert	KO 2563	06.02.07	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.			LDP002-001 00 00-00 f-3	Blatt 1 von 1
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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E-Mail: info@moeller-medical.com Web: www.moeller-medical.com

MöllerMedical

Packaging of the LiquoGuard CSF Tubing Set (LDP002-001 00 00-00 f-3):

No.	
1	LiquoGuard CSF Tubing Set
2	CSF drainage bag
3	ECG-electrode (note: only used for attaching)
4	Blister (PETG), packaging
5	Tyvek, packaging
6	Labeling on packaging (LDP002-001 00 11-00 f-4)
7	Labeling on packaging with individual data (manufacturing date, LOT, shelf life)
8	Secondary packaging (cardboard)
9	Packing for 10 tube sets
10	Labeling on packaging for 10 tube sets
11	Packaging for 120 tube sets
12	Labeling on packaging for 120 tube sets
13	Labeling for patient data (LDP002-001 00 12-00 d-4)
14	Operating manual for tube set (30 004 036)
15	Indication button for EO Sterilization

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 5

COPIES OF THE 510(K) SUMMARIES FOR EQUIVALENT DEVICES

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Back to **Chapter 12. Substantial Equivalence Discussion**

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K030289

HERMETIC PLUS™
EXTERNAL CSF DRAINAGE SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K030289

Hermetic Plus™
External CSF Drainage System

510(k) SUMMARY

FEB 2 6 2003

Submitter's name and address:

Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Donna R. Wallace
Director, Regulatory Affairs
(609) 275-0500

Date summary was prepared:

January 24, 2003

Name of the device:

Proprietary Name:	Hermetic Plus™ External CSF Drainage System
Common Name:	External CSF Drainage System
Classification Name:	Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The Hermetic Plus™ External CSF Drainage System is substantially equivalent in function and intended use to the unmodified External CSF Drainage and Management Systems which has been cleared to market under Premarket Notification 510(k) K972994.

Intended use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure, to monitor cerebrospinal fluid, and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Device Description:

The Hermetic Plus™ External Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients. The systems connect to a ventricular or lumbar catheter via a luer connection to a patient line and ultimately to a drainage bag. The patient line is connected to a graduated burette that is then connected to the drainage bag. CSF can be collected and measured in the burette and subsequently emptied into the drainage bag by opening the stopcock placed in line between the burette and the drainage bag. An antimicrobial vent is included in the burette cap. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

antimicrobial vent used on the Hermetic Plus™ systems will allow better drainage of the CSF to the drainage bag and will resist occlusion after contact with CSF without the need for clamping the burette vent tube.

The Safety Locking Knob of the Hermetic Plus™ system will now contain a titanium screw component and the cord lock of the suspension cord has been changed to an all plastic component.

Safety

The Hermetic Plus™ External CSF Drainage Systems have been demonstrated to be MR safe* when used in the Magnetic Resonance (MR) environment.

*MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb. 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."

Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The systems have been tested for strength of bonded components, leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

Conclusion

The Hermetic Plus™ External CSF Drainage System is substantially equivalent to the unmodified External CSF Drainage Management Systems. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K032817

EXTERNAL DRAINAGE SET

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K032817

OCT - 6 2003

External Drainage Set

510(k) SUMMARY

Submitter's Name and Address:

Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France

Contact Person and Telephone Number:

Anne Bigeard
Regulatory Affairs Specialist
Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France
Telephone: 33 4 93 95 56 00

Authorized Agent in the United States:

Judith E. O'Grady
Integra LifeSciences Corporation
Sr. Vice President Regulatory, Quality and Clinical Affairs
311 Enterprise Drive
Plainsboro, NJ 08536, USA
Telephone: 609-936-2311

Date Summary was Prepared:

September 9, 2003

Name of Device:

Proprietary Name:	External Drainage Set
Common Name:	External CSF Drainage Systems
Classification Name:	Central Nervous System Shunts and Components JXG

Substantial Equivalence:

The External Drainage Set is substantially equivalent in function and intended use to the Unmodified External Drainage Set which has been cleared to market under Premarket Notification 510(k) K910853.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Use:

The External Drainage Sets are intended for cerebrospinal fluid (CSF) drainage, sampling and collection.

Device Description:

The External Drainage Set is designed for cerebrospinal fluid (CSF) drainage, sampling and collection. The system connects to a ventricular or lumbar catheter via a Luer connection to a patient line.

The graduated cylinder of the External Drainage Set is attached to an IV pole and may be moved up and down to change positioning of the graduated cylinder by using the Velcro straps. CSF can be collected and measured in the graduated cylinder and subsequently emptied to the drainage bag by opening the stopcock placed in-line between the graduated cylinder and the drainage bag.

A hydrophobic vent filter is included in the graduated cylinder cap of the External Drainage Set. This vent filter allows air to enter the graduated cylinder to facilitate drainage from the graduated cylinder to the drainage bag while protecting the system from contamination.

Safety:

The External Drainage Set is provided sterile. The External Drainage Set has been tested for tensile strength of bonded components, pressure and leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids in compliance with the Needlestick Safety and Prevention Act, H.R.5178.

Conclusion:

The External Drainage Set is substantially equivalent to the unmodified External Drainage Set. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K061568
CODMAN® EDS 3™
CSF EXTERNAL DRAINAGE SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K061568

Codman
a Johnson & Johnson company

SEP 29 2006

510(k) Summary

Submitter: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person: Jocelyn Raposo
Regulatory Affairs Specialist II
Phone Number: (508) 828-3421
Fax Number: (508) 828-2777

Date Prepared: June 2, 2006

Proprietary Name: CODMAN® EDS 3™ CSF External Drainage System
Common Name: External CSF Drainage System
Classification Name: Central nervous system fluid shunt and components

Predicate Device: K902257 External Drainage System II
K910938 External Drainage System II
K954021 External Drainage System II

Device Description: The EDS 3 system is designed to collect cerebral spinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and the patient. Collecting CSF from the patient is performed in efforts to reduce elevated intracranial pressure (ICP).

Intended Use: Use of the EDS 3 system is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

Performance Data: The fundamental scientific technology of EDS 3 is the same as EDS II. Bench testing was performed for the EDS 3 system. The modified device was deemed acceptable according to the acceptance criteria; therefore, the safety and efficacy of the product was not affected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K962928

MULTI-PARAMETER MONITOR (MPM)

INTRACRANIAL PRESSUER MONITORING SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K962928

DEC 20 1996

PREMARKET NOTIFICATION
510(k) SUMMARY

1. SUBMITTER:

Camino NeuroCare,™ Inc.
5955 Pacific Center Blvd.
San Diego, CA 92121

Donna L. Free (Contact Person)
Phone: 619-455-1115
Fax: 619-455-8298

2. DEVICE NAME:

Trade Name:	a.	Micro-Ventricular Pressure-Temperature Monitoring Kit (110-4HMT) Parenchymal Pressure-Temperature Monitoring Kit (110-4BT)
	b.	Multi-Parameter Monitor (MPM)
Common Name:	a.	Intracranial Pressure and Temperature Monitoring Kit
	b.	Multi-Parameter Monitor
Classification Name:	a.	Intracranial Pressure Monitoring System
	b.	Intracranial Pressure Monitoring System

3. PREDICATE DEVICE:

Camino NeuroCare™ Intracranial Pressure-Temperature Monitoring Kit:

Model 110-4BT is equivalent to:
Camino, Intracranial Pressure Monitoring Kit, Model 070, 853864C
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

Model 110-4HMT is equivalent to:
Camino, Micro Ventricular Pressure Monitoring Kit, Model 110-HM, K914735
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

3. PREDICATE DEVICE:

Camino NeuroCare™ Multi Parameter Monitor:

Model MPM is equivalent to:
Camino, Direct Pressure Monitor, Model V420, K893232
SpaceLabs, Patient Monitor, Model Alpha PC Patient Computer, K842616.

4. DEVICE DESCRIPTION:

The Intracranial Pressure-Temperature Monitoring System consists of a catheter and monitor. The catheter is a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. The Camino catheter has a miniature transducer and thermistor at the distal tip. The pressure transducer is identical to the Camino predicate device. The design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. The transducer is 4F, fiber optic with a pressure measurement range of -10 to 250 mmHg and a temperature measurement range of 30°C -40°C.

The Multi-Parameter Monitor (MPM) is a compact, portable device for use with Camino Pressure-Temperature catheters. The MPM measures Intracranial Pressure (ICP), Intracranial Temperature (ICT) and calculates Cerebral Perfusion Pressure (CPP). The MPM provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport. The monitor is equipped with an high ICP alarm. The dimensions are 274 mm x 216 mm x 89 mm and weighs 4.3 Kg.

5. INTENDED USE:

Model 110-4BT:
Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:
Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended to be used with an external drainage system as indicated by individual manufacturers.

6. SUBSTANTIAL EQUIVALENCE:

Pressure:
The ICP/T catheter and monitor have the same indication statements for monitoring pressure as Camino's predicate devices.

Temperature:
Predicate temperature-sensing devices include the Electromedics, Model 2403, Temperature Probe, K813459A. The predicate probes are used to measure the temperature of a target organ or tissue. Camino's temperature probe has the same use.

Nevertheless, the ICP/T has a difference in the indication statements in regard to temperature. The difference refers to the tissue in which the temperature is taken. For example, the Electromedics predicate catheter is labeled for general temperature use. Other indications include general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care, and neonatal care. The Camino probes have similar labeling in that they are for general uses that may include surgery, critical care, pediatric care and head injured patients. The Electromedics probe is labeled to take a patient's temperature in the esophagus, on the skin surface, in cardioplegia systems and in the myocardium. The Camino pressure-temperature probe is labeled to be used in the brain, with either parenchyma or ventricular placement.

Monitor:
The ICP/T monitor and both predicate monitors display pressure.
The ICP/T monitor and SpaceLabs monitor display temperature.
The ICP/T monitor and SpaceLabs monitor display Cerebral Perfusion Pressure (CPP).
The ICP/T monitor and both predicate monitors display a waveform.
The ICP/T monitor and both predicate monitors display trends.
The ICP/T monitor and both predicate monitors comply with UL Medical Equipment standards.
The ICP/T monitor and the predicate monitors comply with AAMI/ANSI Safe Current Limits standards.

7. PERFORMANCE TESTING:

Camino NeuroCare conducted animal studies to support substantial equivalence. We conducted a comparative study of the subject (test) device measuring intracranial temperature compared with a predicate device, located along side the test device, also measuring intracranial temperature over a varied temperature range. The temperature measurements were ± 0.4°C between the test device and predicate device in the 10 animals tested. These data support the claim of substantial equivalence.

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8. CONCLUSIONS

The contact area of the Camino probe is of the same design, has the same materials, and it is inserted into the body in the same manner as predicate Camino probes. Thus, the questions of safety are the same. The diagnostic effect of temperature probes for general use is to provide temperature information to a physician for whatever use he or she may choose, based on the user's training and experience. The effectiveness of a temperature probe for diagnostic or monitoring use is determined by its ability to deliver an accurate temperature reading. This is the same standard that was used for predicate devices, some of which were cleared for organs and tissues which may have been different form those for which existing predicate devices were cleared.

Based on the above information Camino NeuroCare™ Inc., concludes that the ICP/T Monitoring system demonstrates substantial equivalence to the predicate devices.

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APPENDIX 6

CLINICAL EVALUATION ACCORDING TO MEDDEV 2.7.1

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Back to **Chapter 12. Substantial Equivalence Discussion**

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Clinical evaluation for LiquoGuard

Literature route, acc. to MEDDEV 2.7.1

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Author of the summarized clinical evaluation

Personal data

Dr. med. Bernd Manfred Hölper, born 8. February 1969 in Gießen, married to Dr. med. Dörthe Inge Hölper (neè. Beinroth), 2 children (Elisabeth Clara and Alexander Bernd)

Education and basic military servicet

1975 - 1979	Krofdorf-Gleiberg Primary School
1979 – 1980	Gießen Grammar School (Landgraf-Ludwig-Schule Gießen)
1980 – 5/1989	Ignaz-Günther-Gymnasium Rosenheim, Completion 5/1989 (University Entrance, average grade A)
6/1989 – 9/1990	Training as keyboard radio operator and telecommunications technician, Air Force in Pinneberg/Lengries

Tertiary Education

10/1990 – 3/1996	Medical degree at the Georg-August University in Göttingen
8/1992	Intermediate examination
3/1996	2nd part of the examination
4/1996 – 4/1997	Practical Year: Surgery and Internal Medicine at the Reinhard-Nieter Hospital in Wilhelmshaven and Neurology at the Nordwest Hospital in Sanderbusch
21. April 1997	Completion of medical studies with a "B" average.

Dissertation

2. 7. 1997	Granting of the Degree of a Medical Doctor at the medical faculty of the Georg-August University in Göttingen with the dissertation "Computer simulation and analysis of two artificial neuronal networks oriented to neurobiological models" (Supervision: Prof. Dr. H.-O. Reiber), Grade "A".

Function as physician in practical studies

5/1997 – 9/1998	Active as intern in the neurosurgical clinic of the Fulda Clinic for a duration of 18 months

Research in Richmond/Virginia USA

10/1998 –3/1999	Research at the Commonwealth University of Richmond, Virginia (USA), Neurological Surgery in Prof. R. Bullock and Prof. A. Marmarou's work group, research on intracranial pressure and cerebral metabolism

Function as assistant physician

4/1999 – 3/2005	Active as assistant physician in the neurosurgical clinic of the Fulda Clinic
2002	Awarded the scientific prize of neurological sciences
2001 - 2003	Course participant (European Association of Neurosurgeons)

Examination for specialist

9. 3. 2005	Recognition as neurosurgical specialist at the provincial medical chamber, Hesse

Function as Specialist

Since 3/2005	Active as neurosurgical specialist at the neurosurgical clinic of the Fulda Clinic.

Research focus

Intracranial pressure measurement and intracerebral metabolism in neurosurgical intensive care, evaluation of intracranial sensors (see author's publication index), evaluation of algorithms and assessment of medical data aided by artificial intelligence (neuronal nets), development of image fusion algorithms.

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Scientific activity and author's publication index

Book (first author)

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Product name

LiquoGuard is a CSF drainage system, which is connected to an already existing intrathecal CSF drainage with the possibility to measure CSF pressure while simultaneously draining the CSF. The volume of drained CSF hereby depends on the CSF pressure measured by the system and on the maximum drainage volume defined by the operator.

Product manufacturer

The manufacturer of the product LiquoGuard and its set of consumables is Möller Medical GmbH & Co KG, Wasserkuppenstr. 29-31, 36043 Fulda, Germany.

Purpose

The LiquoGuard system consists of disposable consumables (CSF drainage system) and a control/pump unit. The purpose of the system is to measure CSF pressure in the CSF drainage system and to remove CSF at a determinable quantity via a surgically installed intrathecal CSF drainage, which was selected and installed by medical staff independent of the LiquoGuard system and whose indication does not depend on the use of the LiquoGuard system.

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Indications

Pathophysiological principles for the indication of intrathecal space puncture
The nervous system (brain, meninges) is surrounded by cerebro-spinal fluid (CSF) (6, 20). The production and resorption of CSF is in a stable balance (6, 10). Diseases or injuries to the nervous system or its surroundings e.g. hemorrhages, infections, tumors, cranio-cerebral injury or deformities can disrupt the balance between CSF production and resorption; a collection of CSF in the brain or in the meningeal area can then lead to increased pressure on the nervous system, which could lead to irreversible damage, severe permanent damage or even to death (1, 9, 10, 12-14, 18-20, 22, 24). In order to avoid this potentially life-threatening situation, CSF is drained to the outside (intrathecal CSF drainage) (7, 10, 13, 23). Analogue to this, lumbar CSF drains are used, which are not installed for the correction of a life-threatening situation, but serve the correction of a CSF fistula or the diagnosis of a chronic pathological collection of CSF (normal pressure hydrocephalus).(2, 3, 7, 15, 23)

"**Gold Standard" for the treatment of dysfunctional CSF circulation**
The essential basis for intrathecal CSF drainage is the installation of a drainage system in the CSF space. This is performed via ventricle drainage (usually consisting of silicon or polyurethane) or a stainless steel cannula (e.g. Duisburg needle) (7). Lumbar drainage is achieved by inserting a thin silicon catheter into the intrathecal space (2). Both procedures represent today's "Gold Standard" for intrathecal CSF drainage in dependence of the disease and therapy objective (10, 13). A CSF drainage system is connected to this CSF conductor, independent of the use of the LiquoGuard system. This CSF drainage system is either a system already established on the market or it may be the LiquoGuard system. All operative steps to install the intrathecal CSF drain must be carried out according to the respective indication, independent of the CSF drainage system used later.

Indication for temporary intrathecal liquor drainage
Fundamentally, the LiquoGuard system does not change the indication for intrathecal liquor drainage in any patient, nor does it influence the therapeutical concept, type of treatment, therapy objectives or therapy duration. The LiquoGuard system constitutes a liquor drainage system, whose most important characteristics comply to other liquor drainage systems on the market. Therefore the listed indications for liquor drainage must be understood in the broadest sense, without presupposing the use of the LiquoGuard system or a comparable liquor drainage system, as these systems are interchangeable with each other at all times without the need for a change in therapy or further surgery.

- **Communicating hydrocephalus:** This summarizes all clinical pictures in which liquor production is temporarily in disproportion to liquor resorption, usually during cerebral hemorrhage (subarachnoid hemorrhage, intraventricular hemorrhage), encephalitis and cranial-cerebral injuries. In most cases the cause is resorption dysfunction by obstruction of the Paccioni granulation. There is no alternative treatment to intrathecal liquor drainage for these clinical pictures.
- **Non-communicating hydrocephalus:** Liquor drainage is impaired by a partial or complete occlusion of the liquor draining paths. This may occur through masses (tumors, cysts, hemorrhage, congenital malformation) near

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the foramen Monroi, the 3rd ventricle, the aquaduct, the 4th ventricle or the foramen Monroi and the foramina Luschkae.

- **Therapy-resistant cerebral swelling:** The application of liquor drainage may be indicated in therapy-resistant cerebral swelling caused, for example, by cranial-cerebral injury, cerebral hemorrhage or subarachnoid hemorrhage or by cerebral swelling due to tumors, inflammation or hypoxia, in order to reduce intracranial pressure and to bypass trepanation (the removal of a cranial bone).

Treatment alternatives to CSF drainage

- **Endoscopy:** In a few cases of non-communicating hydrocephalus, endoscopic windowing (e.g. of the lamina terminalis) may be created to communicated with the external CSF paths. However, this is not indicated in all cases of non-communicating hydrocephalus, can only be performed by a few, specially trained neurosurgeons who possess the appropriate equipment (endoscope) and who are available at the required time. However, external CSF drainage cannot be replaced by endoscopic windowing for all clinical pictures of non-communicating hydrocephalus.
- **Therapy-resistant cerebral swelling:** After exhausting all medicinal forms of therapy, the removal of a part of the cranial bone can lead to effective relief of the intracranial pressure. The indication as to when external CSF drainage or cranial bone removal is performed depends on the primary disease, etiopathology, brain swelling dynamics, patho-physiological mechanisms, the patient's age, his overall condition, the prognosis and ventricle width and must be individually decided by the neurosurgeon. As the surgical risk of CSF drainage is considerably lower than that of cranial bone removal, CSF drainage at the appropriate medical indication and tenability is preferred to removal of cranial bone.
- **Shunt implantation**: As a shunt represents an implantable, permanent CSF drainage system and external CSF drainage represents temporary CSF relief, shunt implantation is no alternative treatment option to CSF drainage.

Contraindications

The contraindications do not apply to the use of a liquor draining system such as the LiquoGuard system, but to the application of intrathecal liquor drainage itself. As, however, liquor discharge is only applied in connection with liquor drainage, contraindications described below are in connection with the application of external liquor drainage only.

- **Absolute operative contraindications:** Coagulopathy, thrombocythemia.
- **Relative operative contraindications:** In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does the simultaneous intake of intrathecal antibiotics in the case of ventriculitis.
- **Indication for permanent liquor drainage:** If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculo-peritoneal shunt or a ventriculo-atrial shunt.

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PRODUCT DESCRIPTION

LiquoGuard system components
The LiquoGuard system consists of two components:

1. **Disposable tubing set:** CSF drainage system with male Luer lock connection (3-way cock) to connect to an already surgically installed intrathecal CSF drainage. Distal to the proximal Luer lock connection (3-way cock) is an attached pressure measurement device, in which two piezo-resistant pressure sensors, attached independent of one another, measure CSF pressure within the tube lumen. Both sensors are embedded in a die-cast component; a connection from the tube lumen to the outside does not exist. An attachment clamp is installed in the die-cast component enabling the attachment to a standard electrode with a press-stud. A cable anchored and connected to the pressure sensor electronics can be connected to a confusion proof socket in the LiquoGuard device. A compressible tubing system is distally integrated to the pressure sensors, which can be inserted into a rotor pump. A CSF collecting bag with a reflux valve is attached to the distal end of the tubing system via a 3-way cock.
2. **LiquoGuard device:** LiquoGuard consists of a casing with a transport attachment (bed, crossbeam, round rod) containing the dually installed evaluation electronics of pressure sensors, drive electronics for the rotor pump incl. the rotor pump, drive electronics for the monitor incl. the monitor, process electronics for input via keyboard and operating wheel, the internal power source (battery) incl. mains connection, the display for illustration of various values and data, alarm light emitting diodes, the loudspeaker for audible alarm emittance, the card slot for the insertion and removal of the memory card, the internal memory electronics and the connecting socket for external power supply as well as pressure sensors.

LiquoGuard system functionality
The CSF drainage system is inserted into the rotor pump by lifting the safety flap, whereby the arresting pins in the pump have been designed to be confusion-proof. After connecting the pressure sensor cable to the LiquoGuard device and after switching on the LiquoGuard device, zero calibration must be carried out on both pressure sensors. The CSF drainage system can then be connected to the previously and surgically installed intrathecal CSF drainage. Intrathecal CSF drainage is not a component of the LiquoGuard system; all approved intrathecal CSF drainage systems available on the market may be used. An indication for the installation of intrathecal CSF drainage does not depend on the use of the LiquoGuard system (consumable goods or LiquoGuard device). The housing with the integrated pressure sensors must be attached at the assumed CSF zero height. In the case of intracranial application an adhesive electrode is attached to the head near the audible tract, the external anatomic landmark of the foramen Monroi, in the case of intrathecal spinal application at the height of the proximal end of the catheter. In accordance with current literature, alignment of the zero point in intracranial application should be at the height of the foramen Monroi; the zero point in intraspinal application is at the height of the intrathecal catheter end (10). The casing with its integrated pressure sensors can be clipped to this adhesive electrode. Setting

Setting of therapy-specific parameters
A therapy during reclining CSF drainage is performed irrespective of the CSF drainage system only once CSF has been drained. In this respect CSF drainage

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under all clinical conditions is only required as of a positive intrathecal pressure. The height of the positive intrathecal pressure, as of which CSF is drained, depends on the disease and etiopathology and is determined individually by medical staff, entered as CSF target pressure into the LiquoGuard device via the suitable input interfaces and shown in the display. The pressure sensors continuously record CSF pressure. If the CSF target pressure is exceeded, the rotor pump is started. CSF is removed by the rotation of the pump, conveyed through the CSF drainage system and pumped into the CSF collecting bag. The pump stops once the pressure in the drainage system returns to the specified target pressure. This control keeps the patient's CSF pressure within a pre-defined range (predefined target pressure ± Hysteresis, resulting from the regulation, whereby the height of hysteresis is adjustable, e.g. 0.5 mmHg). As the closed measurement system enables continuous CSF pressure measurement, CSF drainage over and above the target pressure is not possible. The volume and speed of CSF drainage can be controlled by rotational speed and run-time of the pump. The CSF target volume parameter specified by medical staff is used in this respect. This parameter limits the maximum delivery rate and simultaneously defines the speed of CSF drainage. If the intrathecal pressure lies above or below the upper or lower CSF pressure alarm limit, an optical and audible alarm is triggered.

Diagnosis-specific parameters

The LiquoGuard system displays the diagnosis-specific parameter "intrathecal pressure" (ICP) and the drained volume of CSF.

- **Intrathecal CSF pressure:** After zero point calibration performed at startup of the disposable consumable articles, the two pressure recorders of the tubing set integrated into one casing are attached at foramen Monroi level. The CSF pressure column between the intrathecal catheter and the pressure sensors is the existing intracranial pressure. This pressure is not only the control pressure for the LiquoGuard's rotor pump but also represents the Gold Standard for determining intracranial pressure (10, 13). Further diagnostic and therapeutical measures depend on this measurement value. As each set of consumables can be used only once due to an internal electronic registration, repeat pressure measurement or one during application (with existing pressure) is not possible.
- **Drained CSF volume:** The diameter of the tube inserted in the rotor pump and the rotation of the rotor pump defines the volume of drained CSF. This volume is electronically displayed (ml/min, ml/h, ml/24h). The collecting bag also has a measurement scale which enables reading and controlling of the drained liquid volume. The drained CSF volume can indicate an imbalance between CSF production and CSF resorption. The therapeutical consequences may be a permanent CSF drainage (shunt) for the patient.

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Literature research on comparable products with the same purpose (including reasons of comparability)

Literature selection

External CSF drainage has been an established and standardized procedure in neurosurgery for many years, and beyond question in the entire current neurosurgical literature. As the LiquoGuard system does not represent a change in intrathecal drainage, its indication and therefore a possible increase in complications, generally acknowledged textbooks are used in literature evaluation with regard to CSF drainage effectiveness. Data sources for the creation of a literature overview were Medline, Pubmed, including the database of the National Center for Biotechnology Information (NCBI, www.ncbi.nlm.nih.gov) as well as library indexes on neurosurgical textbooks. Additionally, current convention reports of the Deutsche Gesellschaft für Neurochirurgie (DGNC) during the last five years were taken into consideration. Internet research via current search machines (yahoo, google) on intracranial pressure and CSF drainage was also carried out. Overview work from the most important and most renowned neurosurgical textbooks were used for citations on the topic of CSF drainage. Book articles were cited for respective questions regarding the accuracy of pressure sensors, which summarize numerous clinically recognized articles and were written by globally recognized specialists in their respective fields. As CSF drainage is an established, standardized method, book articles were mostly reverted to in connection with indication. Due to the utilization of large overview work published by different authors and various publishers worldwide, there is no indication that important, even negative literature was not used and would therefore distort literature research. No literature sources were explicitly excluded. Citations with an unfavorable or negative evaluation, which limit the use of the LiquoGuard system, are unknown. All used publications stem from recognized, scientific publications and were written by acknowledged experts. The objective of a literature evaluation is the illustration on the necessity of CSF drainage and the illustration of existing CSF drainage systems and pressure measurement systems, their technical details and compliance to the LiquoGuard system.

External CSF drainage

External CSF drainage is comprised of two systems: a catheter/cannula (intrathecal CSF drainage) inserted into CSF space and a CSF drainage system attached to this intrathecal CSF drainage (10, 17).

Intrathecal CSF drainage

The removal of CSF requires the surgical installation of an approved catheter or cannula into intrathecal space. This operative procedure is required for respective indications (subarachnoid bleeding, cerebral hemorrhage, brain tumors, inflammation of CSF paths, displacement of CSF-efferent paths due to tumors and swelling, cranio-cerebral injuries) and undisputed in the entire neurosurgical literature as well as life-saving in many cases.(1, 9, 10, 12-14, 18-20, 22, 24) Although the insertion of intrathecal CSF drainage is a prerequisite for using the LiquoGuard system, it does not change the indication of intrathecal CSF drainage due to its comparability with previous systems. All intrathecal CSF drainage catheters with female Luer lock connections approved for intrathecal CSF drainage, which can be connected to available CSF drainage systems, can also be connected to the LiquoGuard system. The use of intrathecal CSF drainage is in complete compliance and comparability with regard to the application of the system.

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CSF drainage system
All CSF drainage systems are connected to the intrathecal CSF drainage and serve the measurement of the intrathecal pressure as well as the removal of CSF.(10, 17)(10, 17) A CSF drainage system consists of various components which in their totality result in a functional system. These system components of systems established on the market are described below and compared to the LiquoGuard drainage system. The procedure is carried out under the same clinical condition, for the same clinical purpose of CSF drainage at the same part of the body on comparable patients (including age, anatomy, and physiology). CSF is identical; the same materials are brought into contact with the same human body fluids (CSF). Technically speaking, the identical version (Luer lock connection) with the same design exists if we compare the LiquoGuard system with existing CSF drainage systems.

CSF drainage tube system to pressure measurement system: All CSF drainage systems are connected to an intrathecal CSF drainage (10, 17). Current CSF drainage systems as well as the LiquoGuard drainage system consist of a transparent plastic tube system with an attached 3-way cock or an alternative CSF drainage facility. This applies to CSF drainage systems as well as to the LiquoGuard system; both systems are completely comparable with one another regarding this construction stage of the entire CSF drainage system. The tubing system is technically comparable, CSF drainage facilities (3-way cock) are identical, biological properties are appropriate (CSF) and clinical conditions (indication to remove CSF via connection (3-way cock) are the same.

Pressure measurement system
Pressure measurement in existing systems is conducted via a pressure sensor integrated into the CSF drainage system or connected to the lumen of the drainage system via a 3-way cock (10, 17). Correct intracranial pressure measurement requires that the tubing system is distally closed, as an open system cannot create pressure and the CSF will flow in direction of the open system (10, 17). The alignment of the pressure measurement system must be at zero point level (in the case of intrathecal intracranial application this would be the foramen Monroi (8)) in all systems (in previous CSF drainage systems as well as in the LiquoGuard drainage system). Display of pressure in previous systems was enabled by connection to the sensor system at a patient monitor, whereby the LiquoGuard system displays the pressure directly via the display integrated in the LiquoGuard device. Existing pressure measurement systems and the display of the measured pressure are based on the same sensor technology as the piezo-resistant LiquoGuard pressure measurement system (8, 21) and are therefore technically comparable as they measure the pressure of the same biological body fluid in the same clinically comparable patients.

CSF drainage tube system from pressure measurement system to CSF collecting bag
In established systems, CSF is transported to a droplet chamber or a collecting bag on the distal side of the pressure measuring system. To measure the intracranial pressure, the two existing CSF drainage systems must be distally closed to enable reliable pressure measurement. Once the pressure defined by medical staff has been

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reached, the CSF drainage system will be distally opened. Now CSF can drain via the drainage system into the collecting bag, whereby the drop-by-drop addition of CSF from the tubing system into the collecting bag must be set to the zero reference line (intracranial at foramen Monroi). The system must be opened distal to the external air so that the air displaced by inflowing CSF can escape within the collecting bag. Once CSF flow is suspended (target pressure is reached) the system is closed and pressure measurement is continued. Opening and closing intervals depend on the speed of the renewed intracranial pressure increase. In the LiquoGuard system CSF drainage occurs in analogue manner. The closing mechanism for the completion of correct intrathecal pressure measurement is carried out by the rotor pump instead of the 3-way cock or a crimp connection in the LiquoGuard system. If the measured intrathecal pressure rises to a pressure defined by medical staff (target pressure reached) the rotor pump is activated via its electronics and pump rotation leads to CSF removal with transportation of CSF to the collecting bag. If the pressure decreases to target pressure (analog to CSF flow suspension in existing systems), the rotor pump will stop and CSF drainage is suspended. Clinically, the same purpose is pursued under the same conditions, the same patient population and the same indication, i.e. the measurement of intrathecal pressure and the removal of CSF as of a definable pressure level. Both procedures therefore result in the identical clinical effect, the intrathecal pressure decrease as a result of CSF drainage. A biological comparability exists between the systems, as the same human liquid (CSF) is drained using the same materials. Technical comparability exists in the fact that both systems are primarily closed and remove CSF up to reaching a target pressure once a certain intrathecal pressure, measured with the same measurement technology has been reached. Whether CSF is drained by a positive intrathecal pressure via an overflow system (previous established systems) or via a rotor pump, is negligible, as further CSF drainage is prevented once the CSF target pressure has been reached. With regard to the function of the system there are no differences.

CSF volume control

Control of CSF to be drained is on a visual basis in existing system, by persons operating the system reading the CSF level within the collecting bag prior to CSF drainage, then opening the CSF drainage system and waiting until the appropriate CSF volume has drained into the collecting bag. The LiquoGuard system does provide visual control as an analog possibility, as an appropriately comparable scale has been attached to the collecting bag, but the calculation of CSF volume from the rotation of the pump and the diameter of the drainage tube inserted in the pump is more exact and simpler.

Illustration and measurement of CSF pressure and CSF volume

In existing systems, the pressure recorder is attached to the installed patient monitoring system in an appropriate stationary unit like arterial pressure measurement. The illustration of intrathecal pressure is then possible via this patient monitor. In the LiquoGuard system the intrathecal pressure is displayed in the LiquoGuard device itself. Furthermore, and unlike previous systems, the LiquoGuard system permits trend display of previously measured values and data storage (without patient information) onto a suitable memory medium, as well as data transfer to a patient monitoring system. Compliance is therefore given, but the LiquoGuard system provides additional functions.

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Alarm limits for ICP

In existing systems as in the LiquoGuard system, the upper and lower alarm limit of intrathecal pressure can be defined. Both systems activate a comparable visual and audible alarm once alarm limits are reached. In existing systems this is carried out via the patient monitor, whereas the LiquoGuard system has integrated alarm functions, whereby the alarm functions can also be activated via the connected patient monitor.

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Assessment criteria to prove the efficiency and safety of the product

The fact that intrathecal CSF drainage is applied in the same way by both the existing systems as well as the LiquoGuard system makes an assessment of intrathecal CSF drainage unnecessary. The efficiency of intrathecal CSF drainage is globally undisputed. It represents a routine procedure as therapy for intracranial pressure increase (1, 9, 10, 12-14, 18-20, 22, 24).

Expected effect of a CSF drainage system

The expected effect of a CSF drainage system consists of enabling sterile CSF extraction in identifiable quantities via an intrathecally inserted cerebro-spinal fluid drainage in case of intrathecal pressure increase beyond a certain threshold (target pressure) and when a pressure sensor is connected to be able to measure intrathecal pressure reliably by appropriate means ("Gold standard" for intracranial pressure measurement) (5, 8, 13, 21).

Both established systems and the LiquoGuard System make intrathecal CSF pressure measurement possible via integrated pressure measurement in the CSF drainage system. (7, 11, 21, 23) In order to enable pressure measurement, a pressure sensor must be integrated in the tube system or in the ventricle drainage region and zero-point calibration executed for both systems.

For intracranial pressure measurement in conventional systems, the tube system is closed distal to the pressure sensor. Only then does a closed pressure distal position exist, which can be used for intracranial pressure measurement. However, it is not possible to drain any CSF from these systems during this period. In the case of an intrathecal pressure increase in excess of a defined value, CSF extraction takes place by opening the system - for conventional systems by means of the differential pressure between the intrathecal catheter and the height of the distal CSF drainage system tube which leads to the CSF collecting basin. However, if the CSF drainage is open, reliable and correct pressure measurement for existing systems is not possible. Quantification of the CSF volume withdrawn is made visually for these systems, using a measurement scale which is attached to the CSF collection bag.

The LiquoGuard System records intrathecal pressure via the external attachment of pressure sensors at the level of the respective reference point. It is neither necessary to open nor to close the CSF drainage system because, if the target pressure is exceeded, CSF is withdrawn using the rotor pump and when target pressure is achieved CSF withdrawal stopped. As opposed to the existing systems, continuous intrathecal pressure measurement is possible, providing additional safety for the patient during CSF drainage as opposed to risks. The quantification of CSF withdrawn is also visual, using a measurement scale which is attached to the CSF collection bag. However, in addition, the amount of CSF withdrawn can be calculated using the number of rotations of the rotor pump and the tube diameter, providing two alternative methods for CSF quantification.

All in all, the use of the same correcting variables (target pressure, CSF quantity) and the same measurement systems (intrathecal pressure measurement via an externally attached piezo-resistant pressure sensor) for both systems (existing CSF drainage systems and LiquoGuard System) provide comparable effectiveness with regard to intrathecal pressure reduction and the quantity of CSF withdrawn.

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Assessment of the safety of CSF withdrawal

With regard to the period of CSF withdrawal, the quantity of CSF withdrawn differs between the existing systems and the LiquoGuard System.

The CSF quantity for existing systems during the course of time is dependent on the diameter and length of the CSF drainage system, the length and diameter of the intrathecal CSF drainage, the viscosity of the CSF, the height of the distal drainage system (target pressure), the ratio between the patient's CSF production and CSF absorption and the current prevailing intrathecal pressure. It is not possible to determine the CSF drainage amount exactly over the course of time using these systems as the additional times for the named factors cannot be determined (e.g. the CSF absorption rate). Therefore discontinuous CSF withdrawals are necessary, leading repeatedly to slow pressure increase (system closed) and quick pressure loss (distally open system). This can result in quick pressure loss in conventional systems, which can lead to an undesired quick pressure drop with the risk of an aneurysm rupture, especially in case of vascular malformation (aneurysm). Moreover for existing systems opening the system distally is dependent on the presence of a person who operates the drainage system closure mechanism. Hence intrathecal pressure can increase until the respective staff opens the system. As the controls of the rotor pump in the LiquoGuard system always depend on the currently measured intrathecal pressure and the respective target pressure, undesired fast changes in pressure and pressure reductions are impossible due to permanently controlled CSF drainage. There is no clinical indication for discontinuous CSF withdrawals, making continuous CSF drainage whilst maintaining the target pressure the therapeutic objective in all cases.

Moreover, it is also possible to quantify the exact CSF amount to be withdrawn over the course of time because, despite the unknown factors, the amount of CSF to be withdrawn depends on the diameter of the tube system and the rotational speed of the rotor pump and whether both influencing factors are known. The existing CSF drainage systems do not enable a time-based depiction of the CSF drainage amount. It is possible to read out the CSF amount in the drip chamber, however time-based references cannot be established in as far as the drip chamber is not emptied at very short time intervals, also restricting accuracy (low readout accuracy for low CSF amounts) (7). The CSF drainage system LiquoGuard enables highly precise measurement of the CSF feed rate with high time-based resolution, a balance for every hour or every 24 hours and depiction of the continuous feed rate. These parameters can be applied for controlling the pump (setting the maximum total feed rate per hour), not otherwise possible if using conventional systems without incurring personnel costs. This additional parameterization of the discharge flow with a time-based course may be of special significance for certain clinical pictures and concerns, in particular, withdrawal from ventricle drainage. In order to reduce the CSF feed rate, the height distance between foramen Monroi and the drip chamber of an open system is increased here. However this also means that pathological and thus high-risk high intracranial pressure might have to be tolerated. LiquoGuard can avoid this risk by reducing the CSF feed rate and increasing the upper alarm limit slightly, still maintaining CSF drainage, even if within a restricted scope.

Existing systems have a CSF collecting basin which must have an external opening via an air filter. Blocking up, unintentional or deliberate (e.g. whilst transporting patients) closure of the air filter hinders CSF drainage because the air must escape through the incoming CSF. By contrast, an external opening via an air filter is not required for the LiquoGuard System because the rotor pump transports the extracted

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CSF to the collection bag. In this way the risk of an unwanted insufficient CSF drainage can be considerably reduced using the LiquoGuard System. As the insertion of the LiquoGuard tube set in the rotor pump works confusion-proof in one direction, pumping in the opposite direction (distal to proximal) due to user error is not possible. Nonetheless, even if there is a rotor pump malfunction and the rotational direction of the pump is incorrect, the risk of danger to the patient is very low because only the CSF amount actually in the tube system is discharged retrograde and this can also occur in conventional systems in a similar manner if the distal end of the CSF discharge system is attached higher and due to the hydrostatic pressure CSF can run retrograde to the intrathecal CSF drainage. As the LiquoGuard System provides constant pressure monitoring, danger to the patient due to increased intrathecal pressure due to retrograde CSF flow can be ruled-out. This is not possible distally if conventional systems are used and CSF drainage is open. This means that by using the LiquoGuard System the risk of danger to the patient due to retrograde CSF flow is considerably lower than in existing systems.
CSF drainage is only possible when using existing systems when the ventricle drainage is opened, the 3-way cock is open and the air filter for the CSF collecting basin is opened (10, 17). Unintended closure of the CSF drainage system at any one of these points leads to a system occlusion which may remain unnoticed. In contrast, an occlusion of the LiquoGuard CSF drainage system is noticed as there is no CSF pulsation (occlusion proximal to the pressure sensors) or through an increase of the intrathecal pressure values (occlusion distal to the pressure sensors) auf. This leads to direct recognition of danger to the patient if the LiquoGuard System is used and the possibility to avert it, thus minimizing the risk of danger to the patient.
However, the systems used to date have had different disadvantages, caused physically with regard to the open system with an air filter when CSF drainage is desired. As conventional drainage is a distally open system (external pressure compensation is possible in the CSF collecting basin via an air filter), it is not possible to measure CSF pressure in a distally opened external tube system correctly (7, 21). CSF drainage is controlled using the height of the distal tube system which must always be set in accordance with the patient's height (7, 11, 17, 21). A change in the height of the intrathecal catheter in relation to the distal tube system inevitably causes a change to the differential pressure (target pressure) which remains unnoticed if distal CSF drainage takes place in the current systems. This means that the risk for the patient that either an uncontrolled high amount of CSF (differential pressure lower than wanted, distance between intrathecal CSF drainage and external drainage lower) or too low a CSF quantity (differential pressure higher than wanted, distance between intrathecal CSF drainage and external drainage higher) is drained. The LiquoGuard application can reduce this risk considerably because the pressure sensor attached externally to the patient at the height of the intrathecal catheter is carried along when the patient moves, thus averting any pressure changes. This formation not only decreases the amount of work for medical staff in its clinical application and daily routine - it also reduces the risk of incorrectly high or low CSF drainage.(4)

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Assessment of pressure measurement safety

Existing CSF drainage systems possess two varieties of pressure measurement with CSF drainage. The Gold Standard describes the attachment of a pressure sensor to the ventricle drainage and alignment at foramen Monroi level (10, 11). However, pressure measurement is only possible with a tubing system closed distal to the pressure sensor, this arrangement does not permit simultaneous drainage and pressure measurement (16). What is disadvantageous and risky to the patient is that an open system and therefore a deactivated pressure measurement does not guarantee the observation of a tube occlusion or a disconnection. The second variety permits measurement of brain pressure via a pressure sensor directly inserted in the ventricle system, attached at the tip of the ventricle drainage (16, 21). In this case the distal catheter part is open and permits CSF drainage. However, as simultaneous CSF drainage creates an open system, the value of the intraventricular pressure measurement is determined by the height of the drip chamber. Both systems currently available normally work with only one pressure measurement. This means that in case of a technical pressure sensor fault the measurements would lose their reliability, usually a technical redundancy for the safety of the patient does not apply. The CSF drainage system LiquoGuard permits simultaneous pressure measurement and CSF drainage in a closed system. All previously existing risks of unnoticed dysfunctional CSF drainage (disconnection, catheter occlusion) are therefore solved and lead to considerable improvement of patient safety. As this is a closed system, pressure measurement is possible with simultaneous CSF drainage. Simultaneous pressure wave analysis also permits statements on the functionality of ventricle drainage, which is also not possible with the pressure sensors attached to the tip of the ventricle drainage. As both pressure sensors as well as the device-internal processing are redundant in the catheter system, the risk of a technical error measurement as in previous systems can be virtually excluded, as a drift of both sensors in the same direction (positive/negative) in the exact same time resolution with identical amplitude can be classified as unlikely.

All pressure sensors require zero-point calibration before application. In this respect, existing systems do not differ from the LiquoGuard system. However, previous systems permit further zero-point calibrations, which denote two significant risks: 1. the system must be open to air, which promotes germ entry into the tubing system; 2. erroneous, subsequent zero-point calibration with adjoining liquid column can cause an erroneous, low pressure measurement, which can lead to erroneously low intrathecal pressure measurements. As zero point calibration in the LiquoGuard system can only be performed once during initialization of the system and as calibration is recorded in the sensory memory, a second, perhaps erroneously low calibration is impossible. This significantly increases patient safety.

Wrong attachment of the sensor in connection with the zero point (usually foramen Monroi) or unobserved detachment of the pressure sensor can lead to incorrect intrathecal pressure values. This could also lead to erroneous measurement of high intrathecal pressures resulting in CSF drainage. However, as the connection tube between CSF drainage and the pressure sensor is short, pressure difference is only marginal and has no significant influence. In contrast, the CSF collecting bag in existing systems can detach itself from the attachment clamp and fall to the ground. As the connection tube between intrathecal CSF drainage and CSF collecting bag is long, there is a risk of significant pressure differences, which could denote a hazard to the patient. This risk can be significantly reduced due to the technical properties of the LiquoGuard system.

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Safety assessment in CSF drainage occlusion

To ensure correct CSF drainage it must be guaranteed that the entire tubing system, starting at the ventricle catheter to the drip chamber, is not closed (e.g. by 3-way cocks, kinks in the tube, displacement of the inner tube lumen by blood coagulation, etc.) and that pressure balance in the drip chamber to the outside is guaranteed (air filter connected and not jammed, clamp at air filter open).(17) Air filter jamming in particular is difficult to recognize in previous systems, as an external visual inspection (all connections open) does not recognize malfunction and can only be noticed and corrected during air filter exchange or pressure measurement. Recognition of a situation potentially critical for the patient is not possible in previous systems. As pressure measurement is always simultaneously connected to drainage in the new LiquoGuard system, continuous pressure monitoring is possible. An occlusion proximal to pressure sensors is immediately recognized by the absence of the appropriate CSF pressure curve and an alarm is triggered. The occlusion distal to the pressure sensor system is measured by an increase in CSF pressure and an alarm is generated when the upper pressure limit specified by the physician is exceeded. In both systems the removal of a distal tube occlusion and a positive pressure difference between intrathecal pressure and target pressure to the achievement of the target pressure removes a comparable volume of CSF. All in all, the risk of an unnoticed system occlusion can be reduced by the additional measuring systems integrated in LiquoGuard and continuous pressure measurement during CSF drainage without creating additional risks in the application.

Safety assessment to maintain CSF target pressure

All previous systems are based on a distally open tubing system; the desired CSF pressure is set via height adjustment in the drip chamber of the CSF drainage (16, 21, 23). The problem is that when the position of the patient's head is changed (e.g. bed position, self-mobilization of the patient such as sitting up, turning, etc) the height of the drip chamber must be readjusted. If this is not performed, an undesired, large volume of CSF may drain (drip chamber too low in relation to patient's head) or too little CSF is drained (drip chamber too high). This results in serious risks to the patient, as overdrainage with reduced ventricle pressure may cause rupture of bridge veins and transtentorial herniation (clamping) (17). Too little drainage can cause increased CSF pressure and lead to pressure damage in the nervous system (22). The LiquoGuard CSF drainage system avoids these risks as follows: both pressure sensors are configured in such a way that they can be attached at the height of the patient's foramen Monroi by adhesive electrodes. Positioning of the height of the rotor pump and collecting bag is therefore completely independent of patient position. The pressure sensor follows all changes in the position of the head. However, this is only possible if the pressure sensors have been correctly attached to the head. As the proximal connection piece to the ventricle catheter is very short, the pressure difference in case of detachment and suspension in relation to previous systems (drip chamber falls to the ground) is limited. All in all, the system's independence from patient position leads to a significant reduction in risk to the patient and to much easier handling in the daily clinical application.

Safety assessment for disconnection during CSF drainage system application

The disconnection of the tubing system in all previous systems, occurring occasionally during permanent lumbar CSF drainage (patient removes proximal tubing system during change in position or disconnects it when disorientated) leads to spontaneous emptying of CSF to the outside with the risk of a negative CSF

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pressure (risk of herniation, hemorrhage) and CSF infection (no existing sterility, open CSF drainage serves as port of germ entry(17)). As permanent lumbar drainage is commonly applied in wards without a monitoring unit, the disconnection is only recognized after longer periods of time and after loss of significant CSF volumes(2)(17). The LiquoGuard drainage system can detect the problem immediately by measuring acute pressure reduction caused by disconnection in the catheter system and signal an appropriate alarm. The risk to the patient caused by unrecognized CSF drainage over longer periods of time is significantly reduced by the use of the LiquoGuard system.

Safety assessment for sterility of CSF drainage systems

For physical reasons, existing systems require an external system opening for CSF drainage. An air filter must be connected to the CSF collecting container, which can lead to cross-contamination. This risk can be reduced by using the LiquoGuard system, as it is a closed system and does not require the use of an air filter.
Existing systems can be reused contrary to the determination of suitability, whereas multiple use or re-sterilization in the LiquoGuard system is impossible due to single zero point calibration. This excludes the risk of unintentional multiple use of disposable products. All other consumable goods in contact with human body fluids are comparable to the LiquoGuard system and do therefore not denote any additional risk of infection.

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Summary

Verification of effectiveness

The LiquoGuard CSF drainage system is a tube system with integrated redundantly designed pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CNS drainage. The intrathecal CSF drain is used independent of the LiquoGuard system, and the products approved for intrathecal CSF drainage and pressure measurement can be connected to the LiquoGuard system. The indication for insertion of an intrathecal drainage will not be affected by using the LiquoGuard system. As the control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing systems and the LiquoGuard system, the measuring sensors are comparable and the effective mechanism and the function of the CSF extraction by means of a target value-controlled rotor pump in the LiquoGuard system is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard system offers comparable effectiveness to existing CSF drainage systems. Thus both systems similarly enable CSF drainage as a treatment up to target pressure in order to reduce intrathecal pressure, which makes it possible to treat intrathecal pressures leading to a perfusion deficit of the central nervous system. There is technically similar to standard shunt valves with regard to the automated pressure-related CSF flow control. Such devices usually work by tensioning a valve via a spring tension and can be adjusted from outside mechanically, magnetically or by any other suitable method, depending on the design. At a certain preset CSF pressure definable from outside, the valve opens and allows the CSF to flow, until the CSF pressure is below the preset pressure, causing the valve to close automatically (5, 7). This active pressure-controlled CSF drainage is realized in the LiquoGuard system in an analogue way.
By using the LiquoGuard system, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in both systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement.

Risk evaluation of the system

Intrathecal pressure measurement
In the LiquoGuard system, the technical requirements for pressure measurement are comparable to the existing CSF pressure measurement systems that work via a liquid column communicating to the intrathecal space. Both the positioning of the pressure sensors in the tube system as well as the orientation of the pressure sensor in relation to the intrathecal catheter is comparable. Contrary to other systems, however, the LiquoGuard system is designed such that the pressure measurement is performed twice, and in the event of measuring a differing pressure between both sensors, an alarm is activated enabling the malfunction of a sensor to be noticed immediately. Since a faulty measurement of the intrathecal pressure can pose a risk for the patient (excessive CSF pressure risking a compression and perfusion deficit of the CNS, insufficient CSF pressure risking a tensile stress on CNS structures

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leading to hemorrhages, vessel ruptures and shear injuries), the double measurement with mutual control of both pressure sensors allows the significant reduction of the risk of faulty pressure measurement in comparison to existing systems. The prevention of pressure equalization to ambient air pressure with already inserted systems, with the consequence of a wrong high or wrong low intrathecal pressure reading, further increases the safety of the patient in the LiquoGuard system.

CSF extraction
The LiquoGuard system, contrary to existing systems, allows continuous pressure measurement even during CSF extraction. Therefore, there are no further additional risks associated with using the LiquoGuard, but rather the risk of an uncontrolled CSF extraction under existing systems (wrong difference height set, patient moves during CSF extraction with open system, height of CSF drainage bag changes during CSF extraction, CSF drainage system is disconnected while drainage is in progress) can be significantly reduced by using the LiquoGuard system. Thus the risk of excessive CSF pressure risking a compression and perfusion deficit of the CNS, or of insufficient CSF pressure risking a tensile stress on CNS structures leading to hemorrhages, vessel ruptures and shear injuries can be reduced by using LiquoGuard. Hemorrhages (13, 17) caused by the application of intrathecal CSF drainage are not affected by the used CSF drainage system; there is no increased hemorrhage risk by using the LiquoGuard system. Other risk sources for the patient such as wrong catheter positions (11, 17) are also not related to the CSF drainage system and pose an independent risk that is neither reduced nor increased by using the LiquoGuard. .

Quantification of the CSF extraction volume
A comparable visual determination of the extracted CSF volume by reading the quantity of CSF on scales attached to the drainage bags, allows a basic CSF volume determination with both existing CSF drainage systems and the LiquoGuard system. Additionally, the LiquoGuard system can compute the extracted CSF volume by means of the number of rotations of the rotor pump and the tube diameter, thereby allowing not only a safety-relevant redundancy of the CSF volume determination, but also a quantification of the CSF volume in high time resolution.

Closed vs. open CSF drainage system: Existing systems allow reliable intrathecal pressure measurement with a closed CSF drainage system, and CSF drainage with an opened CSF drainage system. If the CSF drainage system is occluded distally from the pressure measurement (clogging of tubing system, tube closed by 3-way cock, clogging or closing of air filter at the CSF drainage bag) and the pressure measurement is not connected to the liquid column, a very high CSF pressure may build up without being noticed. This can lead to a severe risk for the patient, as it may result in a compression of the CNS with the danger of a perfusion deficiency. The risk of an unnoticed CSF pressure increase can be significantly reduced due to the continuous CSF pressure measurement with the closed system (LiquoGuard system), no air filter is required, and the CSF pressure measurement is possible simultaneously and independently from each other at any given time. The risk of a malfunction of the rotor pump control in the LiquoGuard system through a faulty pressure measurement is highly unlikely due to the double pressure measurement design.

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Disconnection and occlusion of the CSF drainage system

With existing systems in closed status as well as with the LiquoGuard system, during connected liquid column, any disconnection of the system with CSF leak can be immediately noticed due to a rapid drop in pressure at the pressure sensors below the lower pressure limit. Contrary to the LiquoGuard system, where it is possible to recognize a disconnection even under CSF drainage conditions, this is not possible with the existing systems under deactivated pressure measurement during CSF drainage. Here the danger is that CSF can leak out unnoticed in large quantities with the risk for the patient that due to insufficient CSF pressure there is a risk of tensile stress on CNS structures leading to hemorrhages, vessel ruptures and shear injuries. This risk can be significantly reduced by using the LiquoGuard system, without any identifiable additional risks for the patient. An occlusion proximal to the pressure sensors will lead to a suppression of pressure pulsations, which in existing CSF drainage systems can be visually displayed via a patient monitor connected to the pressure sensor, and in the LiquoGuard system both via a connected patient monitor as well as via the display of the LiquoGuard device. Contrary to existing systems, however, the LiquoGuard system is computing the pulsations and triggers an acoustic and visual alarm above or below defined alarm parameters. This will make the clinical staff aware of a possible system occlusion proximal to the pressure sensors. There are no other additional risks involved for the patient, but the risk of an unnoticed intrathecal pressure increase with the consequence of a compression and perfusion deficiency of the CNS can be significantly reduced by the LiquoGuard system in comparison to the existing systems. An occlusion distally from the pressure sensors will in both systems equally cause the CSF drainage to be suspended. With existing systems, this situation may remain unnoticed if the pressure sensor is not connected to the liquid column (e.g. by connecting the pressure sensors via 3-way cock). With the LiquoGuard system, a distal occlusion will lead to a measurable pressure increase, which will trigger an acoustic and visual alarm when the upper alarm limit for the CSF pressure measurement is exceeded. Therefore, the continuous CSF pressure measurement by means of the LiquoGuard affords a significant improvement of the CSF pressure monitoring with a decrease in the patient risk.

CSF system sterility

Handling the connection of the CSF drainage system to the CSF drain is comparable in all CSF drainage systems, here there are no identifiable additional risks by using the LiquoGuard. However, with an open system a bacterial contamination through the air filter might occur, which is not possible with a closed system (LiquoGuard). Additionally, the rotor pump prevents a CSF reflux from the tube/drainage bag system into the intrathecal space, which further reduces the infection risk. Any multiple use of the tube system with a possible germ contamination is virtually impossible due to the electronic protection and unique zero calibration of the pressure sensors. All in all there are no indications of any increased infection risk by using the LiquoGuard system; there are rather significantly less points of entry for a bacterial contamination of the system with the LiquoGuard system. Using the LiquoGuard system has no influence on the principle risk of an infection of the CSF drainage system (8, 17).

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Conclusion

It has been shown in the existing recognized literature that the CSF drainage is a recognized and established method in neurosurgery for many years for the diagnostic and treatment of patients with diseases of the CNS. The risks associated with the surgical insertion of a CFS drain are not depending on the CSF drainage system chosen and thus not on the use of the LiquoGuard system. The objective of intrathecal pressure measurement and CSF extraction is achieved both by existing CSF drainage systems as well as by the LiquoGuard system in comparable effectiveness. Contrary to existing systems, however, by using the LiquoGuard system, the risks of erroneous pressure measurement, sensor fault, and false pressure measurement by changing the reference height of the patient, unnoticed catheter occlusion and catheter disconnection as well as the infection risk can be reduced.

Biologically, the identical material is used for the drainage (CSF). Neither insertion technique, material nor the indications are influenced or altered by using the LiquoGuard. Therefore, there is no difference in the surgical risks for inserting the relevant ventricular or lumbar drainage when using the LiquoGuard. The intrathecal drainage is inserted with the identical patient population at the same place in the body (ventricular system, lumbar CFS system) (7, 13). The pressure measurement is performed by piezo-resistive pressure sensors that are established and described for the use in intracranial pressure measurement (10, 11, 21). Fundamental risks that do not depend on the method of CSF drainage and occur after insertion of a CSF drain (ventricular catheter, permanent lumbar drainage catheter) are described in major trials; these are infections (8, 17), hemorrhages (13, 17), wrong catheter positions (11, 17), occlusions (17), overdrainage (17).

The surgical procedures will not be changed in any way; also the indications for a surgical intervention remain unchanged. No material risk can be identified, as existing systems are made of comparable material and are used as soon as sterile catheter material becomes available.

In summary, from a functional point of view existing systems are identical to the LiquoGuard system (CSF drainage, pressure measurement), but the pressure-controlled CSF drainage via a rotor pump (LiquoGuard) offers a clear reduction of technical, application-specific and patient-specific risk sources, without generating new risk sources at the same time. All patient-relevant risks of usual systems can be significantly reduced by using the LiquoGuard. There is no additional risk to users or third parties..

Fulda, 23. August 2006

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Annex: Bibliography

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APPENDIX 7

OPERATING MANUAL FOR THE LIQUOGUARD CSF DRAINAGE SYSTEM

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US

LiquoGuard® CSF

Operating Manual

CE 1275

Möller Medical GmbH, Wasserkuppenstr. 29-31, D - 36043 Fulda
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2 Manufacturer

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The manufacturer reserves the right to make technical improvements.

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3 General Safety Instructions

3.1 Explanation of the safety symbols

Important information is marked in these operating instructions. This information is vital to exclude danger to patient and operating personnel, and to avoid damage or malfunction.

Achtung	Warning, important information
Gefahr	Caution! Hazard to patient or operating personnel
Hinweis	Information or help
	Application part BF
CE 1275	Conformity to medical guideline 93/42 EEC
~	Identification symbol for electrical and electronic devices
	Alternati ıg voltage
	Alarm signal deactivation switch AUDIO PAUSE
	Consult instruction for use
SN	Serial number
	Manufacturer
REF	Catalogue number
LOT	Lot number
	Date of expiration
	Date of manufacture
	Application range

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General Safety Instructions

STERILE EO	Sterilized using ethylene oxide
	Do not use if packaging is damaged
	Do not reuse
	Do not resterilize
MRI	Not for use in an MRI field
PHT DEHP	Contains or presence of phthalates
	Overall length

Each application of the unit is subject to precise knowledge of and compliance with these operating instructions. This operating manual does not replace the inservice of the user by the sales representative. The device must only be operated by qualified personnel or those with an equivalent level of knowledge and experience.

If components are used that do not correspond to the original parts of the manufacturer, the performance, safety and EMC behaviour may be impaired.

3.2 Manufacturer

The manufacturer can be regarded as being responsible for the safety, reliability and serviceability of the unit if:
assembly, upgrades, resettings, changes or repairs are only carried out by personnel who have been authorised to do so by the manufacturer. The electrical installation of the respective room complies to the appropriate requirements and the device is used according to the operating manual.

3.3 Precautionary duties of the operator

The operator is responsible for proper operation of this medical product.
Only qualified personnel may operate this unit. Operating instructions do not replace a proper inservice. Clinical application may only be performed by people who have been properly inserviced by qualified personnel.

The unit may not be operated if connected to power supplies whose soundness is doubtful. The supply voltage must match the details specified on the nameplate. Liquids must not penetrate parts of the device, which carry electrical voltage. Do not spray cleansing fluid into the memory card slot. Unplug the AC power cord prior to cleaning.

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3.4 Supplementary devices

Supplementary devices are not part of the unit's delivery scope:
Any additional equipment that is connected to the analogue and digital interfaces of the device must be proven to meet the requirements of the relevant EN specifications, (e.g. EN60601 for electrical medical devices). All device configurations must also satisfy the applicable version of the electrical system safety standard EN60601-1-1. Any operator connecting the additional devices is the system configurer and is therefore responsible for ensuring that the system safety standard EN60601-1-1 is upheld. In case of questions, please contact the manufacturer.

3.5 Single-use

Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.

3.6 Electro-magnetic emission

The ***LiquoGuard® CSF*** is suitable for operation in the stipulated electro-magnetic environment. The customer and/or operator of the ***LiquoGuard® CSF*** should ensure that it is used in one of the electro-magnetic environments described below.

Measurement of emitted interference	**Conformance**	**Guidelines for the electro-magnetic environment**
Emitted high-frequency interference acc. to CISPR 11	Group 1	
Emitted high-frequency interference acc. to CISPR 11	Class B	The ***LiquoGuard®*** uses HF energy exclusively for its own function. Its HF emittance is therefore very low and interference with neighbouring electronic devices is improbable.
Harmonic emittance acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emittance acc. to IEC 61000-3-3	Not applicable	

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3.7 Recommended safety distances

Recommended safety distances between portable and mobile HF telecommunication devices and *LiquoGuard®*			
LiquoGuard® is intended for operation in an electro-magnetic environment, in which HF disturbances are controlled. The client or operator of ***LiquoGuard®*** can assist in avoiding electro-magnetic disturbances by keeping to the minimum distances between portable and mobile HF telecommunication devices (transmitters) and ***LiquoGuard®*** - depending on the output power of the communication device, as stipulated below.			
Capacity transmitter power [W]	**Safety distance dependent on transmission frequency [m]**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

3.8 Electro-magnetic resistance

Resistance test	IEC 60601 - testing level	Conformance level	Electro-magnetic. Environment / Guidelines
Discharge of electro-static electricity (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should consist of wood or concrete or tiles. If the floor is covered with synthetic material, relative humidity should be at least 30 %.
Rapid transient electrical disturbances/ bursts IEC 61000-4-4	±2 kV for power lines ±1 kV for input and outtput lines	±2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Surge voltages Surges IEC 61000-4-5	±1 kV Normal mode voltage ±2 kV Common mode voltage	±1 kV Normal mode voltage ±2 kV Common mode voltage	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage IEC 61000-4-11	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	The quality of the supply voltage should correspond with that of a typical business or hospital environment. If the operator of the product demands continued functions even during the occurrence of power supply interruptions, we recommend the use of an uninterrupted power supply or battery.
Magnetic field for supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields for the net frequency should correspond with typical values as found in business and hospital environments.
Note: U_T is the AC supply voltage prior to application of the testing level.			

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3.9 Electro-magnetic resistance for non-life-supporting devices

Resistance tests/ Standard	IEC 60601-testing level	Conformance level	Electromagnetic environment / Guidelines
Conducted HF-resistance variable according to IEC 61000-4-6 Radiated HF-resistance acc. to IEC 61000-4-3	$3\ V_{eff}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	$3\ V_{eff}$ 3 V/m	Portable and mobile radio devices should not be used at a distance to the product, including lines, of less than the recommended safety distance, which is calculated according to the equation corresponding to the transmission frequency. **Recommended safety distance:** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{V_1}]\sqrt{P}$ for 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ for 800 MHz to 2.5 MHz with P as nominal transmitter power in Watt (W) acc. to transmitter manufacturer stipulations and d as recommended safety distance in meters (m). According to an on-site[a)] examination, the field intensity of stationary radio transmitters ought to be lower than the correlation level[b)]. Disturbances may occur in the environment of devices carrying the following symbol.

Notes:
NOTE 1 The higher frequency range applies to 80 MHz and 800 MHz.

NOTE 2 These guidelines may not be applicable in all cases. The diffusion of nominal electro-magnetic factors is influenced by absorption and reflection of buildings, objects and people.

[a)] The field intensity of stationary transmitters, such as radio base stations and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and TV transmitters theoretically cannot be predetermined accurately. An examination of the site should be considered in order to determine the electro-magnetic environment of the stationary transmitter. If the measured field intensity at the site, at which the product is used, exceed the above mentioned conformance levels, the product should be observed to prove the intended function. Unusual performance characteristics may require additional measures, such as changes to the alignment or position of the product.

[b)] The field intensity should be less than 3 V/m at 150 MHz to 80 MHz.

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4 Purpose

Möller Medical's ***LiquoGuard® CSF*** is a

- pressure controlled
- and / or volume controlled

tube pump for use in: monitored medical rooms in hospitals only.

The purpose of *LiquoGuard® CSF* with the tube set for *LiquoGuard®* REF.-No.: **92 007 836 (1500 mm/59.06 inch) or REF.-No.: 92 008 568 (2000 mm/78.74 inch) is the targeted pumping of CSF fluid.**

LiquoGuard® may not be used as an infiltration pump or infusion pump.

LiquoGuard® does not serve diagnostic purposes.

4.1 Indications for Use

The ***LiquoGuard® CSF*** system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The ***LiquoGuard® CSF*** system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The ***LiquoGuard® CSF*** system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

4.2 Contraindications

The contraindications do not apply to the use of a CSF draining system such as the ***LiquoGuard® CSF*** system, but to the application of intrathecal CSF drainage itself. As, however, CSF discharge is only applied in connection with CSF drainage, contraindications described below are in connection with the application of external CSF drainage only.

Absolute operative contraindications: Coagulopathy, thrombocythemia.

Relative operative contraindications: In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does simultaneous intake of intrathecal antibiotics in the case of ventriculitis.

Indication for permanent CSF drainage: If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculoperitoneal shunt or a ventriculo-atrial shunt.

4.3 Combination with other products

LiquoGuard® CSF may only be used in connection with Möller Medical's tube set for ***LiquoGuard®*** **REF.-No.: 92 007 836 (1500 mm/59.06 inch)** or **REF.-Nr.: 92 008 568 (2000 mm/78.74 inch)** , the tube set may only be used in connection with the ***LiquoGuard®***.

The tube set for ***LiquoGuard®*** REF.-No.: 92 007 836 or. REF-No.: 92

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008 568 is connected to a surgically implanted CSF draining catheter and does not come into contact with the body.
The tube set for ***LiquoGuard®*** REF.-No.: 92 007 836 or. REF-No.: 92 008 568 may only be connected to ventricular drainage catheters with an internal diameter of >= 1 mm (0.039 inch) and with lengths of <= 350 mm (13.78 inch) or lumbar drainage catheters with an internal diameter of >= 0.7 mm (0.028 inch) and a length of <= 800 mm (31.5 inch).

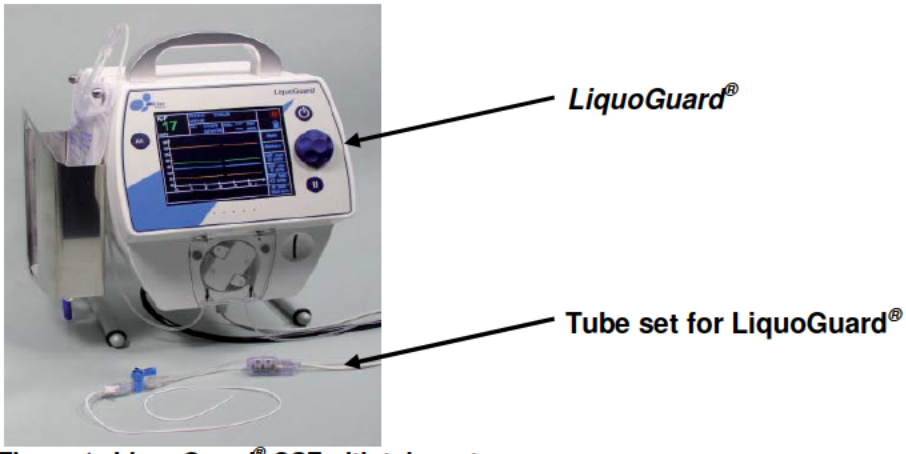

Figure 1: *LiquoGuard® CSF* with tube set

4.4 Patient population

The application may be considered for neonatal to geriatric patients.

4.5 Remaining risk

LiquoGuard® CSF is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error. The remaining risk for the patient exists mainly in the selection of parameters unsuitable for the patient or other application errors. The operator must be aware of this risk.
LiquoGuard® CSF does not serve diagnostic purposes.
For application during computer tomography (CT), the tube set may remain attached to the patient. ***LiquoGuard® CSF*** must be disconnected.

Application during Magnetic Resonance Tomography (MRT) or near an MRT device is prohibited.

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5 Set-Up and Installation

Ensure that the package has been delivered to you without damage. Please inform your sales representative immediately of any transport damage.

5.1 Unpacking the Device and Checking for Contents

Delivery of ***LiquoGuard®*** always consists of one carton. When unpacking ***LiquoGuard®***, ensure that no parts remain in the package and that all parts are present.

The delivery scope consists of (1 item each):

- ***LiquoGuard® CSF***
- AC power cord
- Operating manual

Every manipulation of ***LiquoGuard®*** requires exact knowledge and observance of these operating instructions. These instructions do not replace proper user training. Only qualified personnel may operate this unit. ***LiquoGuard®*** must be prepared according to cleaning guidelines prior to first application. For cleaning, use a mild detergent or disinfectant (e.g.: 70 % alcohol).

We suggest that packaging is retained for further use.
LiquoGuard® may only be shipped in the original packaging.

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5.2 Installation

Remove ***LiquoGuard® CSF*** from its packaging and place it on a suitable, steady surface.

LiquoGuard® CSF can be:

- safely positioned in a suitable, stable location.
- suspended on a 25 mm (0.98 inch) x 10 mm (0.39 inch) wall rail.
- or attached to an IV pole with a diameter of 25 mm (0.98 inch).
- or universally attached to various IV poles or the patient's bed with the attachment pole (accessory).

Observe the maximum tube length of 1.5 m/59.06 inch (REF.-No.: 92 007 836) or 2 m/78.74 inch (REF.-No.: 92 008 568) between catheter and ***LiquoGuard®***.

Figure 2: *LiquoGuard®* standing on base feet

Figure 3: *LiquoGuard®* - view from behind
Attachment system for wall rail 25 mm (0.98 inch) x 10 mm (0.39 inch)

Figure 4: *LiquoGuard®* - view from behind
Pole clamp

Insert the AC power chord into ***LiquoGuard® CSF*** at the lower side of the casing side and into a plug with connected protective earth conductors. Please observe the stipulated voltage values on the type plate.

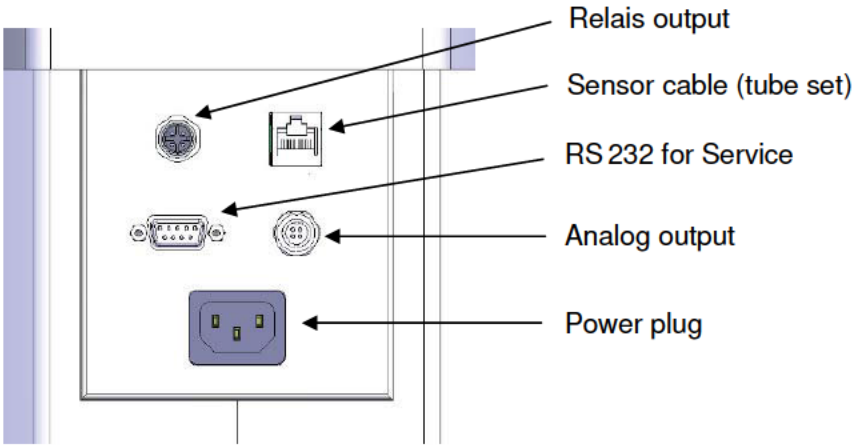

Figure 5: *LiquoGuard®* - View from below - Connections

The relay output can be used for an alarm connection to the device call system (frequently also known as the diagnostics call or nurse call). The function of this connection must be

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Set-Up and Installation

checked and validated in individual cases (Please Observe the prerequisites for Supplementary devices in Chapter 3.4 on Page 7).
This further alarm routing does not eliminate the need to control the patients. The alert notices from the ***LiquoGuard® CSF*** must be controlled in every case.

Connecting the AC power cord to ***LiquoGuard®*** puts the device into standby mode.

Further startup requires a tube set for ***LiquoGuard®*** by Möller Medical, **REF.-No.: 92 007 836** or **REF-No.: 92 008 568.**

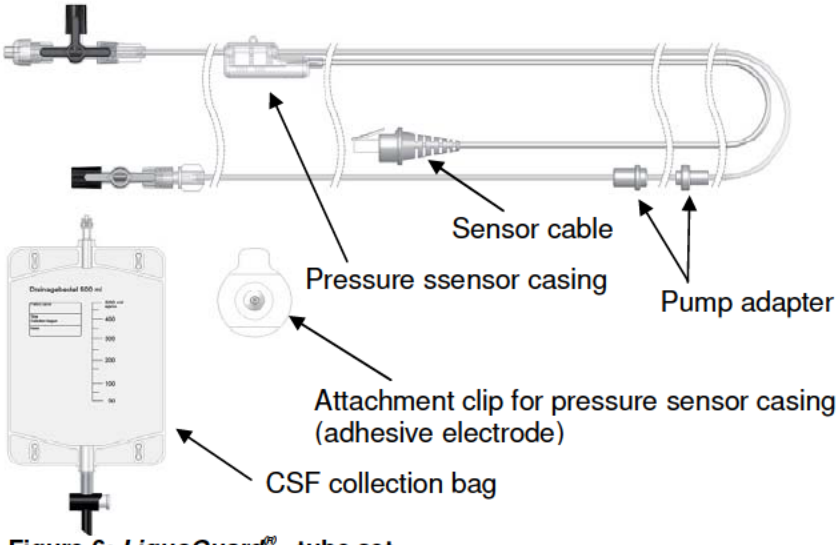

Figure 6: *LiquoGuard®* - tube set

To avoid false alarms, you should familiarise yourself with the alarm concept of ***LiquoGuard® CSF*** (see Page 15).

Please continue reading starting at page 30 for information on Application and operation.

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6 Alarm concept

The ***LiquoGuard® CSF*** alarm concept is designed in such a way that during correct operation the operator is always notified of alarm conditions by visible and audible alarms (i.e. an operator must always be within earshot and visibility range). ***LiquoGuard® CSF*** is equipped with a physiological and technical alarm condition. Alarm condition priority is stipulated with "HIGH Priority" for all alarm conditions. ***LiquoGuard® CSF*** creates visible and audible alarm signals. The alarm system is designed without self-regulating alarm signals.

6.1 Alarm system description

Terms and definitions

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm condition	Condition of the alarm system once it has determined a possible or real threat.	Excess of upper or lower alarm limit	
Alarm condition delay	Time between occurrence of an alarm condition either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), up to system determination of an existing threat.	See chapter 6.2	
Alarm limit	Limit value used by an alarm system to determine an alarm condition.	See chapter 6.2	Control panel
Alarm OFF	Condition of indefinite duration, in which an alarm system or a part thereof does not issue alarm signals	The user can set certain alarm conditions to OFF If these are not useful due to the condition of the patient. It is the responsibility of the user to set these consciously to OFF.	
Alarm paused	Condition of limited duration, in which an alarm system or a part thereof does not issue alarm signals	No possible setting	
Alarm presetting	Set of saved configuration parameters, including the selection of algorithms and initial values for the use of algorithms, which influence or change the effect of the alarm system.	N/A	
Alarm reset	Action performed by operator to cancel an alarm signal, for which there is no currently associated alarm condition.	N/A	

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Alarm concept

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm settings	Alarm system configuration including but not limited to: - Alarm limits - Properties of all conditions of alarm activation and - The values of parameter variables, which determine the function of the alarm system.	In some cases adjustable by user (see chapter 6.2)	
Alarm signal	Signal type created by the alarm system to display the existence (or the occurrence) of an alarm condition.	- Visible alarm signal - Audible alarm signal The audible alarm signal has an audio pressure level of 55dBA at a 1-metre distance	Visible impulse signal via red LED light in service screen. On-board sound emitter
Delay in alarm signal emittance	Time from start of alarm condition to emittance of alarm signal.	Depending on alarm condition, see chapter 6.2	
Audio OFF	Condition of unlimited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	settable	refers to all alarm conditions active at the time of key activation
Audio paused	Condition of limited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	Settable to a maximum of 180 minutes.	refers to all alarm conditions active at the time of key activation
De-escalation	Process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	No application	
Escalation	Process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	No application	
False negative alarm conditions	Missing alarm condition, if a valid triggering occurrence in the patient, in the device or in the alarm system has occurred.	Dual safety-Probability very low	
False positive alarm conditions	Existing alarm condition, if no valid triggering occurrence in the patient, in the device or in the alarm system has occurred.		
Information signal	Every signal, which is not an alarm or reminder signal.	Applies.	
Self-retaining alarm signal	Alarm signal which continues to emit after its triggering occurrence has been eliminated, until it is stopped with a deliberate operator action.	Does not apply.	
Non-self-retaining alarm signal	Alarm signal, which automatically stops if the associated triggering occurrence has been eliminated.	Applies.	
Physiological alarm condition	Alarm condition originating from a monitored, patient-related variable.	Applies.	
Technical alarm condition	Alarm condition originating from a monitored, device or alarm system-related variable.	Applies.	

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6.2 Alarm system overview

Alarm conditions	Pulsation frequency not correct	Lower pressure limit value undercut	Upper pressure limit value exceeded
Physiological alarm condition	Pulsation frequency too small (limit value)/ too large (limit value)	Measured pressure too low	Measured pressure too high
Technical alarm condition	n.a.	n.a.	n.a.
Alarm limit	Pulsations frequency (<=30) or (>= 180)	Lower pressure limit value (P-min) Adjustable by operator	Upper pressure limit value (P-max) Adjustable by operator
Alarm condition delay	Averaged value in 12 sec.	Filtered measurement value	Filtered measurement value
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	Not adjustable by operator Specified to 20 sec	Not adjustable by operator Specified to 20 sec
Alarm signal	Audible / Visible	Audible / Visible	Audible / Visible
Alarm signal description in display	Pulsation alarm!	Measured pressure too low	Measured pressure too high
Audio paused or Audio off	YES	YES	YES

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Alarm concept

Alarm condition	Pressure constant	Sensor defective or disconnected
Physiological alarm condition	Measured pressure too constant	n.a.
Technical alarm condition	n.a.	a) „Sensor defective“: Difference between the two sensors is too high b) „Disconnection“: cable can't be detected anymore
Alarm limit	standard 0.2 mmHg; adjustable by operator OFF or 0.1-2 mmHg	[illegible] sensors is > 4 mmHg
Alarm condition delay	12 seconds	a) „Sensor defective“: n.a. b) „Disconnection“: 3 Seconds
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	a) „Sensor defective“: specified to 20 Seconds b) „Disconnection“: n.a.
Alarm signal	Audible / Visible	Audible / Visible
Alarm signal description in display	Pressure too constant	Sensor defective or disconnected!
Audio pausedor Audio off	yes	no

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Alarm concept

Alarm condition	**Physiological alarm condition**	**Technical alarm condition**	**Alarm limit**	**Alarm condition delay**	**Delay in alarm signal emittance**	**Alarm signal**	**Alarm signal description in display**	**Audio paused or Audio off**
Battery empty	**n.a.**	**Voltage of battery too low**	**Internal device specification**	**n.a.**	**Not adjustable by operator Specified to 20 sec**	**Audible / Visible**	**Battery empty, connect to AC**	**YES**
Internal safety measures from hardware and software tests -dual safety- **These alarm condition or alarm signal descriptions are not displayed. In the case of such alarm conditions, *LiquoGuard®* must be checked by Service.**	**n.a.**	**Internal device assessments**	**Internal device specification**	**n.a.**	**Not adjustable by operator Specified to 20 sec**	**Audible / Visible**	**Device error x**	**YES**

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6.3 Inspection of alarm functions

Connecting the AC power chord to ***LiquoGuard® CSF*** results in a short peep tone and the two inner red diodes light up. This is a test for the emergency alarm (audible and visible).
A function test is also performed when ***LiquoGuard® CSF*** is activated. An audible information signal is created and the two external red diodes, as well as the central blue diode light up. The motor also starts up and the current software versions as well as the bus address are displayed for a short while.

6.4 Alarm system, dual safety

The path from pressure measurement by ***LiquoGuard® CSF*** to the alarm was designed according to dual safety aspects. This entails 2 sensors in the tube set, dual measurement value recording and processing, as well as various means of alarm emittance.
The two outer red LEDs are activated by ***LiquoGuard®***'s main controls. Alarm signals here (rapid flashing) are supported by displayed information. The audible signal in the main control is a trumpet call.
The two adjacent red LEDs are controlled by the monitoring system. They usually flash slightly delayed from the other LEDs at a slower rhythm.
If the monitoring system determines an error at the main controls, which does not issue an audible alarm, the monitoring system will issue an audible alarm in the form of a rhythmic beep with a fixed frequency. This condition is termed an emergency alarm. It can be cancelled by pressing the standby button three times. If the device returns to this condition repeatedly, the device should be checked by Service.
If a technical fault occurs during battery operation, the device may issue a continuous high-pitched tone. This is also an alarm signal. It can only be cancelled by reconnecting the device to the AC power. There is no other way to cancel this supply alarm.

Important:
The alarm system only refers to ***LiquoGuard® CSF*** itself. Possible signals from an external connected system do not release the operator from his duty to promptly and appropriately react to alarm situations signaled by ***LiquoGuard® CSF*** even if an external system should not display this alarm condition.

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7 Product description

7.1 *LiquoGuard® CSF* design

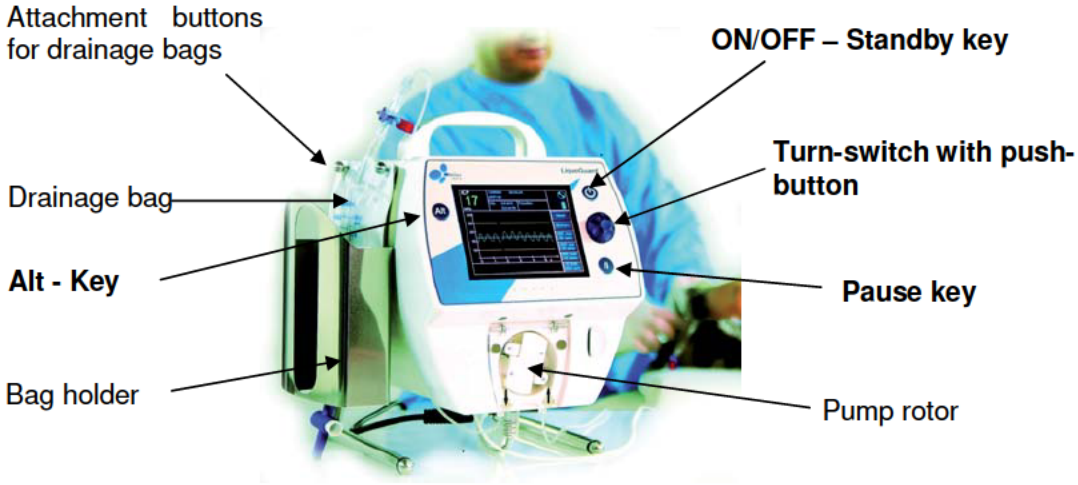

Figure 7: *LiquoGuard® CSF* - design

LiquoGuard® CSF is switched on and off with the **ON/OFF - Standby key**. All functions of the display control panel are set with the **turn-switch**.
You can change between pause mode and active mode of ***LiquoGuard®*** using the **pause switch**. The pump is switched off in pause mode. The **Standby-key** returns you to the next higher menu level from all sublevels. Pressing the **Alt-key** changes the menu items on the right display edge (see „Second selection menu“, page 25).

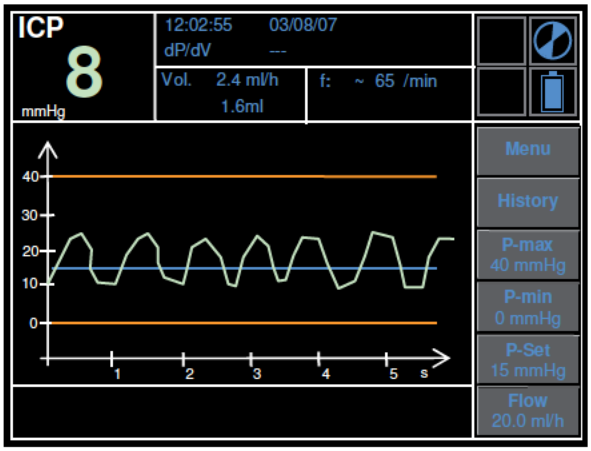

Figure 8: Display of the *LiquoGuard® CSF*

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7.2 Display fields

The monitor design of ***LiquoGuard® CSF*** is divided into display fields and display operating fields.
The **display fields** provide you with the following information:

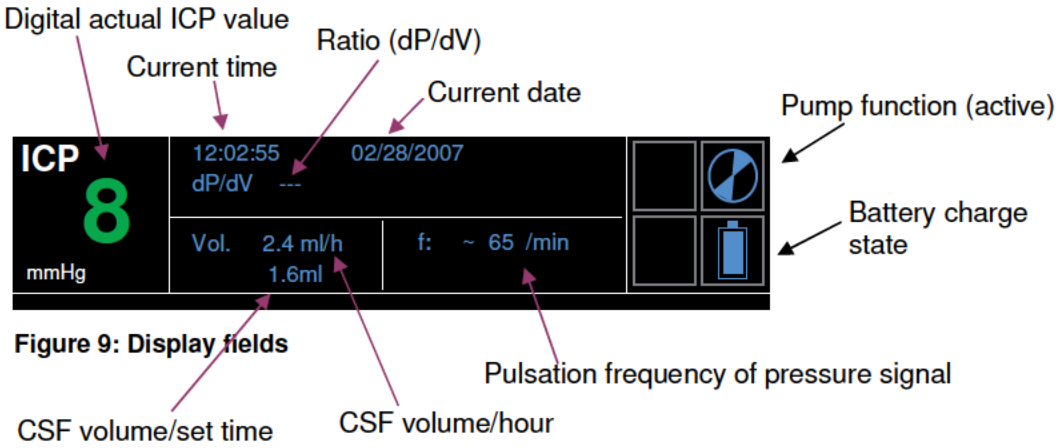

Figure 9: Display fields

7.2.1 Digital actual ICP value or actual P_{CSF} value [mmHg]

The digital actual ICP value/actual P_{CSF} value [mmHg] is the filtered pressure value [mmHg], measured by the pressure sensors. ICP: IntraCranial Pressure [mmHg]; P_{CSF}: Pressure of **C**erebro**S**pinal **F**luid [mmHg]

7.2.2 Ratio dP/dV [mmHg/ml]

Ratio of pressure to volume (Volume elasticity co-efficient, Compliance). This can only be displayed when at least 0.5 ml were pumped between pump start and pump stop and if this created a pressure difference of at least 2 mmHg.
Permanent compliance measurement requires hysteresis set to 1.5 mmHg (under: Sub-menu Extended application; (1) Hysteresis controller [mmHg]).
Note: Accuracy is not better than 20-30%.

7.2.3 Date/Time

These two fields automatically display the current date and current time. The current settings can be changed in the menu.
The date can be displayed in three formats:
DD.MM.YYYY, MM/DD/YYYY, YYYY-MM-DD, e.g.: 28.02.2007; 02/28/2007; 2007-02-28
Note: If the date/time was changed during an application, data (Date/Time) may appear twice or display gaps.

7.2.4 Pulsation frequency of pressure signal (f: ~ ---/min)

This displays the pulsation of the CSF recognised by the device. This recorded pulsation and the alarm conditions are integrated into the alarm concept of the ***LiquoGuard®***. The alarm limits are:

- Upper alarm limit → f >= 180/min
- Lower alarm limit → f <= 30/min

With sufficiently large fluid pulsation the pulsation frequency complies approximately with the pulse of the patient. In the ventricular mode, pulsation alarm is on by default and is an additional monitoring function to increase patient safety.

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It can however be de-activated if required, e.g.: in case of craniectomy/operative decompression: First press the alt key and the right display will appear with a menu containing 5 to 6 sub items (see page 25: “Second selection menu”), Then select "pulse" and set to "NO". The pulsation alarm remains de-activated until this is explicitly changed or a new application is started.
Pulsation recognition is not reliable for permanent lumbar drainage and is therefore not displayed. In this case alarms due to pulsation are not triggered.

7.2.5 CSF volume/hour (Vol. 0.0 ml/h)

This field displays the CSF volume per hour that has been pumped off. The value is always averaged to 15 minutes (adjustable in the system menu) and is updated every minute.

7.2.6 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h)

This field displays the CSF volume per "x" hours that has been pumped off. Variable „x“ can take values between 2 and 24 (steps of 2; see page 45 Duration of volume balance [h]) The value always displays the actual volume in this period. It is updated on an hourly basis. As long as the set balance time (e.g. 24 hours) has not been reached, the actually conveyed volume is displayed in ml. If this function is set to "OFF" in the system menu, the volume measuring function is active, i.e. balancing no longer takes place, and only the conveyed volume is displayed. This counter can always be reset to zero using the alt key and "Reset volume" (see page 25: “Second selection menu”).
Note: In the event that the tubing is changed more frequently for one individual patient without turning off the device, the entire balance will be continued until the end of its use so that the total quantity drained can be read at the end.

7.2.7 Battery charge state

LiquoGuard® CSF was designed for battery supplied operation for a maximum of 3 hours. A progressive decrease of battery capacity is an indication for a damaged battery (contact service). The display field Battery SOC indicates the current battery charge state during battery operation. During mains operation, a filling symbol indicates charging. A full symbol indicates a full battery. During battery operation the battery symbol is red and the blue LED flashes to show the operator that it is not connected to AC power.

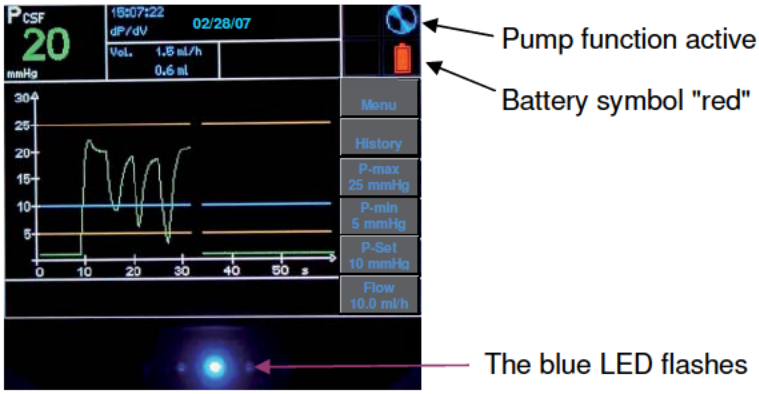

Figure 10: Battery charge state

Before the battery is entirely depleted it will sound an alarm and display: "Battery empty, connect to AC!“ The device must then be connected to AC power immediately. If this does not occur, the display will turn black after approx. 5-10 minutes and the alarm continues to sound for a few more minutes. The device will then deactivate until it is reconnected to AC power. Discharging the battery completely can cause permanent damage and thus should be avoided. Complete charging of an empty battery requires approximately 8 hours.

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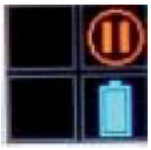
7.2.8 Pump function



If pump mode is set to "Pause", the pump will not work. To access the pump function you have to press the "Pause"-key.

Figure 11: Pump function - Pause

7.2.9 Graphic display of patient parameters

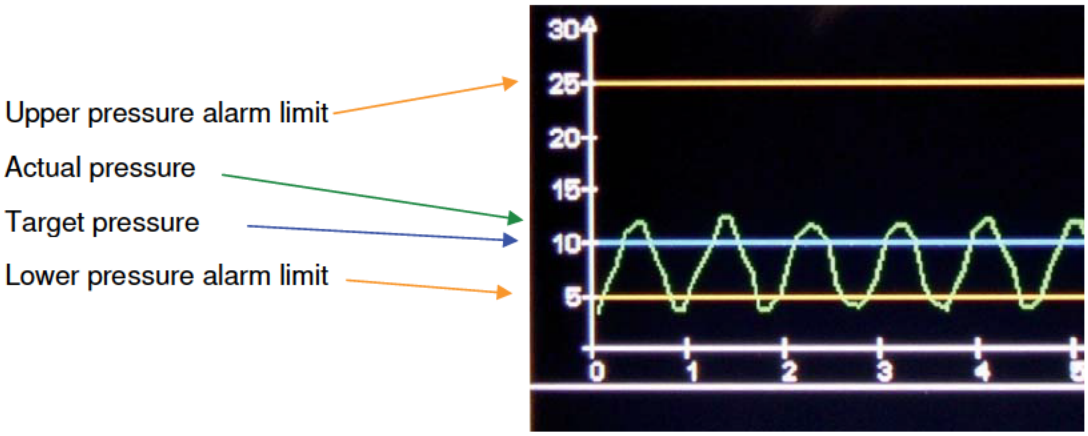


Figure 12: Display of pressure values

The upper pressure alarm limit (P-max) is the upper adjusted alarm limit for the alarm condition. The lower pressure alarm limit (P-min) is the lower adjusted alarm limit for the alarm condition.

7.3 Display operating fields

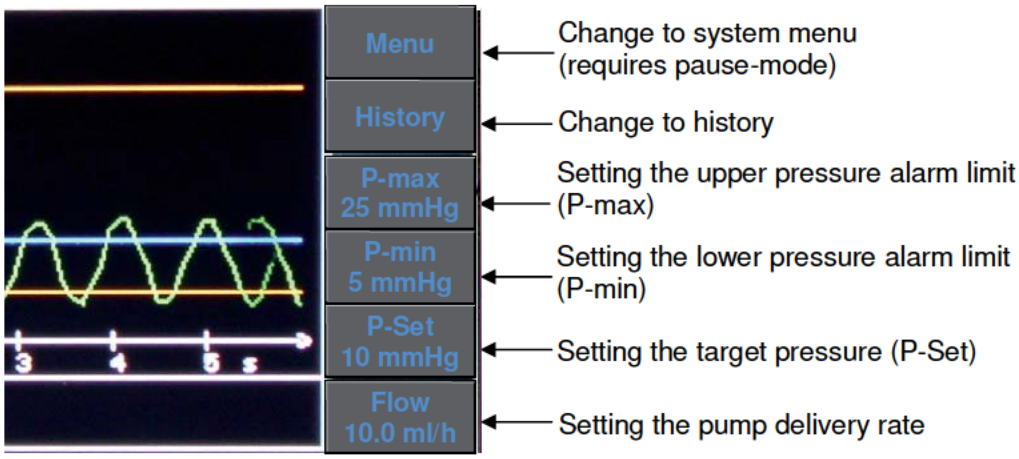


Figure 13: Display operating fields

The display control fields are selected via the turn-switch of ***LiquoGuard® CSF*** whereby the display control fields change their background color. The respective activated field is highlighted in light blue. Pressing the turn switch activates the selected display operating field and highlights it dark blue. By turning the turn switch changes can now be made in

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this field. Further depression of the push button activates the changes. (A text will appear in the display as a reminder: "Confirm changes with the wheel".) If the desired function is not confirmed within a preset time by pressing the turn switch, a timeout will occur. A negative confirmation tone is created (400 msec deep tone). In this case the originally set value is kept.

7.3.1 Quick reference guide - Setting/Changing of values:

1. Press the blue turn-switch. The “menu” field will now be highlighted.
2. By turning the switch you can move the illumination to the desired field.
3. By pressing the switch again, the highlighted field turns dark.
4. Now you can set the desired value. Important: You have to confirm this value by pressing the turn-switch again. If you forget to confirm, the new value will not be maintained and after a short interval the device will go back to the old value (operation timeout).
5. After confirmation of the new set value the field is highlighted again.
6. By turning the switch you can move the illumination again to another field.

Notes:

- If the switch is not touched for a short interval, there will be an operation timeout (no field is highlighted anymore) and you have to start at the beginning.
- By each short pressing of the Standby key you can go one step back.

To adjust the patient parameters please also read starting at Page 33.

7.3.2 Second selection menu

Pressing the Alt-key changes the menu items on the right display edge:

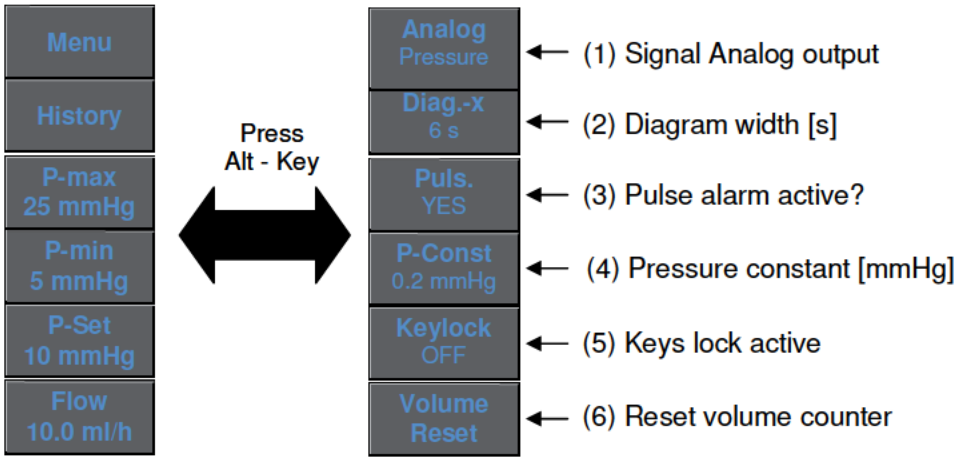

Figure 14: Second selection menu

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After the timeout period, which also applies for the system menu, you are returned to the standard key allocation as this contains the most information for the application.
Note:
If an audible alarm is active, pressing the Alt key will take you to the alarm pause selection (see page 38 Audio paused or Audio off). Therefore the Alt key has 3 levels, whereby only 2 are used without an alarm.

(1) Signal analog output

Meaning: Selection of the value to be issued via the analog output.

Possible parameter settings: Zero, Pressure, Flow

Note: The "Zero" setting serves offset correction purposes. The Pressure setting issues a value for pressure analog to the CSF-pressure measured by ***LiquoGuard® CSF.***
The same scale (20 ml/h correspond with 20 mmHg) can also be used to issue the pump flow corresponding to the history view.
This may be expedient as pressure regulation is active and if the pressure is consistent. Subsequently the quantitative size is the volume flow.

(2) Diagram width [s]

Meaning: The spread of the X-axis in the display diagram (Display) is stipulated by the Diagram Width (s).

Default value: 6 seconds (ventricular), 60 seconds (lumbar)
Minimum value: 6 seconds
Maximum value: 10 minutes

(3) Pulsation alarm active?

Meaning: Pulse recognition can be de-activated in the system menu, if patient conditions do not permit accurate measurement.

Possible settings: YES, NO (Default value: YES)

Notes:
- This parameter can only be set for ventricular application. The pulsation alarm is always de-activated for lumbar applications.

Attention: There is no reliable alarm function for catheter occlusions, catheter disconnections, or collapsed ventricles if the pulsation alarm is deactivated.

(4) Pressure constant [mmHg]

Meaning: A value of 0.2 [mmHg] means that the minimum pressure and the maximum pressure during the past 12 seconds (120 measured values) must differ by more or equal to 0.2 mmHg, so that no alarm is issued for "Pressure too constant". The alarm delay time of 20 seconds applies here, too.
The purpose of this function is to recognize a torn off/occluded catheter. The function is available for ventricular and lumbar drainage but not for the infusion test.

Default value: 0.2 mmHg
Minimum value: 0.1 mmHg (resp. OFF)
Maximum value: 2.0

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(5) Keys lock active [min]

Meaning: To prevent unintentional chages to the operating field parameters, "Keylock" can be set, so that ***LiquoGuard® CSF*** creates a keys lock after a certain inactive period. By default this function is set to OFF.

Default value: OFF
Minimum value: OFF (keys lock inactivated)
Maximum value: 60 minutes

Figure 15: Keys lock active

Symbol for active keys lock

If the keys lock is active, a key will appear in the display and no further settings can be performed via the operating field. The key lock is deactivated by pressing and holding the "**Alt key**" for 2 seconds. The lock is automatically re-activated if the preset time has lapsed without key activation.
Note: the keys lock is automatically de-activated every time an audible alarm signal is sounded. This also applies for the opening of the lid, if the question appears: "Interrupt application?".

(6) Reset volume counter

The volume counter is reset to zero when confirming "Volume reset".

Note: The key "Volume reset" is only active if "Duration volume balance" is set to "OFF" in the system menu.

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7.4 Technical Data

Order number:	**00 002 563**
LiquoGuard® dimensions:	Length x Width x Height: 280 mm x 210 mm x 315 mm (11.02 inch x 8.27 inch x 12.4 inch)
Weight:	approx. 4.8 kg (10.58 lb)
Electrical supply: Voltage 100 – 240 VAC (alternating voltage)	
Frequency	50 – 60 Hz
Current consumption	0.5 – 0.2 A
General characteristics:	
Operating conditions: Temperature Humidity	 +10 °C to +40 °C (+50 °F to +104 °F) 30 to 75 % rel. humidity
Transport - storage conditions Temperature Humidity	 -10 °C to +50 °C (+14 °F to +122 °F) less than 90 % rel. humidity
Protection category	IP 20 - ***LiquoGuard® CSF*** IP 20 - Tube set for ***LiquoGuard®***
Pump rate	1 ml/h to 120 ml/h (variably adjustable)
Flow rate accuracy	± 15 %
Pressure range	-15 mmHg to +75 mmHg
Accuracy of pressure sensors (according to data sheet)	 ± 0.5 mmHg
Display accuracy of system	± 2 mmHg
Application temperature range	+10 °C to +40 °C (+50 °F to +104 °F)
Relay output:	pure switch output for extra-low voltages of 25V AC / 60V DC, Current limitations: 3 A
Output signal of analog interface: Direct connection	 5.9 mV/mmHg (Tolerance: ± 12 mV or ± 10 % *)
With TruWave adapter cable	33 µV/mmHg (Tolerance: ± 66 µV or ± 10 % *) *The highest value is valid respectively.

<u>Attention</u>: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

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7.5 Recurring inspections

LiquoGuard® CSF must be subjected to safety inspections at least every 12 months. Documents on safety inspections can be requested from the manufacturer.

In addition to the safety inspections, further maintenance of the *LiquoGuard® CSF* is required in order to verify measures for the dual safety of the device.

Maintenance must be conducted by a maintenance center approved by the manufacturer. Information on maintenance can be requested from the manufacturer`s service division (see page 52). Enter safety inspections into the equipment log book and document inspection results. If the device is not fully functional or safe to operate, it must be repaired immediately by device service personnel. The safety inspections and technical measurement checks can be performed by the Service department of Möller Medical service@moeller-medical.com.

7.6 Dimensions, weight and transport information

LiquoGuard® CSF dimensions with packaging:	Length x Width x Height: 580 mm x 430 mm x 415 mm (22.83 inch x 16.93 inch x 16.34 inch)
Weight:	approx. 8 kg (17.64 lb)
Transport and storage conditions	
Temperature:	-10°C to +50°C (+14°F to +122°F)
Humidity:	less than 90 % rel. humidity

When transporting, do not stack more than 3 cartons above one another.

The external packaging is a folding corrugated cardboard box. The internal packaging is made from polyethylene foam rubber.

The packaging material is highly flammable and represents a fire hazard. Keep away from naked flames and do not smoke!

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8 Application and operation

LiquoGuard® CSF may only be switched on if power supply is conveyed via power input. The ***LiquoGuard®*** is ready for operation once the **ON/OFF – Standby – button** is activated. ***LiquoGuard®*** starts with a recognition signal and the current software versions as well as the Bus address are displayed for a short while.
Note: The emergency alarm is tested when ***LiquoGuard®*** is plugged in. This means you will have to hear a short beep. A function test is also performed when ***LiquoGuard®*** is activated (see page 20 "Inspection of alarm functions").

As a first step the subsequent display screen will appear.

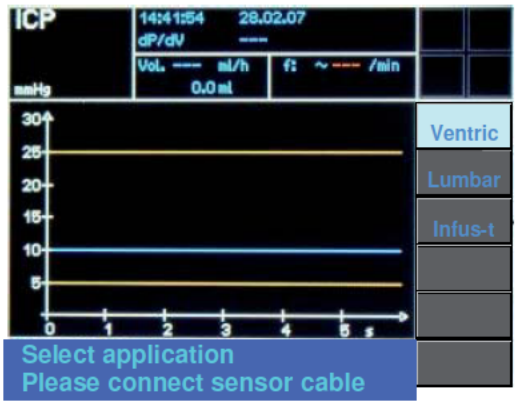
Should you not have written the data from the last patient to the memory card, this procedure can be carried out now (confirmation with the turn switch). All existing data is fully deleted once a new tube set is connected.
(This step can be skipped by activating the alt key or the standby key.)

Figure 16: Write data to memory card?

Select the desired application in the next step:

- **Ventricular drainage (Ventric)**
- **Lumbar drainage (Lumbar)**
- **Lumbar infusion test (Infus-t)**

Please read page 36 (Ventricular drainage) or page 37 (Lumbar drainage) or as of Page 54 (Option: Lumbar Infusion Test).



Turn the turn-switch to move the highlight to the desired field. Press the turn-switch to confirm the desired application.
(By pressing the "Alt" key or the "Standby" key the device is switched off.)

Figure 17: Select application

The following steps apply only to the following applications: Ventricular drainage or lumbar drainage. An additional software upgrade is required to run the device application option

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of "lumbar infusion test". This special application is described in detail in Chapter 12 (Option: Lumbar Infusion Test) as of Page 54.

8.1 Connection of the tube set

Please be sure to see that the following procedures are carried out:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.
2. Connect the tube set to the drainage bag and fasten the drainage bag to the holder provided

Note: Insert the drainage bag into the top of the bag holder at the ***LiquoGuard®*** (see Page 21, Figure 7).The drainage bag is freely suspended by the upper attachment buttons at the bag holder.

3. Insert the tube set into the pump: Ensure that the connecting pieces are correctly seated in the guides. Turn the pump rotor counter-clockwise by three rotations. Check whether the pump tube was correctly threaded.

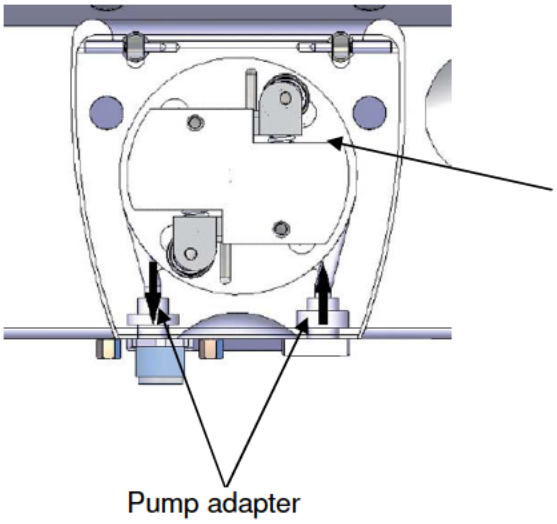

Figure 18: Pump rotor

As a first step you open the front cover of the pump and insert the tube set with the pump adapters into the pump receptacles.

Then thread in the pump tube by manually rotating the pump rotor to the left, threading via this rotor edge.

Manually turning the pump rotor counterclockwise for at least three rotations ensures that the tube is not jammed anywhere.

Then close the front cover.

4. Turn the stop cock of the 4-way manifold by 180° flow direction from the pump to the catheter… and remove the protective cap on the catheter side.

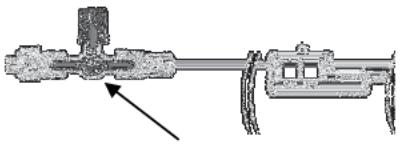

Figure 19: Stop cock setting before the application

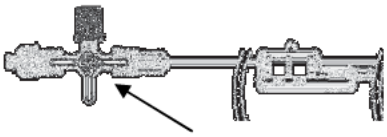

Figure 20: Stop cock setting during the application

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5. If you haven't done it yet: Connect the sensor cable to the ***LiquoGuard®*** (connection under the device).

Figure 21: Connect sensor cable to pump

Notes:

- In the event that a tube set had previously been attached, the point concerning "connect the sensor cable to the pump and wait" will be skipped, since the device will automatically recognize the tube set.
- Should you select a tube set that is unsuitable or which has already been used, the following message will appear: "wrong tube set for this application" and/or "please change the tube set". In this case, disconnect the tube set from the device. The following message will then reappear: "Sensor cable - connect to the pump and wait". Either connect a tube set which is suitable for the selected application or go back a step using the ESC key, in order to select an application for which the tube set is suitable.

6. Connect the catheter to the tube set (Please observe page 10 "Combination with other products").

7. Use the adhesive electrode (attachment area depends on application, see Pages 36/37) to attach the pressure sensor housing to the patient. Follow the display to do so:

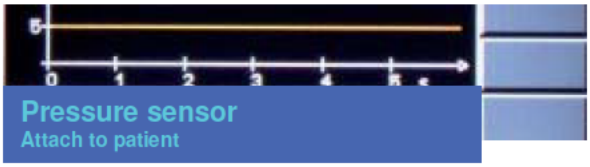

Figure 22: Attach pressure sensor

Until this point in time, the tube set can still be disconnected, use the "Esc" key to return to the beginning step-by-step. The tube set is not yet marked as being used.
As soon as the catheter and the pressure sensor are connected to the patient and this is verified by activating "Okay", the tube set is marked as used and can no longer be employed for a new application. A brief notice appears stating, "Connect sensor cable to the pump and wait", whereby the device checks to see whether the sensor cable is actually connected. At this point the alarm function will activate and the device is put into normal operating mode.

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Notes:

- During all steps observe also the instructions displayed on the ***LiquoGuard®*** and always adhere to the prescribed sequence of steps.
- After you have connected the tube set to the catheter, attached the pressure sensor housing to the patient and confirmed with "OK", ***LiquoGuard®*** electronically marks the tube set as used and it cannot be used again.

ATTENTION:

To avoid possible CSF reflux, always close the 4-way stop cock between the tube set and the catheter before removing or replacing the tube set.

The tube set must be replaced after a maximum of 120 continuous operating hours.

Attention: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

8.2 Setting of patient parameters

Setting of patient parameter target values is carried out via the display control fields, as described as of page 24. For LiquoGuard there are 2 target value settings for application as well as 2 safety settings for the alarm limits:

Setting the patient parameters may only be carried out by qualified personnel.

8.2.1 P-max:

P-max (mmHg) is used to set the upper alarm limit for **LiquoGuard®** alarm conditions. If the filtered actual ICP value is higher than the upper pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 25 mmHg
Minimum value: limited by P-Set
Maximum value: 75 mmHg

8.2.2 P-min:

P-min (mmHg) is used to set the lower alarm limit for ***LiquoGuard®*** alarm conditions. If the filtered actual ICP value is smaller than the lower pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 0 mmHg
Minimum value: -15 mmHg
Maximum value: limited by P-Set

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8.2.3 P-Set or P-Stop

During ventricular application **P-Set** (mmHg) is used to set the target value for pressure regulation. If the filtered actual ICP value (mmHg) reaches a pressure higher than **P-Set**, the ***LiquoGuard®*** pump is activated and pumps off the CSF. Pumping continues until the filtered actual ICP value reaches a pressure value lower than **P-Set**. The symmetrical hysteresis value (standard 0.5 mmHg) of this regulation is adjustable in the menu.
During lumbar application **P-Stop** (mmHg) is used to specify the value under which the pump no longer conveys.

Default value:	15 mmHg
Minimum value:	2 mmHg or limited by P-min
Maximum value:	limited by P-max

8.2.4 Flow

Flow sets the pre-selected flow rate of the ***LiquoGuard®*** pump (ml/h). Therefore pumping of the CSF can be influenced by time.

Default value:	20 ml/h
Minimum value:	1 ml/h
Maximum value:	50 ml/h (ventricular application)
	20 ml/h (lumbar application)

Notes:

- When starting a new application (by switching on the device), the parameters are always automatically reset to the standard values.
- In the event that an application is interrupted or when a tube set is renewed (without turning off the device), the parameter values last used will remain set.

Default values:

- **P-max: 25 mmHg**
- **P-min: 0 mmHg**
- **P-Set: 15 mmHg**
- **Flow: 20 ml/h**
- **Pulse alarm: "ON"; coupled to: Filter time Control 1.0**
- **Pressure constant : 0.2 mmHg**

ATTENTION:

An adjustment of the standard values may only be carried out by specialists.
Before every use, the user should check to see whether the momentary settings are suitable for the patient!

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8.3 Short checklist

After attaching the tube set and setting all patient parameters, ***LiquoGuard® CSF*** works independently. Before letting the system work independently you should review the following short checklist:

- **Is the tube set correctly inserted in *LiquoGuard®*?**
- **Are the catheter and drainage bag connected correctly?**
- **Are the stop cocks of the tube set in the correct position for the application?**
- **Are the set patient parameters correct?:**
  - **P-Set or P-Stop - *Pressure setting parameters***
  - **Flow - *Pump delivery rate settings***
- **Are the set alarm limit values correct for the following alarm conditions:**
  - **P-max - *upper alarm limit value for the alarm condition***
  - **P-min - *lower alarm limit value for the alarm condition***
- **Is the pulsation alarm activated?**
- **Is the "Pressure constant" alarm activated and properly set?**

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8.4 Ventricular drainage

During ventricular drainage, ***LiquoGuard® CSF*** functions as a pressure controlled tube pump. Adjustment specification here is **P-Set.** The pressure housing must be attached at the height of the Foramen Monro. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore the position of the sensor at the head must be considered when evaluating pressure values.

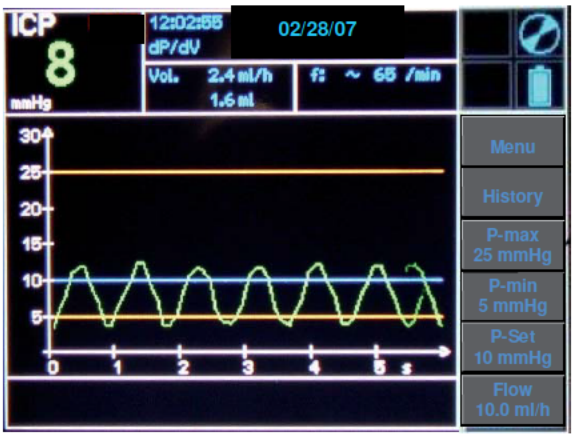

Figure 23: Display setup during ventricular drainage

There are 4 physiological alarm limits during ventricular drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)
- **Measured pulse frequency invalid** (f <= 30/min - fixed limit value)
- **Measured pulse frequency invalid** (f 180/min- fixed limit value)

ATTENTION:
In both important cases of catheter blockage and collapsed ventricles it is usually the case that the pulse can no longer be measured, which triggers an alarm - if activated!

By default, pulsation alarm is set to on. It is an additional monitoring function to increase patient safety (see page 22: Pulsation frequency of pressure signal (f: ~ ---/min)).

It would be expedient to deactivate pulse recognition in the system menu, if patient conditions do not permit accurate measurement. As an indication to the operator that pulse recognition is deactivated, the system displays “(f:)" instead of “f:“.

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8.5 Lumbar drainage

During lumbar drainage, ***LiquoGuard® CSF*** functions as a volume controlled tube pump. The specified setting here is the pump flow rate (**Flow**). During lumbar drainage, pulse recognition is deactivated, the time axis is set to 60 seconds by default and P-Set becomes P-Stop (see page 34, P-Set or P-Stop).
The pressure sensor housing should always be on or slightly below the level of the catheter end in the spine. Ask the patient about his sleeping behaviour. Patients sleeping on their sides should have the pressure sensor housing attached to their backs. Patients sleeping on their backs should have the pressure sensor housing attached to their sides. A safety cushion (available as an accessory) can be applied to avoid pressure pains. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore avoid that the patient lies on the side, at which the sensor is attached.

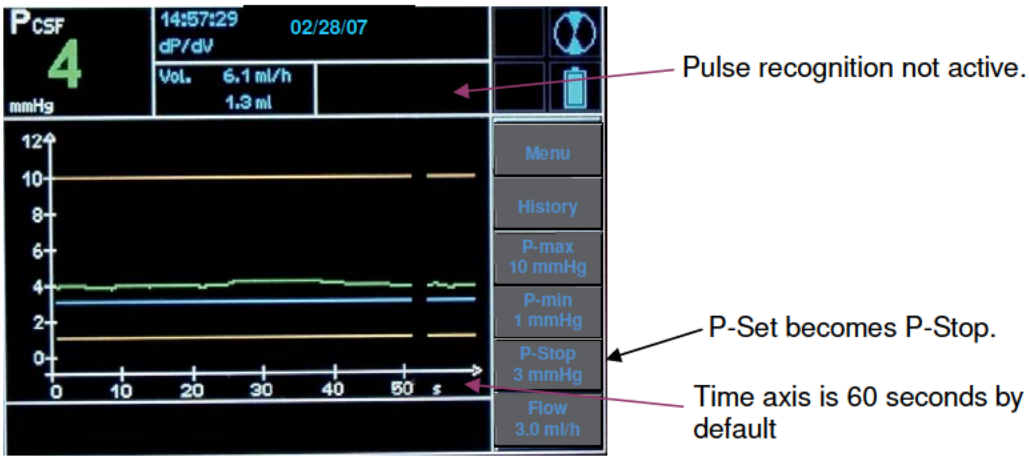

Figure 24: Display setup during lumbar drainage

There are 2 physiological alarm limits during lumbar drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)

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8.6 Audio paused or Audio off

In case of an alarm condition, the alarm signals are created with a 20 second delay. The alarm condition is also displayed. In case of multiple alarm condition these are displayed alternatively. (In the example contained in Figure 25 "Measured pulse frequency invalid!" alternates with "Measured pressure too low!".)
Additionally a key menu with 4 options appears on the right hand side of the display: Audio Pause 20 min (duration settable in system menu), Audio Pause 60 min, Audio Pause 180 min and Audio off.

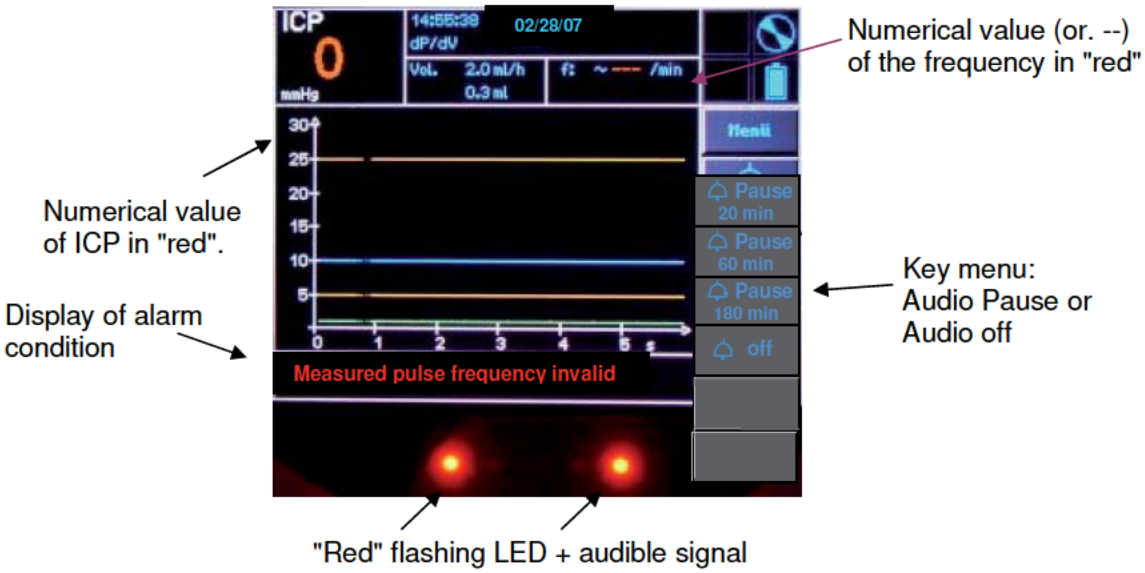
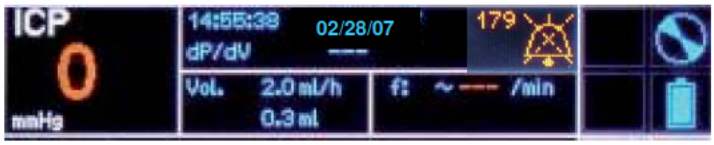


Figure 25: *LiquoGuard® CSF* in alarm mode

The *LiquoGuard® CSF* alarm system cannot be deactivated. The function "Audio paused" or "Audio off" can create a condition in which no audible alarm signal is emitted.



Use the turn switch to select the desired bell (Audio Pause 20 min, Audio Pause 60 min, Audio Pause 180 min or Audio off) and press the turn switch to confirm the function "Audio paused" or "Audio off". This condition is displayed by a crossed out red bell. The remaining duration in minutes is displayed on the left hand side (see Figure 26). In the case of "Audio off" it displays "OFF".

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"Audio paused" and "Audio off" refer to all alarm conditions active at the time of key activation.
In the case of the 3 audio pause time, the cancellation of the alarm condition does **not** lead to the cancellation of "Audio paused". In the case of "Audio off" the cancellation of the alarm condition does lead to the cancellation of the condition "Audio off".

Example:
- Alarm due to low pressure and pulse
- Audio Pause 20 min was pressed
- Both alarm conditions are cancelled and return (within 20 minutes) → Audio Pause remains constant
- Pressure rises to overpressure alarm: An audible alarm is sounded
- Renewed activation of Audio Pause 20 min
- The old alarm pause is deleted, the new pause now applies for 20 minutes for overpressure only!

Notes:

- The delay time of 20 seconds applies for each individual alarm condition.
- In the case of alarm conditions "Sensor defective or disconnected" and "Device error" the pump is stopped, irrespective of further conditions. This is marked by the display of a red pump symbol.
- If an alarm is created and if alarm paused is not pressed for 1 hour, the pump is stopped (this does not apply for exceeding P-max). This is also displayed by a red pump symbol. If alarm pause is pressed, the pump restarts immediately if the alarm condition permits this.
- Aside from the alarm condition (displayed in red), possible reasons for the alarm condition may also occur (e.g. "frequent causes: Catheter occluded/disconnected, ventricles collapsed, …). These should provide an indication for the possible reason for this alarm condition, although it is the responsibility of the medical personnel/the physician to determine the actual reason for this alarm condition.
- Should "Audio pause" or "Audio off" be activated, this setting can be cancelled by activating the "Audio on" button (through "Audio on" an audible (acoustic) alarm signal will be reactivated). The "Audio on" field can be reached by pressing the alt key twice.

Figure 27: *LiquoGuard® CSF* – „Audio On"-key

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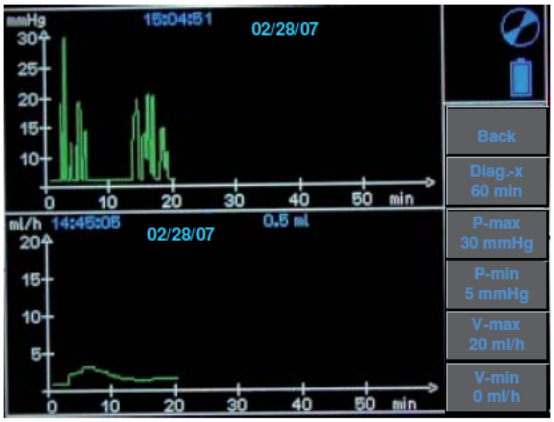
8.7 History

You can move to the "History" function via the display control field key "**History".** You can leave the "History" function via the Standby key, as well as via the Back button or the Alt key.
In the "History" function 2 diagram fields are displayed:

The upper diagram displays the pressure value [mmHg] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].



Display operating keys

Figure 28: History frame

The lower diagram displays the pumped-off CSF volume [ml/h] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].

Display control keys:

- **Diag.-x**
  This key is used to set the time spread of the axis (x-axis) from:
  - 10 seconds to 120 seconds in increments of 10 seconds,
  - 3 minutes to 120 minutes in increments of 1 minute,
  - 3 hours to 72 hours in increments of 1 hour,

  The setting is the same for both diagrams.
- **P-max** / **P-min**:
  You can use these two keys to set the spread of the pressure values (y-axis) in the upper diagram (adjustable from -50 mmHg to 99 mmHg).
- **V-max/V-min** :
  You can use these two keys to set the spread of the volume values (y-axis) in the lower diagram (adjustable from 0 ml/h to 130 ml/h).

You can view the long-term process of the two diagrams in time frames using the turn-switch.
The two blue digital displays in the lower diagram will show you the time frame for time and date of the y-axis position. The volume value on the right indicates how much CSF (ml) was conveyed in that precise time period (whereby the balance is determined from the displayed measurement values).

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8.8 Output of memory data

The internal memory of ***LiquoGuard®*** provides space for 150.000 data sets.
In the following table you can see the relation between sampling interval and memory storage time:

Sampling interval	Memory storage time
6.0 s	10d 09h 39m
5.0 s	8d 16h 03m
4.0 s	6d 22h 26m
3.0 s	5d 04h 49m
2.5 s	4d 08h 01m
2.0 s	3d 11h 13m
1.5 s	2d 14h 24m
1.0 s	1d 17h 36m
0.5 s	20h 48m
0.2 s	8h 19m
0.1 s	4h 09m

Please remember: The smaller the sampling interval, the more frequently the data will have to be stored on a card, since the data will otherwise be overwritten.

The following data is stored in the internal memory of ***LiquoGuard® CSF.***

- Date
- Time
- Pressure
- Flow
- Compliance
- P-Set
- Flow-Set
- Pause: 1 if pause, otherwise 0
- Pumping: 1, is pump is activated, otherwise 0
- Marker: at the moment always 0
- Statuscode

Table headlines:

Date	Time	Pressure	Flow	Compliance	P-Set	Flow-Set	Pause	Pumping	Marker	Statuscode

An MMC or SD memory card (format: FAT 16) can be used to read out data created by ***LiquoGuard® CSF***. Insert the memory card into the slot next to the pump, whereby the contacts must point towards the pump head. ***LiquoGuard® CSF*** will ask whether the data must be written to the card. Confirmation with "Yes" will immediately start the copying process. The card symbol will change its color to orange; the inside of the symbol will display the percentage of the already copied data. After copying is completed, the symbol changes back to blue and the card can be removed.

Figure 29: Symbol for memory card

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During writing the software checks whether a memory card is full. The writing procedure becomes irregular towards the end and if there is insufficient space, the error message "Error while writing to card!“ will be displayed. The started file is subsequently deleted and the card symbol will display “Err“, until the card has been removed.
In this case ensure that there is sufficient memory on your card and then resave. (A full internal memory requires approx. 4 - 5 MB memory capacity).

ATTENTION: The card must not be removed during the copying process!
All data on the memory card may be irretrievably lost!

8.9 Replacement of tube set

After 5 days, ***LiquoGuard® CSF*** displays two round flashing red arrows in the info field of the keys lock (see page 26) together with the red text "Please change tube set!". This indication is not an alarm. If keys lock is active, the tube set symbol alternates with the key symbol. After 7 days, ***LiquoGuard® CSF*** emits the same message as an alarm. The alarm pauses can be used here, but the alarm does not disappear during this application.
In order to perform a proper change of the tube set, the application has to be interrupted with "Set change" (see 8.10).

Figure 30: Symbol for tube set replacement

8.10 Interruption of an application

There are 2 ways to interrupt an application:

1) Press and hold the **"ON/OFF – Standby – key"** for at least 2 seconds
2) Open the front cover of the pump of the ***LiquoGuard® CSF***

Both of these ways cause a new selection menu to appear on the right side of the display showing 4 different points to be selected (Interrupt, END, Change set, Esc)

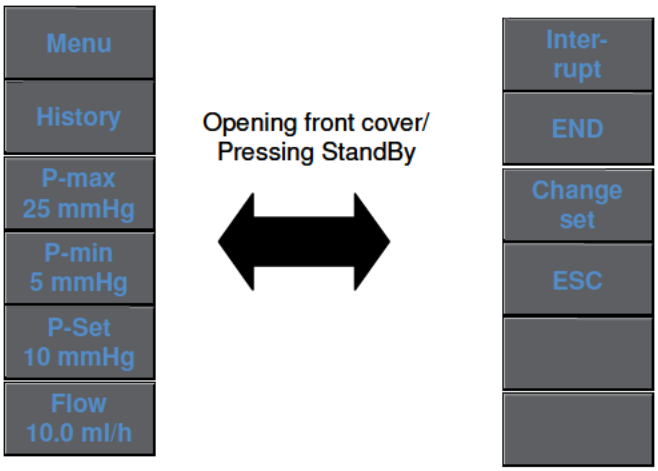

Figure 31: Interrupt, END, Change set

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Should you wish to change the tube set, select "Change set". If you want to interrupt the application (e.g. to perform a CT), select "Interrupt". In both cases, the next question to appear will be, "Interrupt application?". By selecting "Yes", the question, "valve to catheter closed?", will appear.
Be sure to see that the shut-off valve to the catheter is closed, then verify this with "Okay". The tube can now be removed (and reconnected later) or the tube set can be renewed.
When the tube set is reattached, one should not forget to open the shut-off valve to the catheter once again.

Notes:

- If the sensor cable is disconnected, the notice "Interruption, connect tube set" will appear and the symbol for a circulating pump will be displayed in red. The measuring value will be displayed as -- . In the data record you can recognize this condition as measuring values < - 90 mmHg
- Pulling the plug from the tube set without following the instructions described above will always lead to the alarm condition of "Sensor defective or disconnected". Should this occur, reattach the plug. Should you wish to end or interrupt the application, or to change the tube set, please follow the instructions described above.
- When the alarm condition "Sensor defective or disconnected" appears, it is impossible to activate "Audio pause" or "Audio off". An intentional removal of the tube set must be performed using the 4 keys on the right edge of the display (Interrupt, End, Change set, Esc; see Figure 31) (as described above, these 4 keys can be activated using the Standby key or by opening the cover). The device will recognize any other procedure as being faulty.
- With "Esc" you will always be able to return to the normal control display.

8.11 Exiting the application

Press and hold the ON/OFF - Standby key for at least two seconds. As described under 8.10, a selection menu with 4 points will appear. Select "End". The question "Sure to turn off the device?" will appear and the total volume of the application will be displayed. If confirmed with "Yes", ***LiquoGuard® CSF*** will exit the application and switch off.

Please observe that you cannot start a new application with the used tube set.

Should you have forgotten to read out the data via the memory card, you can restart ***LiquoGuard® CSF*** and read out the data one last time. The connection of a new tube set deletes all existing data.

In Standby mode (***LiquoGuard® CSF*** - is connected to AC power) the blue LED flashes and the battery is charged.

If the AC power chord is disconnected, ***LiquoGuard® CSF*** is switched off.

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8.12 Demonstration mode

The device has a demonstration mode ("Demo mode"), which may only be used for the purpose of performing demonstrations and for teaching! The Demo mode can be recognized through the red flashing "Demo" indicator to the upper left of the display (to the right and beside ICP/P_{CSF}).
One automatically comes to the Demo mode when a special, unsterile demonstration tube set is connected.
Note: In the Demo mode, the device will turn off automatically after a certain period of time without previous warning! The Demo mode should NEVER be used on a patient!

8.13 System menu

Use the display control field key “Menu” to access the "System menu". However, access to the system menu is only possible if ***LiquoGuard® CSF*** is in "Pause mode". The selection bar is moved with the turn-switch. The corresponding sub-menu is selected by pressing the turn-switch. The submenus consist of several parameters that are displayed in sequence. A further parameter is always reached by pressing the turn-switch. You can now change the preset value by turning the turn-switch. A value being edited is displayed as orange during this time. If you want to accept the changed value, press the turn-switch. A text will appear in the display as a reminder: "Confirm changes with the wheel".

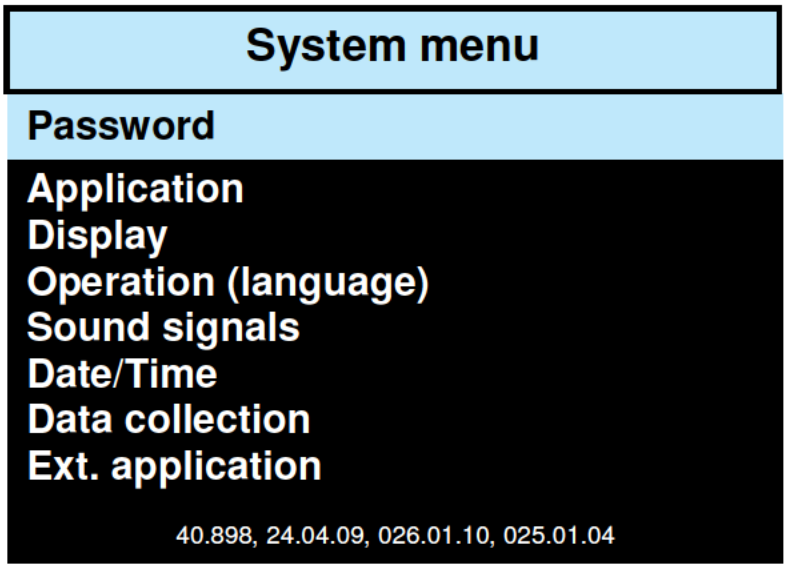

Figure 32: System menu

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Input of figures in the system menu is also possible in numbers. To activate this function during number input in the system menu, press the Alt key. A numeric keyboard appears in which you can enter values using the wheel. Press “END” to accept the values. Values which are too large are automatically limited by the maximum value. The Alt key therefore no longer serves as Esc at this point.

Figure 33: Numerical input

If the value is not to be adopted, leave the level with the Standby key or wait until the system menu is automatically exited - a negative confirmation tone is then sounded. You can set the time for automatic exiting (Standard 60 seconds).

8.13.1 Sub-menu Password

This point currently has no function for the operator. All menu items remain visible for the operator.

8.13.2 Sub-menu Application

The settings for the application are made in the Application sub-menu.

(1) Sampling rate memory [s]

Meaning: Time step in which a measured value is saved to memory.

Default value: 6.0 seconds
Minimum value: 0.1 seconds
Maximum value: 600 seconds

(2) Duration of volume balance [h]

Meaning: Time step for calculating the volume balance – also see page 23 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h).

Default value: 24 hours
Minimum value: OFF (set values: OFF, 2 h … 24 h, steps of 2)
Maximum value: 24 hours

(3) Flow increment

Meaning: This setting changes the increment for the operating field "Flow" (ml/h).

Default value: 1.0
Minimum value: 0.1
Maximum value: 10.0

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(4) Pressure increment

Meaning: This setting is used to change the time step for the operating fields "P-max / P-min / P-Set" (mmHg).

Default value: 1.0
Minimum value: 1.0
Maximum value: 10

(5) Duration Audio pause

Meaning: This setting sets the time for the shortest possible duration of "Audio paused".

Default value: 20 minutes
Minimum value: 1 Minute
Maximum value: 20 minutes

(6) Define application

Meaning: This can be used to reset the type of application during an application.

Possible parameter settings: lumbar, ventricular
(No default value, setting remains after reset)

8.13.3 Sub-menu Display

The settings for the display are made in the "Display" sub-menu.

(7) Range diagram

Meaning: The pressure axis in measuring mode is automatically scaled according to the alarm limits. In order to display a larger range, 20 % more than the upper alarm limit and 20 % less than the lower alarm limit are shown. The percentage is always related to the upper alarm value.

Default value: 20 %
Minimum value: 0 %
Maximum value: 100 %

Example: P-min = 5 mmHg, P-max = 25 mmHg, the diagram ranges from 0 mmHg (5-5) to 30 mmHg (25+5).

(8) Timeout backlight [s]

Meaning: In order to save power or to have a darker screen during night operation, the background lighting automatically switches into the darkest setting after an adjustable time (seconds). If this function is not wanted, the parameter can be set to OFF. During battery operation, the display is always darkened after 5 seconds.

Default value: OFF
Minimum value: OFF
Maximum value: 600 seconds

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(9) Brightness Display

Meaning: The brightness of the background lighting of the display is preset here. The value directly affects the display as it is changed so that the user can find the correct setting more easily. Setting is made in 4 steps.

Default value: 4
Minimum value: 1
Maximum value: 4

(10) Colour mode

Meaning: You can select a colour mode setting between 1 and 0.

"1" " means "dark" display background colour
"0" " means "light" display background colour
(Default value: “dark” display background colour)

8.13.4 Sub-menu Operation (language)

The "Operation" sub-menu contains functions that relate to the behavior of the unit with respect to the user.

(1) Language (language)

Meaning: The display language can be set here, and further languages can be stored.

Default value: ENGLISH
Value (depending on configuration): DEUTSCH, ENGLISH, Français, Svenska

(2) Operation Timeout [s]

Meaning: Settings or key activations are exited after a set time in seconds, independent of the level or in which parameters the input is carried out. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the input can only be exited by pressing the service screen "Standby" or "Alt". This time does not apply to the system menu.

Default value: 10 seconds
Minimum value: 1 second
Maximum value: 120 seconds

(3) Timeout menu [s]

Meaning: The system menu is closed after the preset time in seconds, independent of the level or the parameter currently being entered. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the system menu can only be exited by pressing the service screen "Standby" or "Alt".

Default value: 60 seconds
Minimum value: OFF
Maximum value: 600 seconds

8.13.5 Sub-menu Sound signals

The operator cannot change the volume of the activation signal.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.13.6 Sub-menu Date/Time

The system clock of ***LiquoGuard®*** can be set or changed respectively in this sub-menu.

(1) Date format

Meaning: Setting the date format

Default value: DD.MM.YYYY
Possible parameter settings: DD.MM.YYYY; MM/DD/YYYY; YYYY-MM-DD

(2) Clock: Year

Meaning: Setting of the current year

Minimum value: 2001
Maximum value: 2099

(3) Clock: Month

Meaning: Setting of the current month

Minimum value: 1
Maximum value: 12

(4) Clock: Day

Meaning: Setting of the current day

Minimum value: 1
Maximum value: 31, depending on the set month

(5) Clock: Hour

Meaning: Setting of the current hour

Minimum value: 0
Maximum value: 23

(6) Clock: Minute

Meaning: Setting of the current minute

Minimum value: 0
Maximum value: 59

(7) Clock: Second

Meaning: Setting of the current second

Minimum value: 0
Maximum value: 59

8.13.7 Sub-menu Data collection

(1) Decimal point

Meaning: Decimal markers in figure display on memory card. This setting is required for various countries.

Default value: Comma
Possible parameter settings: Comma, full stop

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(2) Data format MMC

Meaning: Setting the data format output depending on evaluation software

Default value: ASCII
Possible parameter settings: ASCII, LABpilot

8.13.8 Sub-menu Extended application

(1) Hysteresis controller [mmHg]

Meaning: This setting pre-selects a defined hysteresis for the pressure controller (target pressure curve). The hysteresis is symmetric to the target value, i.e. a target value of 12 mmHg and a hysteresis of 0.5 mmHg starts the pump at a pressure higher than 12.5 mmHg and will pump until the pressure is lower than 11.5 mmHg.

Default value: 0.5 mmHg
Minimum value: 0.5 mmHg
Maximum value: 1.5 mmHg

(2) Filter time control [s]

Meaning: The measured value for display of the digital pressure value can be filtered to avoid too high pressure changes of the digital pressure value as well as a continuous on and off of the pump. In order to filter out the pulse beat, the value must be set to at least 1.0 seconds. The set value displays after which time period 63% of the new value was reached after a step.

Note: This value is coupled to the pulsation alarm during ventricular drainage. If the pulsation alarm is ON, it is activated, the value is automatically set to 1.0; if pulsation alarm is OFF, it is set to 0.0 (in order to achieve a more rapid reaction time for the pump). This can be set manually by way of the system menu, but will once again be returned to the standard values when an adjustment is made for the pulsation alarm.

Default value: 1.0 (lumbar drainage, lumbar infusion test and ventricular drainage if pulsation alarm ON); 0.0 (ventricular drainage if pulsation alarm OFF)
Minimum value: 0.0
Maximum value: 60.0

(3) Filter time display or filter time display lumb. [s]

Meaning: The measured value for display in the diagram can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. If a clearly higher value is selected instead of a time resolution of 6 seconds, we recommend setting a longer filter time to enable the display of an averaged value. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 0.0 ventricular drainage; 0.5 lumbar drainage / lumbar infusion test
Minimum value: 0.0
Maximum value: 60.0

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(4) Filter time history [s]

Meaning: The measured value to store the data for the history function and the memory card can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. But then the scan time for the memory must obviously be set to 0.1 seconds. For a storage time of 1 second or more you should also select a filter constant of 1 second or more, so that averaged values can be stored. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 1.0
Minimum value: 0.0
Maximum value: 60.0

(5) Average value volume [min]

Meaning: Period for the calculation of the average volume flow

Default value: 15
Minimum value: 15
Maximum value: 60

(6) System information

Meaning: The setting "Yes" is used to display system information serving Möller Medical service staff for remote diagnosis.

(7) Reset System menu

Meaning: With the setting or changing of Reset System menu to "Yes", all changed setting parameters in the system menu are reset to standard values stipulated by the manufacturer. If confirmed with "No", all settings changed by the operator will be retained.

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9 Troubleshooting

***LiquoGuard®* CSF may not be opened by the operator!**

This chapter describes some problems which may occur in connection with ***LiquoGuard® CSF*** Several possible solutions are listed for each problem. The first proposed solution is generally the most suitable. If the problem is not resolved, work through the proposed solutions in the order listed until the fault is rectified. ***LiquoGuard® CSF*** must always be switched off during connection or disconnection of connectors, with the exception of the tube set. If this does not remove the error, please contact the Möller Medical service division: service@moeller-medical.com.

Problem	Solution
Not functional, the display is switched off. Or ***LiquoGuard® CSF*** cannot be activated.	***LiquoGuard® CSF*** is not correctly connected to the AC power supply. Check power supply, switch on any multiple sockets, and check feed line. If these possibilities can be excluded, the error must be corrected by the service centre.
Pump does not rotate.	Pump is in "PAUSE" mode
Moistness penetrated the connectors	Pull AC power chord. Allow connectors to dry.
The device issues a rhythmic beep	Indicates an alarm. Press the Standby key 3 times in succession. If the device returns to this condition repeatedly, the device should be checked by Service.

If these measures do not eliminate the problem, the device should be inspected by Möller Medical service personnel.

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10 Service

If the solution to a problem cannot be found, please contact the responsible service centre of Möller Medical.

Each return delivery of ***LiquoGuard® CSF*** must exclude risk of infection by a previously conducted disinfection procedure. The disinfectant may not be sprayed into the memory card slots.

Consumable materials should be disposed of in accordance with hospital guidelines.

Service Information

Never open the device if it is connected to the power supply. Attention - even then internal unit parts can still be voltaged.

Möller Medical service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
D – 36043 Fulda
Phone: +49 (0) 661 / 94 19 5 - 0
Fax. +49 (0) 661 / 94 19 5 - 90
http://www.moeller-medical.com
E-mail:info@moeller-medical.com

Service
Phone: +49 (0) 661 / 94 19 5 - 48
Fax. +49 (0) 661 / 94 19 5 – 92
E-mail:service@moeller-medical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11 Accessories

The products described here represent only a small selection of the equipment available for ***LiquoGuard® CSF***. The currently valid list of equipment (including the prices) can be requested from Möller Medical on a separate Order form (neurochirurgie-vertrieb@moeller-medical.com; +49-(0)661-94195-85).

11.1 Tube set for LiquoGuard®

REF.-No.: 92 007 836 (1500 mm/59.06 inch)
1 cmpl packed Article No.: **00 002 650**

REF.-No.: 92 008 568 (2000 mm/78.74 inch)
1 cmpl packed Article No.: **00 002 911**

11.2 *LiquoGuard®* Software: Lumbar Infusion Test

Additional option for ***LiquoGuard®*** Article No.: **00 003 165**

11.3 Tube Set for the Lumbar Infusion Test *LiquoGuard®*

REF. No.: 92 008 646 (1500 mm)
1 cmpl packed Article No.: **00 002 962**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12 Option: Lumbar Infusion Test (Not available in the US)

Unlike in CSF drainage, this application consists of infusing artificial cerebrospinal fluid (CSF) into the spinal canal.

ATTENTION: A prerequisite for the lumbar infusion test is that the operator is familiar with the regular use of ***LiquoGuard®,*** that she/he has received extensive training on the device and has read and understood the instruction manual in its entirety.

12.1 General Description

The lumbar infusion test is an established clinical method for indirect measurement of the CSF absorption capability of patients with normal pressure hydrocephalus (NPH). Following the puncture of the intrathecal space, a suitable infusion system with combined pressure measurement is connected, fluid is pumped into the subarachnoid space of the patient at a defined flow rate, and the cerebrospinal pressure is measured simultaneously. The user determines the flow rate and detects the initial and final fluid pressure values.
In the lumbar infusion test with ***LiquoGuard®***, artificial CSF ("infusion solution" - saline solution or CSF substitute) is infused into the patient at a defined flow rate (volume flow rate "Flow"). The pressure value prior to infusion (P-Start) and the stabilized pressure value during infusion (Plateau) are required to compute the ROF (Resistance to OutFlow). The ROF is computed as follows:
(Plateau [mmHg] – P-Start [mmHg]) / Flow [ml/min].
This value is indicated on the ***LiquoGuard®*** display. The ROF dimension is [mmHg / (ml/min)]. The display indicates this in the same manner, although "Flow" is adjusted in [ml/h].
The patient must lie down for the duration of the application to avoid excess pressure.
Qualified personnel must be present for the duration of the application. The measured value depends directly on the initial pressure and the plateau pressure set by the physician. The physician is therefore directly responsible for the measurement results.

Attention:
Reaching a plateau level is dependent on the health of the patient. The physician must monitor the patient constantly and must interrupt or discontinue the test using the Pause key in cases where the patient is observed to demonstrate dangerous pressure levels. The evaluation of these pressure levels is alone the responsibility of the physician; the ***LiquoGuard®*** serves merely as an aid to make this work easier.

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Option: Lumbar Infusion Test (Not available in the US)

12.2 Purpose

The option "lumbar infusion test" of the ***LiquoGuard®*** may only be used in conjunction with the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646**. This tube set also contains the spinal cannula (touhy needle) which is needed for the infusion test.

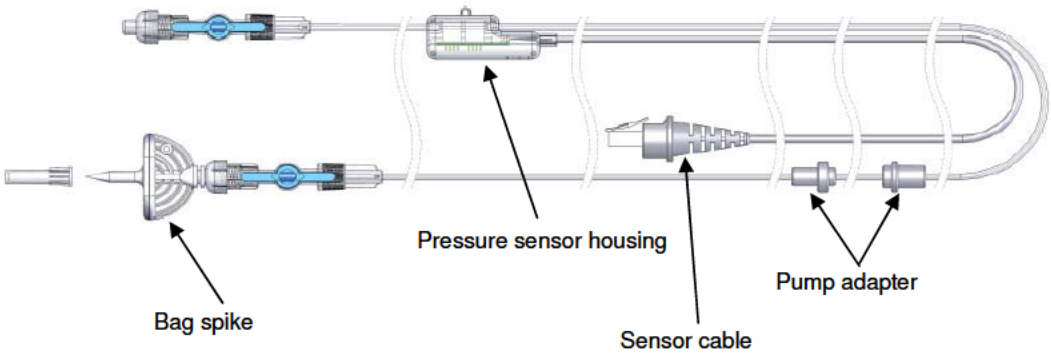

Figure 34: Tube set for lumbar infusion test (spinal cannula and adhesive electrode not displayed)

The purpose of the tube set "tube set for lumbar infusion test ***LiquoGuard®***" is to convey at constant flow rate up to 100 ml infusion solution (physiological saline solution or CSF substitute) through the spinal canal with simultaneous pressure measurement. The purpose of the device in conjunction with the tube set is: "to carry out the lumbar infusion test".
The appropriate location for its application includes monitored medical hospital rooms or neurosurgical practices. Qualified personnel must stay with the device/patient for the entire duration of the application.
The application time is limited to one hour.

The tube set for the lumbar infusion test is intended for use in combination with ***LiquoGuard®*** and must therefore be connected to this system, i.e. the set alone cannot fulfill the intended purpose of the system. It has been designed exclusively for the infusion of CSF-like fluid into the subarachnoid space and must not be used for the infusion of drug solutions or other constituents. The lumbar infusion test only serves for NPH diagnosis by means of the evaluation method referred to as "lumbar infusion test" in the related literature. The withdrawal of CSF or the connection to other body systems (e.g. blood system) are incompatible with its intended use.

For this special application ***LiquoGuard®*** may be used for the infusion of fluid (saline solution or CSF substitute) into the spinal canal.
It is, however, not an infusion pump because the lumbar infusion test serves diagnostic purposes and is continuously monitored by the operator.

ATTENTION: The lumbar infusion test must not be the only means of diagnosis resulting in measures taken on the patient.

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Option: Lumbar Infusion Test (Not available in the US)

12.3 Indications

Diagnostic indications for lumbar infusion test

The nervous system (brain, spinal cord) is surrounded by cerebrospinal fluid (CSF). The production and absorption of CSF are in a stable balance. Normal pressure hydrocephalus (hereinafter abbreviated as NPH) is a disease that involves an imbalance between the production and absorption of CSF. Patients with this clinical picture can show numerous different symptoms such as gait disorders (magnetic gait), memory disturbances and micturition problems (incontinence). These symptoms are typical of NPH, but can also be diagnosed in individuals with other cerebral disorders (such as Alzheimer's disease or other dementia problems). The treatment of NPH involves the continuous drainage of CSF from the ventricles of the brain into another body cavity, usually intraperitoneal (ventriculoperitoneal shunt = VP shunt) or into the blood system (usually into the atrium, i.e. ventriculo-atrial shunt = VA shunt). In order to determine whether and how a shunt system can contribute towards successful therapy, meticulous diagnosis must be performed in order to ascertain whether a patient actually suffers from NPH. Besides the determination of clinical symptoms, imaging diagnosis is required in order to check for typical NPH symptoms (extension / disproportion of ventricles, effacement of the cerebral sulci, etc). Since, however, the combination of clinical and imaging exams is not sufficient for safe diagnosis, further examination methods must be applied. Besides continuous lumbar drainage, the lumbar infusion test represents an additional method for NPH diagnosis verification.

12.4 Execution of the lumbar infusion test

The puncture of the intrathecal space is a prerequisite for the lumbar infusion test. The patient is usually placed in the lateral position, the skin in the centreline of the lumbar spine is disinfected, and under sterile conditions the subarachnoid space is punctured using a suitably dimensioned spinal cannula. As soon as the proper CSF flow is ensured, a tube system is connected to the positioned needle. This tube system is connected to a pressure measuring device. Using an infusion pump, sterile, CSF-like fluid can be infused via the tube system. Prior to starting the infusion, the initial pressure must be measured. Afterwards, the fluid is infused at a defined rate (in most cases 1 to 2 ml/min) while continuously measuring the pressure until a specific plateau pressure has been reached, or until a critical pressure value forces the attending physician to abort the test. To calculate the ROF ratio (resistance to outflow, indicated in mmHg/ml/min), the pressure difference determined (plateau pressure – initial pressure) is divided by the flow rate (ml/min). A ratio higher than the critical value (in most cases 12-18 mmHg/ml/min) is an essential criterion for the diagnosis of an NPH. However, expert literature does not describe the lumbar infusion test as a single method for NPH diagnosis, and this method is not suitable for this purpose.

Puncture of the subarachnoid space

The subarachnoid space is punctured by means of a spinal cannula (usually a Touhy needle).

Intrathecal CSF drainage

The withdrawal of CSF requires the surgical installation of an approved cannula into the intrathecal space. This surgical intervention is indicated in case of suspicion of NPH.

12.5 Contraindications

The contraindications determined for any other puncture of the subarachnoid space also apply in this context:

Absolute contraindications: Blood coagulation disorders, thrombocythemia, superficial or deep infections of the skin, bone, meninges or brain. Especially in case of cerebral,

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meningeal or intraventricular infections (encephalitis, meningitis and ventriculitis), increased intracranial pressure, CSF passage dysfunctions and expansive spinal column or cord processes

12.6 Use in Conjunction with other Products

The option "lumbar infusion test" of the ***LiquoGuard®*** may only be used in conjunction with the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646** by Möller Medical. Accordingly, the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646** may only be used with the option "lumbar infusion test" of the ***LiquoGuard®***.

12.7 Patient Population

This application may only be used on patients with suspected normal pressure hydrocephalus (age group: usually middle-aged to elderly).

12.8 Remaining Risks

The use of ***LiquoGuard®*** with the "lumbar infusion test" option poses the following risks when carrying out the lumbar infusion test: increased CSF pressure, fluid infusion outside the subarachnoid space in the event of malpositioning of spinal cannula, cerebrospinal fluid infection.

12.9 Application and Operation

The lumbar infusion test is incorporated as option and can be selected via the menu prompt at the beginning (see Page 30). If the option is available, "*Infusion test*" is displayed on the screen when the device is switched on (when software version is displayed).

As the lumbar infusion test is a diagnostic procedure during which small pressure differences are decisive, qualified personnel must stay with the patient throughout the entire process and attend the application. This is important as changes in the position of the patient would more significantly affect the measurement than the additional infiltration.

The operator must manually start and finish the procedure as the automatic mode is risky for the same reasons. In this way the operator specifies the initial pressure as well as the changed final pressure.

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Option: Lumbar Infusion Test (Not available in the US)

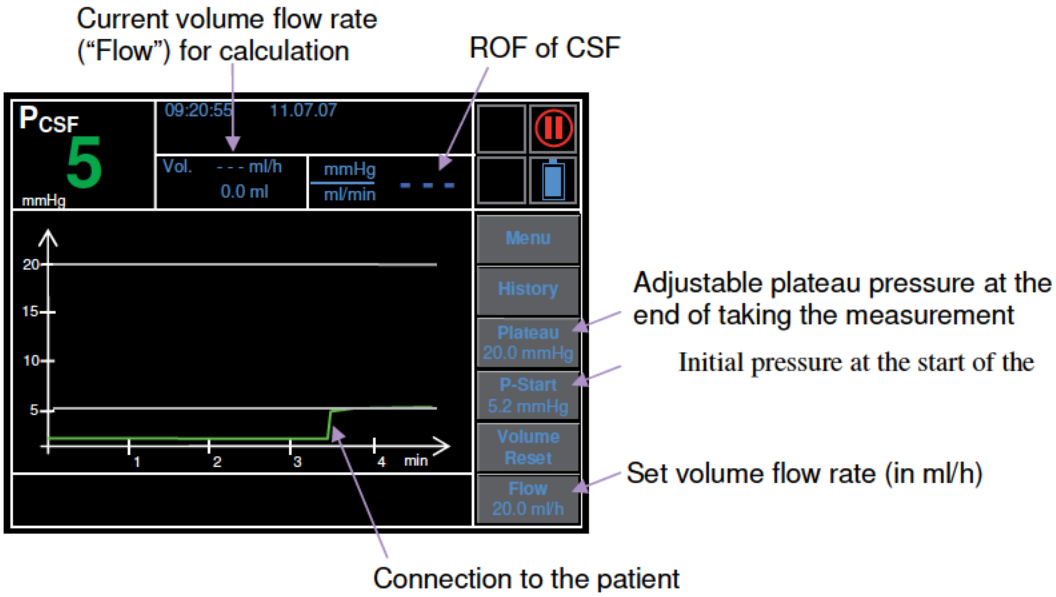

Figure 35: Display setup for option "lumbar infusion test"

Notes:

- The filtered pressure values only are displayed.
- Two horizontal gray curves are displayed rather than the alarm limits. The operator sets one curve to the initial pressure value. The second curve can then be set to the final pressure value.
- The pressure axis scaling is based on these two curves; however, they can be moved directly on the screen prior to accepting the values. The display is rescaled by accepting the values.
- These two cursor values and the set volume flow rate are always used to compute the CSF flow resistance. The physician has to make the moment he accepts this value as the actual measured value dependent on the current pressure signal; meaning the moment when the measured pressure has actually reached the upper plateau.
- The motor no longer stops during pumping when the pressure has dropped below the lower alarm pressure, but rather when the upper alarm limit is exceeded.
- There is no "Pressure too constant" alarm for the infusion test. This parameter is also skipped in the menu.
- The "History" function is also available for the infusion test. A wider pressure range can be viewed here when taking the measurement.
- Data storage and data transfer to a memory card work in the same way as in the Drainage Mode.

12.9.1 Preparation

For the first steps please see at page 30.
→ „Select application": For the lumbar infusion test select "Infus-T".

Afterward, please carry out the following procedures:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.

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Option: Lumbar Infusion Test (Not available in the US)

2. Insert the tube set into the pump (see page 31).

3. "Sensor cable - connect to pump and wait."
→ If you haven't done it yet: Connect the sensor cable to the pump (see page 32). The next step is indicated automatically.

4. "Bag with infusion solution - connect to tube set and confirm."
→ Remove the protective cap from the spike and use it to prick the container with the CSF substitute.
As soon as you have verified with "Okay", the pump will begin running with a maximum velocity.
Note: By pressing ESC, you will be returned to "Connect the sensor cable to the pump and wait". If the sensor cable is still connected, the device will automatically continue to the next step ("… container with the infusion solution…"). Should you wish to interrupt this process, you must first disconnect the sensor cable from the device and then press Esc. Hereby, you will return to "Connect sensor cable to the pump and wait", where you can now press Esc once again in order to return to the site where a particular application can be selected.

5. "Fill tube – Press END once tube is filled."
→ Remove the protective cap from the one way stop cock and fill (aerate) the tube set.
Wait until fluid starts dripping from the tube set, then press "END".
Note: If air still remains in the tube set, the measurement may be inaccurate and air may be pumped into the patient.

6. Remove the additionally wrapped spinal cannula (Touhy needle) from the packaging and puncture the patient. Wait until the cannula is filled with CSF.

7. Connect the cannula with the tube set.

8. "Pressure sensor - Attach to patient."
→ Attach the pressure sensor to the patient to avoid inaccurate measurements. After you have pressed "Okay", the current pressure will be applied as "P-Start" (initial pressure). This is typically the correct pressure for starting the application. The operator, however, can still change this value at a later stage.

Note: Until this point in time, the tube set can still be removed by pressing "Esc" and returning step-by-step in order to start at the beginning. The tube set is not yet marked as being used.
As soon as you have connected the catheter and the pressure sensor to the patient, and have verified this with "Okay", the tube set is marked as used and can no longer be used elsewhere. Once again, the message "Connect sensor cable to the pump and wait" appears briefly, whereby the device controls whether or not a sensor cable has actually been connected.
As of this point in time, the alarm function is also activated and the device is in normal operation.

12.9.2 Taking the Measurement

At the end of the menu prompts the ***LiquoGuard®*** is in Pause mode, i.e. the pump is inactive. Now check whether the current pressure is relatively constant and whether it complies with the automatically set start curve ("P-Start"). If the start curve does not comply with the constant pressure, adjust the start curve using "P-Start".
If the pressure is not constant, please check whether the sensor was attached correctly. The patient must remain still, otherwise fluctuations in pressure may occur.

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Option: Lumbar Infusion Test (Not available in the US)

Once the pressure is stable (constant) and the start curve is correctly set, press the "Pause" key to start the pump.

Notes:

- If the current pressure and the start curve are identical, only the start curve will be visible.
- The display runs from the right-hand to the left-hand side. The current values are always indicated on the right-hand side (unlike the Drainage Modes).
- No value is displayed as long as the pump is in Pause mode because there is no volume flow rate ("Flow").
- When the pump mode of the device is activated, the pump is always active for 8 seconds, after which pumping is interrupted for 2 seconds in order to measure the pressure until pumping once again resumes, a procedure which continues repeatedly.

12.9.3 Infiltration

The pressure increases after the pump is activated until a new stable pressure plateau has been reached. This constant pressure that corresponds to the set flow of the pump is required to compute the "ROF of CSF". The operator must set the reached plateau pressure via "Plateau", whereby she/he must ensure that this plateau value is actually stable and does not rise further.
"ROF of CSF" is always computed with the currently applicable settings/values, so that the operator has an idea what the probable result may be at the end of taking the measurement.
If "Flow" is changed during the application, the operator will have to wait for a stable plateau pressure again.

Note:

- The start curve (P-Start) can be adjusted throughout the application.
- In practice it is often difficult to reach a stable plateau value. The final value is subject to strong variation. In this case, it must be ensured that the pressure does not increase any further. The attending physician is responsible for setting the correct plateau pressure value.

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Option: Lumbar Infusion Test (Not available in the US)

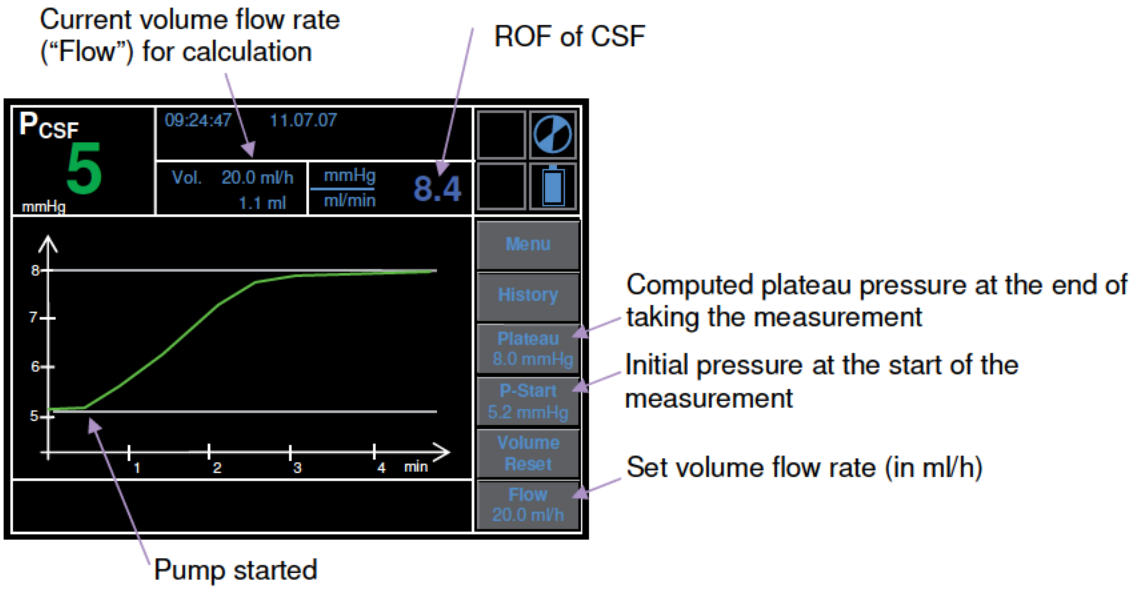

Figure 36: Display setup for option "lumbar infusion test" during the application

Setting options:

- **Plateau**: P-Start to 75 mmHg, default value: 40 mmHg
- **P-Start**: -15 mmHg to Plateau, default value: 0 mmHg
- **Flow**: 1 - 120 ml/h, default value: 20 ml/h

12.9.4 Alarms

Alarms can occur for "Pressure too high" (upper alarm limit exceeded) and "Pressure too low" (dropping below lower alarm limit) throughout the infusion test. These alarms can be set to "Audio paused" or "Audio off" analog to the drainage mode (see also Page 38). Press the "Alt" key (also see Page 25) to call up a second menu selection. Here you can adjust the alarm limits.

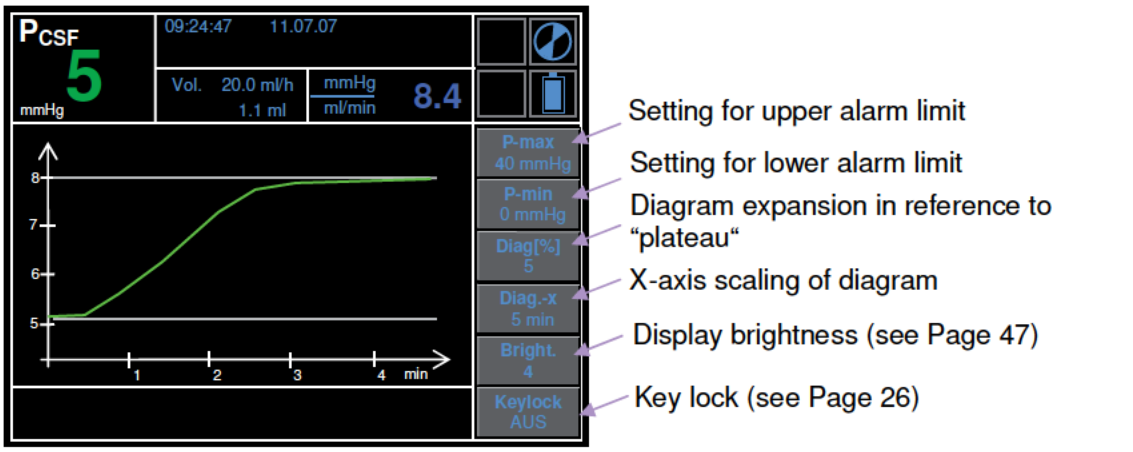

Figure 37: Display setup for option "lumbar infusion test", 2nd selection menu

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Option: Lumbar Infusion Test (Not available in the US)

Setting options:

- **P-max**: P-min to 75 mmHg, default value: 40 mmHg
- **P-min**: -15 mmHg to P-max, default value: 0 mmHg
- **Diag [%]**: 0-50, default value: 0
- **Diag. x**: 60 seconds to 20 minutes, default value: 5 minutes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 8

LABELS FOR THE LIQUOGUARD CSF

Back to **List of Appendices**
Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF – DEVICE LABELING

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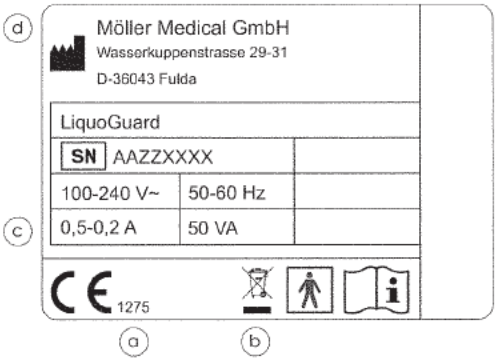


Aufschlüsselung der Seriennummer:

AA = Herstelljahr d.h.: Für Herstelljahr 2004 ist AA = 04
ZZ = Herstellmonat d.h.: Für Monat November ist ZZ = 11
XXXX = fortlaufende Gerätenummer mit 0001 beginnend unabhängig von Herstelljahr und Herstellmonat.

Schrift: Schwarz

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 007 982		Allgemeintol. DIN ISO 2768 m	Maßstab 1:1 Werkstoff: gef. aus: 30 000 146 Halbzeug:
						Datum	Name	Typenschild LiquoGuard
					Bearb.	16.03.06	DE	
					Gepr.	25.02.10		
e	Symbole geä.	KO3262	25.02.10	Mü-De	Norm			
d	Hersteller	KO 3014	08.10.08	AH				
c	geändert	KO 2488	07.09.06	LW				
b	hinzu	KO 2455	19.07.06	DE				
a	geändert	KO 2443	19.07.06	DE				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP001-001 01 01-000			Ers. für: LDP001-001 01 01-00 d-4

Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für Patent- und Gebrauchsmuster Eintragung vorbehalten.

Zuletzt gespeichert von sdehler am 25. Feb 2010 10:33:33

Werkstoff-Nr.:

LDP001-001 01 01-00 e-4

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

149,5 (e)

100 (e)

(b)

Möller Medical GmbH
Wasserkuppenstrasse 29-31
D-36043 Fulda

LiquoGuard, REF 00002563

SN AAZZXXXX

100-240 V~	50-60 Hz
0,5-0,2 A	50 VA

CE 1275

(a)

Aufschlüsselung der Seriennummer :

AA = Herstelljahr d.h.: Für Herstelljahr 2006 ist AA = 06
ZZ = Herstellmonat d.h.: Für Monat Februar ist ZZ = 02
XXXX = fortlaufende Gerätenummer mit 0001 beginnend unabhängig von Herstelljahr und Herstellmonat.

Schrift : Schwarz

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 007 865	Allgemeintol. DIN ISO 2768 C	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gef. aus : 30 004 755 (e) Halbzeug:	Werkstoff-Nr.:
						Datum / Name	Kartonaufkleber	
					Bearb.	17.03.06 / DE		
					Gepr.	09.08.10	LiquoGuard	
e	hinzu/geändert	KO3380	09.08.10	MÜ-De	zul. gespeichert von: sdehler	17.01.2011 13:24:48		
d	Symbole geä. & hinzu	KO3262	01.03.10	Mü-De	Vertraulich/Confidential			
c	überarbeitet	KO3044	11.12.08	Mü-De	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP001-001 00 01-00 e-4	Blatt 1 von 1
b	geändert	KO 2488	07.09.06	LW				
a	geändert	KO2443	14.07.06	DE				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP001-001 00 01-00 0-4		Ers. für: LDP001-001 00 01-00 d-4	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 9

LABELS FOR THE LIQUOGUARD CSF TUBING SET, 1500MM

Back to **List of Appendices**
Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF TUBING SET, 1500MM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 650

REF.: 92 007 836

1500 mm

+40°C (104°F)
+10°C (+50°F)

STERILE EO

MRI

PHT DEHP

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

20009691 - 2010-03

(b)

(b) Achtung! Originalablage des PDF's für Fertigung: Dokumentenablage_Gültig

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 690		Allgemeintol.	Maßstab 1:1 / Gewicht: / Volumen:
								Werkstoff: bez.: Druckerei Mergard / Werkstoff-Nr.: 14,8 cm x 10,5 cm Halbzeug: JAC script weiß, Klebstoff D131 80g/m²
						Datum	Name	Verpackungsaufkleber
					Bearb.	29.03.07	LW	
f	kpl. überarbeitet	KO3262	02.03.10	Mü-De	Gepr.	02.03.10		Schlauchset "LiquoGuard" 1500 mm
e	Logo + Anschrift	KO 3010	29.09.08	AH	Norm			
d	neues Logo	KO 2981	03.07.08	AH	zul. gespeichert von:	sdehler	02.03.2010 09:26:00	
c	Text überarbeitet	KO 2835	17.03.08	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Die Rechte für Gebrauchsmuster Eintragung vorbehalten.			LDP 002-001 00 11-00 f-4
b	hinzu	KO 2801	15.01.08	LW				Blatt 1 von 1
a	Art.-Nr. hinzu	KO 2733	04.12.07	LW				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-001 00 11-00 0-4			Ers. für: LDP 002-001 00 11-00 e-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF TUBING SET, 1500MM – PACKAGING LABELING: VARIABLE DATA

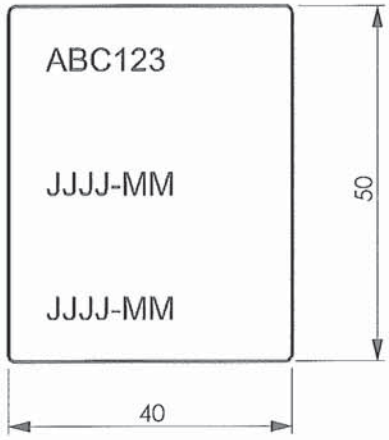
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(a) Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 687	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:
							Halbzeug: Rollen - Haftetiketten 50 x 40 mm	
						Datum / Name	Aufkleber	
					Bearb. 28.03.07 LW			
					Gepr. 15.03.12		für Schlauchset "LiquoGuard"	
					zul. gespeichert von: ahorwart	15.03.2012 11:05:01		
					Vertraulich/Confidential			
b	Haltbarkeit	KO3769	15.03.12	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Es sind alle Rechte vorbehalten insbesondere Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP002-001 00 09-00 b-4	Blatt 1 von 1
a	Chargenbez. geä.	KO 467	07.02.11	MU-De				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-001 00 09-00 0 - 4		Ers. für: LDP002-001 00 09-00 a-4	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF TUBING SET, 1500MM – PATIENTS STICKER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-001 00 12-00 d-4

LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			
LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			
LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			
LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			

LiquoGuard®
Drainageset

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

30004037 – 2009-03

Achtung! 1. Originalablage des PDF's für Fertigung : Dokumentenablage _Gültig

2. "Chargenbezeichnung" und "Verwendbar bis" werden chargenspezifisch angepasst!!!

MöllerMedical
Wasserkuppenstrasse 29-31 • 36043 Fulda
Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com

Art.-Nr.: 30 004 037

Allgemeintol.

Maßstab 1:1 | Gewicht: | Volumen:

Werkstoff: bez.: Druckerei Mergard | Werkstoff-Nr.: (c) 6,8 cm x 8,5 cm

Halbzeug:

	Datum	Name
Bearb.	29.01.08	LW
Gepr.	16.03.09	
Norm		

Patientenaufkleber

Schlauchset "LiquoGuard" 1500 mm

Zust.	Änderung	KB-Nr.	Datum	Name
d	Größe Ref-Nr., Art.-Nr. Datum geändert	KO 3105	16.03.09	HOR
c	Größe, 4 Aufkleber	KO 3058	07.01.09	HOR
b	Logo + Anschrift	KO 3010	29.09.08	AH
a	neues Logo	KO 2981	03.07.08	AH

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Dateiname: LDP002-001 00 12-000 - 4

Ers. für: LDP002-001 00 12-00 c-4

LDP002-001 00 12-00 d-4

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 10

LABELS FOR THE LIQUOGUARD CSF TUBING SET, 2000MM

Back to **List of Appendices**
Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF TUBING SET, 2000MM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 911

REF.: 92 008 568

2000 mm

+40°C (104°F)
+10°C (+50°F)

STERILE EO

MRI

PHT DEHP

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

20008691 - 2010-03

Achtung! Originalablage des PDF's für Fertigung : Dokumentenablage _Gültig

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 691		Allgemeintol.	Maßstab 1:1 / Gewicht: / Volumen:
								Werkstoff: bez.: Druckerei Mergard / Werkstoff-Nr.: 14,8 cm x 10,5 cm Halbzeug: JAC script weiß, Klebstoff D131 80g/m²
						Datum	Name	Verpackungsaufkleber
					Bearb.	29.03.07	LW	
f	kpl. überarbeitet	KO3262	01.03.10	Mü-De	Gepr.	01.03.10		Schlauchset "LiquoGuard" 2000 mm
e	Logo + Anschrift	KO 3010	29.09.08	AH	Norm			
d	neues Logo	KO 2981	03.07.08	AH	zul. gespeichert von: sdehler		02.03.2010 15:43:18	
c	Text überarbeitet	KO 2835	17.03.08	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwider-			Blatt 1 von 1
b	hinzu	KO 2801	15.01.08	LW				LDP002-003 00 04-00 f-4
a	Art.-Nr. hinzu	KO 2735	04.12.07	LW	muster Eintragung vorbehalten.			
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-003 00 04-00 0-4			Ers. für: LDP 002-003 00 04-00 e-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF TUBING SET, 2000MM – PACKAGING LABELING: VARIABLE DATA

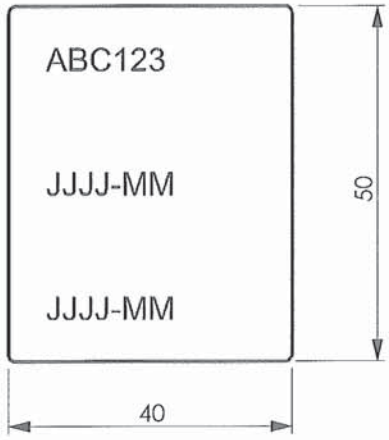
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(a) Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

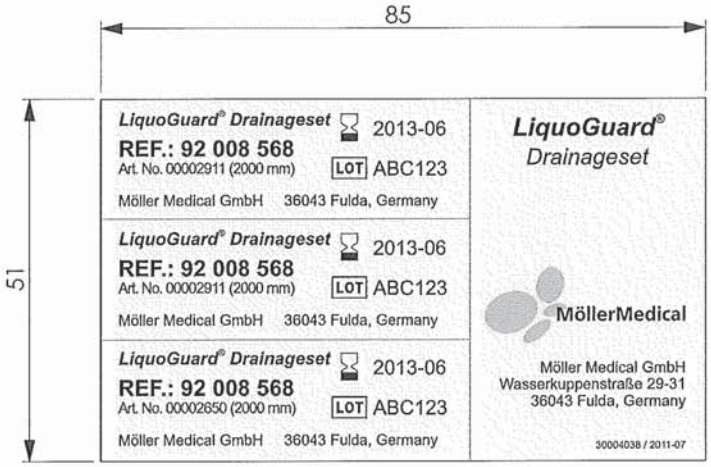
MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 687	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:
							Halbzeug: Rollen - Haftetiketten 50 x 40 mm	
						Datum / Name	Aufkleber	
					Bearb. 28.03.07 LW			
					Gepr. 15.03.12		für Schlauchset "LiquoGuard"	
					zul. gespeichert von: ahorwart	15.03.2012 11:05:01		
					Vertraulich/Confidential			
b	Haltbarkeit	KO3769	15.03.12	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Es sind alle Rechte vorbehalten insbesondere Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP002-001 00 09-00 b-4	Blatt 1 von 1
a	Chargenbez. geä.	KO 467	07.02.11	MU-De				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-001 00 09-00 0 - 4		Ers. für: LDP002-001 00 09-00 a-4	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF TUBING SET, 2000MM – PATIENTS STICKER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016



Haltbarkeit des Produktes = 1 Jahr 11 Monate

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 30 004 038	Allgemeintol.	Maßstab 1:1 / Gewicht: / Volumen:
							Werkstoff: gef. aus: 70 000 889 / Werkstoff-Nr.:
							Halbzeug:
					Datum	Name	Patientenaufkleber
					Bearb. 29.01.08	LW	
					Gepr. 29.07.11		Schlauchset "LiquoGuard" 2000mm
e	4-flg. in 3-flg. Aufkl. geä.	KO 3577	29.07.11	MÜ-De	zul. gespeichert von: sdehler	29.07.2011 10:12:59	
d	Größe Ref.-Nr., Art.-Nr., Datum geändert	KO 3105	16.03.09	HOR	Vertraulich/Confidential		
c	Größe, 4 Aufkleber	KO 3058	07.01.09	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte		LDP002-003 00 05-00 e-4 / Blatt 1 von 1
b	Logo + Anschrift	KO 3010	29.09.08	AH			
a	[illegible]	[illegible]	[illegible]	[illegible]			
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-003 00 05-00 0-4		Ers. für: LDP002-003 00 05-00 d-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 11

STERILITY VALIDATION REPORT

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

APPENDIX 12

STERILITY VALIDATION REPORT

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

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(b)(4)

APPENDIX 13

ACCELERATED AGING TEST REPORT

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

(b)(4)

[redacted]

APPENDIX 14

BIOCOMPATIBILITY TESTING

(b)(4)

[redacted]

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10357; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or 301-796-8146

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

APPENDIX 15

DEVICE HAZARD ANALYSIS

(b)(4)
[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 16

SOFTWARE REQUIREMENT SPECIFICATION

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SOFTWARE ARCHITECTURE DESIGN

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APPENDIX 18

SOFTWARE DESIGN SPECIFICATIONS SERIAL COMMUNICATION INTERRUPT

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SOFTWARE DESIGN SPECIFICATIONS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10357; Released by CDRH on 07/08/2016

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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SOFTWARE DESIGN SPECIFICATIONS

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8116

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SOFTWARE DESIGN SPECIFICATIONS

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SOFTWARE DESIGN SPECIFICATIONS OPERATION

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SOFTWARE DESIGN SPECIFICATIONS

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[redacted]

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3110

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[redacted]

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SOFTWARE DESIGN SPECIFICATIONS

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SOFTWARE DESIGN SPECIFICATIONS

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SOFTWARE DESIGN SPECIFICATIONS

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SOFTWARE DESIGN SPECIFICATIONS

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APPENDIX 29

TRACEABILITY ANALYSIS

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[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SOFTWARE DEVELOPMENT PLAN

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SOFTWARE VERIFICATION AND VALIDATION

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ELECTROMAGNETIC COMPATIBILITY, DIN EN 60601-1-2

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LIQUOGUARD CSF SYSTEM CLINICAL TRIAL

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APPENDIX 61

LIQUOGUARD CSF SYSTEM PUBLICATIONS

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B.M. HOELPER

CLINICAL STUDY REPORT OF A NEW PRESSURE AND VOLUME CONTROLLED CSF DRAINAGE SYSTEM (LIQUOGUARD)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical study report of a new pressure and volume controlled CSF drainage system (LiquoGuard®)

B.M. Hoelper

Neurosurgical Center Gelnhausen, Main-Kinzig Kliniken, teaching hospital of the Goethe University Frankfurt, Germany

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Summary.

Introduction. Lumbar and ventricular CSF drainage is applied in various indications in neurosurgery. Until now, open hydrostatic systems mostly including a dripping chamber were used. This report presents first experimental and clinical experience using a new, closed CSF drainage system capable of simultaneously draining CSF and measuring CSF pressure (LiquoGuard®).

Material and Methods. CSF pressure is measured by a dual external pressure sensor device taped at an anatomical reference point of the patient and CSF is drained by a peristaltic pump. For ventricular application, drainage is pressure controlled, while in lumbar drainage a constant flow rate can be defined. For experimental evaluation, hydrostatic pressure as well as comparison to an independent pressure sensor technique was calculated for static pressures and pressure changes. During clinical application, intraventricular pressure measured by the new system was compared to established ICP devices (internal and external pressure transducers) in 16 patients. Lumbar drainage with constant flow rate was performed in 4 patients.

Results.
Experimental data comparing the LiquoGuard® pressure sensor to hydrostatic pressure levels and pressure measured by an calibrated pressure measurement device revealed in ranges < 100 mmHg a high accuracy with deviation of 0 – 3 mmHg. Ventricular CSF pressure also was comparable to established sensors (Raumedic Neurovent and standard external pressure transducer). Calculated drained volume differed from measured volume within the drainage bag < 5 % if total CSF amount was > 100 ml. Slit ventricle syndrome was detected early by loss of CSF pulsation, oscillating CSF pressure and reduction of CSF outflow. Catheter occlusion was stated if CSF pressure remained low in contrast to slit ventricle syndrome.

Discussion.
Both experimental and clinical data indicates that the new device allows a precise external CSF pressure measurement with low sensor drift along with the possibility to

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drain CSF simultaneously due to a closed drainage system. This results in several clinical advantages: Adjustment of a dripping chamber is not necessary any more leading to enhanced patient safety and mobility. Lumbar drainage is facilitated by a constant flow rate. Critical conditions such as slit ventricle syndrome or catheter occlusion can be detected by the integrated CSF pulsation detection in addition to alterations in CSF pressure and outflow. Therefore, the system can facilitate handling of ventricular and lumbar drainage and might enhance safety for the patient.

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I INTRODUCTION (BACKGROUND AND RATIONALE)

Lumbar and ventricular drainage of CSF is a daily routine method in neurosurgical practice (3, 5, 10, 18) in several indications. Ventricular CSF drainage might be needed in situations caused either by obstruction of CSF outflow (e.g. by subarachnoid haemorrhage, obstruction of CSF flow by tumor or blood as well as infectious diseases) of distrubtion of CSF resorption (1, 4, 5, 9-11, 13-15, 17, 19). Furthermore, lumbar CSF drainage is needed to treat CSF fistulas or establish diagnosis in normal pressure hydrocephalus (6). However, several important disadvantages occur with current ventricular and lumbar systems. For pressure controlled CSF drainage, permanent alignment of the dripping chamber to anatomical reference points is necessary. Furthermore, reliable measurement of ICP is possible only in a closed drainage system: by positioning the dripping chamber for example above the reference point, only the hydrostatic pressure difference between the fluid level inside the tube and the pressure sensor is measured. Other nursing problems such as disconnection and occlusion of the CSF drainage are frequently registered with long time delay. Additional, technical inconsistencies of pressure measurement due to sensor malfunctions (e.g. sensor drift) and incorrect handling (wrong zero leveling, incorrect adaptation to the monitoring system) might cause wrong ICP readings. By this, the patient might be without surveillance of CSF pressure and imprecise determination of drained CSF volume. In lumbar drainage, nowadays it is very difficult to achieve a continuous CSF flow over time, since CSF outflow depends on position of the catheter, pressure difference between catheter and dripping chamber, positioning of the patient and CSF-dynamics (CSF production, resorption and outflow).

The presented new system (LiquoGuard®) is an externally closed system which might allow drainage of CSF parallel to CSF pressure measurement. Technically, in contrast to the dripping chamber the system is externally closed by a peristaltic pump and by this it allows simultaneous CSF drainage and pressure measurement. Therefore, there should be no need for a dripping chamber due to pressure controlled drainage. Additional, continuous CSF flow especially in the use of lumbar drainage might be possible.

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II STUDY OBJECTIVE AND DESIGN

Study Objective

Purpose of this study was to evaluate if dripping chambers can be replaced by the LiquoGuard® system without any clinical changes and if the LiquoGuard® system is reliable concerning the applicability, accuracy of CSF drainage and CSF pressure measurement. The intend of the LiquoGuard® device to minimize most sources of error mentioned above due to the closed fluid system is evaluated. Furthermore, clinical practice in mounting the pressure sensors at the reference point is studied. In addition, LiquoGuard® is observed in the following clinical situations: catheter disconnection, catheter occlusion and collapsed ventricles. The accuracy of both sensors and the frequency of inconsistencies between both sensors (sensor drift) will be analyzed. For lumbar drainage, the ability of the LiquoGuard® system to drain CSF continuously and the accuracy of drained fluid volume are further examined.

Study Design

For 20 Patients requiring external CSF drainage (ventricular or lumbar) instead of the usually applied dripping chamber the external CSF drainage system LiquoGuard® is used with the same intend to treat. Since the presented new system (LiquoGuard®) is a externally closed system which allows drainage of CSF parallel to CSF pressure measurement, the ICP will be compared to an independent alternative ICP and the calculated CSF volume is compared to the collected CSF volume.

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III SAFETY AND EFFECTIVENESS PARAMETERS

A. Key Safety Parameters

CSF pressure. Most important for ventricular CSF drainage is the correct adjustment of intraventricular pressure. This is performed either externally by adjusting the dripping chamber or by mounting (either taping or fixing by suture) of the ICP pressure sensors (LiquoGuard®). By this, LiquoGuard® must allow to drain comparable CSF volumes to maintain intraventricular CSF pressure. To exclude increased ventricular CSF pressure due to inadequate drainage, an additional external pressure sensor was installed parallel to the LiquoGuard® CSF pressure sensors. Furthermore, alarm functions are activated if CSF pressure is out of physiological ranges.

Drained CSF volume. The CSF volume drained by LiquoGuard® was calculated by the device and displayed. Furthermore, the amount of collected CSF was measured afterwards. To exclude a larger deviation of drained CSF volume, it was possible to read the collected volume outside the drainage bag. Therefore, assuming that a withdraw of a larger amount of CSF might lead to a decrease of CSF pressure, additionally the CSF pressure was measured and a lower CSF pressure alarm was predefined. By this, the drainage of larger CSF amounts should be registered.

B. Key Effectiveness Parameters

Aim of each ventricular and lumbar CSF drainage is to allow CSF flow from the CSF space to an external reservoir, either with determination of the CSF pressure (most ventricular drainage systems) or of the CSF volume (most lumbar drainage systems). Therefore, the effectiveness of the LiquoGuard® system has to be determined by its ability to withdraw CSF from the intrathecal space (ventricular or lumbar), either controlled by the CSF pressure or by the volume. Since the withdrawn CSF can be sampled in the drainage bag, the effectiveness of the LiquoGuard®-System can be measured directly and immediately during clinical practice.

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IV PATIENT ENROLEMENT

A. Inclusion Criteria

In the study, neurosurgical patients with the need of a ventricular or lumbar drainage were included. All patients underwent an operative procedure to introduce an external drainage catheter into the CSF space. However, this was done independent of the use of a conventional system or the LiquoGuard® system. Indications with the need of an external drainage are subarachnoid hemorrhage, intraventricular hemorrhage, head trauma, ventriculitis, CSF fistula and normal pressure hydrocephalus.

B. Exclusion Criteria

Since the operative procedure to apply an external drainage device does not differ between the conventional drainage systems and the evaluated system, no additional operative or nursing step must be done. Therefore, there are no exclusion criteria that can be assumed to be exclusion criteria for the use of the LiquoGuard® system which differ from the exclusion criteria for all external CSF drainage systems. For completion, relative exclusion criteria for external lumbar or ventricular drainage (both conventional dripping chamber and LiquoGuard® system) are pathologies in haemeostasis, coagulopathies, and severe infections disease. However, in many cases CSF drainage has to be applied immediately in life threatening situations.

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V STUDY MATERIALS AND METHODS

A. Description of Device

The LiquoGuard® system (Moeller Medical, Fulda, Germany) consists of a device including a peristaltic pump, inputs for pressure sensors, and several external interfaces. The external drainage system consists of a tube with two integrated pressure sensors. The tube can be inserted into the peristaltic pump and the sensors are connected to the pressure sensor interface. After zeroing of the sensors, CSF drainage can be immediately started and current ICP, CSF pulsation (for ventricular drainage) as well as withdrawn CSF volume are displayed. Sensor information provided by the manufacturer is a sensor accuracy ± 0,375 mmHg, long-term drift of < 1 mmHg and a total system deviation of < 2 mmHg, manufacturer states that the volume calculated by the device deviates ± 15% in maximum. Upper and lower ICP alarm threshold can be set. For ventricular drainage, pulsation of the CSF is detected, displayed and loss of pulsation leads to an activation of an alarm function.

B. Patient Entry

For evaluating the possibility of continuous CSF drainage, the LiquoGuard® system was connected the ventricular drainage in 16 patients and lumbar drainage in 4 patients. In ventricular application, the LiquoGuard® pressure sensor was taped to the patient head at the level of the foramen Monroi and ICP was measured by an additional intraventricular applied pressure sensor catheter (Raumedic Neurovent®) or by an external pressure transducer connected to the external tubing system by a three way connector.

C. Surgical Procedure

For application of the LiquoGuard® CSF drainage system no surgical procedure is needed. However, the application of each external CSF device requires an operative procedure independent on the use of the external drainage system. For ventricular drainage, a burr hole was performed according to standard landmarks (about 2 cm lateral of the superior sagittal sinus and 0.5 cm anterior to the coronal suture, mostly right-sided). After incision of the dura, a ventricular catheter was introduced with a

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length of about 5-6 cm into the ventricular system until CSF dropped out of the drainage. Then, the catheter was either tunneled and sutured to the skin or was fixed by a PEEK bolt (Raumedic). For lumbar drainage, a standard lumbar drainage kit (Integra) was used. The intrathecal space was approached in the level of L3/4 or L4/5 by a Touhy-Needle and the lumbar catheter was introduced in cranial direction with a length of 5-15 cm. Externally, the catheter was sutured to the skin and additionally taped.

D. Postoperative Care

After ventriculostomy, ICP was adjusted to 10-20 mmHg depending on the disease of the patient and according to the previous standard of the height of the dripping chamber. Drained CSF volume was set in the range between 5 to 25 ml/h for ventricular drainage. Upper alarm was set at 20 – 40 mmHg, lower alarm at 0-5 mmHg according to the patient's disease. ICP measured by the external independent pressure sensor was either recorded automatically every minute or manually by the nursing staff every half hour along with the ICP displayed by the LiquoGuard®, Drained CSF volume was collected and measured every 24 hours for balance. Furthermore, the complete drained CSF volume was measured and simultaneously the volume calculated and displayed by the LiquoGuard® was recorded.

For lumbar drainage, flow rate was set to 5 – 13 ml/h, upper pressure alarm at 40 – 70 mmHg, lower pressure alarm at 0 - 5 mmHg. Pressure from LiquoGuard® and the additional pressure sensor was time locked collected for the complete monitoring time.

Each alarm of the LiquoGuard® had to be prompted by the nursing staff. In cases of an exceeding ICP either the CSF flow rate was increased or other standard steps (medical treatment of elevated ICP or diagnostic procedures) were performed. In cases of an ICP below the lower alarm the threshold was either further lowered, the position of the patient was altered or the mounting of the ICP sensor was checked. In cases of a pulsation alarm and/or a low ICP without visible CSF pulsation, continuity of the ventricular or lumbar catheter was checked and in case of an obstruction the catheter was flushed.

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E. Patient Follow-up

Each patient was followed up during the time of treatment and several days after treatment routinely for clinical signs of CSF infections. However, since the treatment is finished after withdrawing of the ventricular or lumbar catheter, no further follow-up is required and was performed concerning the external CSF drainage system.

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VI STATISTICAL METHODS

After collection of ICP data, the difference between both values was calculated and statistically evaluated for significant differences (Mann-Whitney-U Test). CSF volume was displayed by the LiquoGuard® with hourly and daily balance and total drained CSF amount. The withdrawn CSF volume colleted in the drainage bag was measured and the difference was calculated. All statistical Analysis was performed by using SPSS (V. 12.0).

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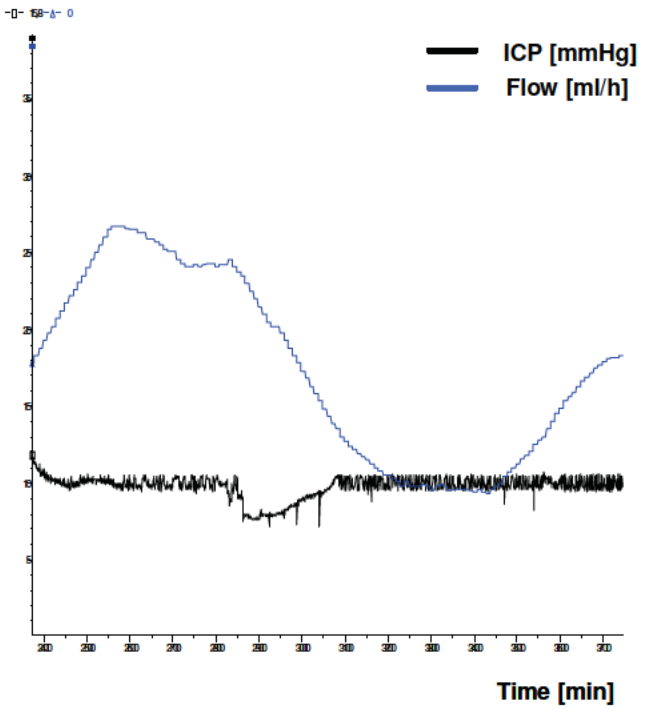
VII RESULTS

Replacement of dripping chamber.

In 20 patients, previous applied dripping chamber was replaced by the LiquoGuard® system (both in ventricular for 16 patients and lumbar application in four applications). After setting of the parameters (desired ICP, maximal CSF drainage in ml/h and alarm limits), in all patients CSF drainage was continued analogous to the dripping chamber. In 16 patients, the self-adhesive pad mounted at the head of the patient had to be replaced, no complications were seen during this procedure. In clinical routine, a standard setting with a maximal flow rate of 20 ml/h is sufficient in most cases. Flow rates of 5 – 20 ml/h are also frequently seen in external dripping chambers.



This graph depicts the flow of CSF (blue line) controlled by the LiquoGuard® system. The ICP was kept at 10 mmHg or below representing the functioning of the system to maintain ICP in predefined range.

For patient transport, mostly the dripping chamber is switched off which might lead to an intermittent increase of ICP. Since the LiquoGuard® system runs on recharchable batteries, there is no need to disconnect the drainage system and thus drainage is also possible during transportation. Furthermore, also during angiography, CT and transport into the OR a continuous CSF drainage is possible which might lead to a better surveillance of the patient and might minimize the risk of ICP peaks during transport without any recognizable negative consequences for the patient.

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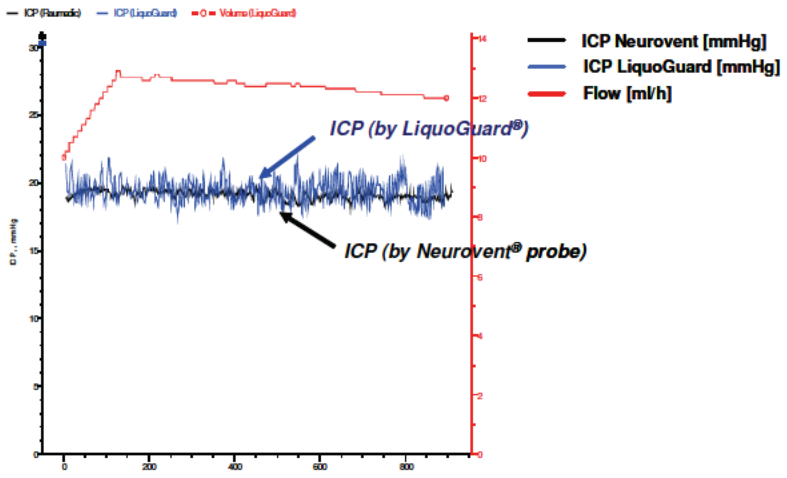
ICP measurement

In ventricular application, ICP measurements between LiquoGuard® and an alternative pressure measuring method differed in a range of 0 – 3 mmHg. The maximal deviation was found between the LiquoGuard® pressure sensor readings and the compared external pressure transducer with 3 mmHg, while differences between the Raumedic Neurovent® and the LiquoGuard were below 3 mmHg. No statistical difference was found during measuring periods between external ICP or intraventricular Raumedic Neurovent® probes and the LiquoGuard® ICP values.



ICP measured by LiquoGuard® (blue line) and an comparable intraventricular system (Raumedic Neurovent® probe, black line) showed absolutely comparable ICP values with deviation < 1 mmHg. The red line indicates the CSF flow controlled by the LiquoGuard® system.

No sensor malfunction was observed in these measurements, however in 4 patient a second disposable drainage system had to be connected due to an operating time of the tube of more than 5 days (as recommended by the manufacturer).

CSF volume

The differences between the drained CSF compared to the calculated volume calculated by the LiquoGuard® was < 10% and no statistical significant difference was found if total drainage volume was > 100 ml. Therefore, both accurate pressure measurement and calculated volume by LiquoGuard® can be used for clinical purpose. Critical situations such as slit ventricle syndrome were detected at a very early point in a typical pattern with loss or CSF pulsation and increasing variability or CSF pressure. Additional, catheter occlusions for both lumbar and ventricular applications were immediately detected by sudden decrease of CSF pressure and

loss of CSF pulsation. For lumbar application, continuous CSF drainage is possible even during mobilization of the patient, while catheter occlusion, malpositioning and disconnection of the catheter were prompted by an alarm.

Collapsed ventricles.

In two patients collapsed ventricles were detected in cranial CT. Prior to CT, in both patients the ICP measured by the LiquoGuard® system altered in an oscillating fashion below the desired ICP, CSF pulsation was lost and the CSF flow rate was reduced (Figure 3). Pausing of CSF drainage led to an equilibration of ICP at pathological levels (> 35 mmHg) with CSF pulsation.

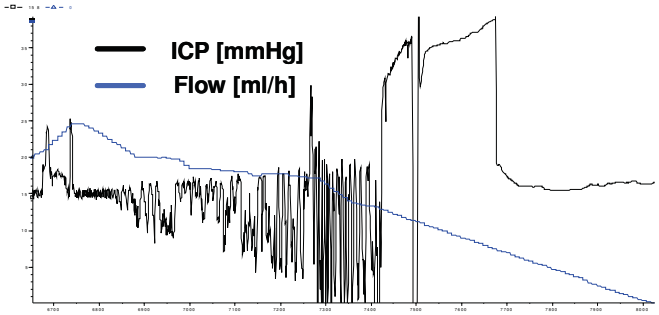


Figure 3. Decrease of CSF outflow or production from the ventricles leads to decrease in CSF flow displayed by the LiquoGuard® (as seen in the blue line) indicating a clinical situation which might be due to collapsed ventricles. Since CSF flow is very low, the amount of drained CSF by the LiquoGuard® is also in very low ranges and a withdraw of small amount of CSF leads to sudden and high changes in ICP. This can be seen in an increase of ICP oscillation, here in the range between 0 and 20 mmHg.

Catheter occlusion.

Several intermittent occlusions of the lumbar and ventricular catheters occurred. Mostly, occlusion was caused by obliteration of the internal lumen of the tube, but in two patients CSF drainage was not possible due to partial withdrawal of catheter to an extradural position. In all situations, CSF pressure was very low (0 – 2 mmHg), CSF pulsation and flow was not detectable (figure 4). Flushing the tube by a small amount of sterile isotonic saline solution ended immediately the occlusion in cases not caused by extradural catheter position.

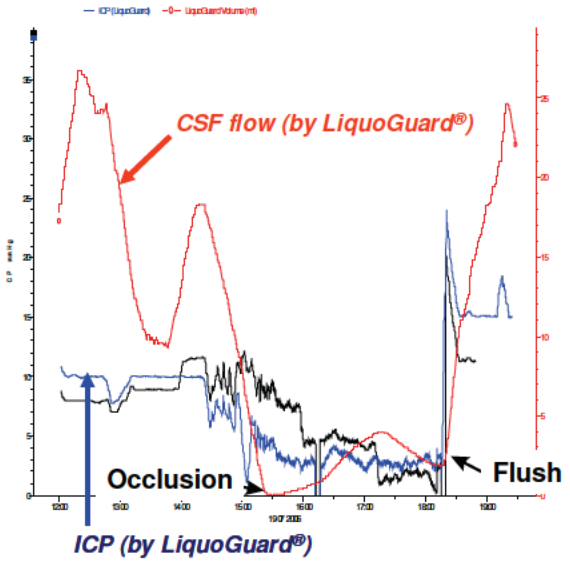


Figure 4. Typical presentation of a catheter occlusion which immediately leads to an reduction of CSF flow (red line) and a decrease of ICP. The ICP decrease is caused by withdrawing of CSF by the LiquoGuard® system without efflux of CSF from the ventricular system.

Clinical.

For evaluating the possibility of continuous CSF drainage, the LiquoGuard® system was connected to ventricular drainage in 16 patients and to lumbar drainage in 4 patients. In ventricular application, the LiquoGuard® pressure sensor was taped to the patient head at the level of the foramen Monroi and ICP was measured by an additional intraventricular applied pressure sensor catheter (Raumedic Neurovent®) or by an external pressure transducer connected to the external tubing system by a three way connector. ICP was adjusted to 10-20 mmHg depending on the history of the patient, drained volume was set in the range between 10 to 25 ml/h. Upper alarm was set at 35 – 40 mmHg, lower alarm at 5 mmHg. For lumbar drainage, flow rate was set to 5 – 13 ml/h, upper pressure alarm at 40 – 60 mmHg, lower pressure alarm at 2 - 5 mmHg. Pressure from LiquoGuard® and the additional pressure sensor was time locked collected for the complete monitoring time. Additional, the drainage volume was colleted and measured in a calibrated cylinder for further comparison to

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the LiquoGuard®. Any occurring alarms, handling problems by the nursing staff were documented.

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VIII DISCUSSION / CONCLUSIONS

Experimental work showed a very stable and reliable pressure measurement by the LiquoGuard® which works in the ranges provided by the manufacturer (complete deviation of the pressure < 2 mmHg). No differences were found in hydrostatic pressure differences and in continuous increase and decrease of pressure. The deviations of the pressure sensor is comparable to other external applied CSF pressure sensors (8, 21) and drift is even lower compared to miniaturized sensors applied into the intradural space (2, 7, 8, 12, 16) Therefore, the applied sensor seems to be suitable for low pressure seen in intracranial and lumbar applications. In clinical setup, ventricular pressure was also measured with high reliability compared to commercially available external and internal pressure sensors. Sensor drift seen in most sensors applied intracranially is negligible and malfunction of one pressure sensor can be detected easily due to the dual architecture of the system. There is only one commercially available system (Raumedic Neurovent duo, 16) offering the possibility to measure two pressures, but in contrast to this the LiquoGuard® compares the two measured pressures continuously. The slight difference between the pressure measured by the LiquoGuard® compared to the external pressure sensor was due to slight differences in positioning the sensor related to the level of the foramen Monroi. The LiquoGuard® pressure system can be taped using an ECG electrode to the patient head, the risk of deviation concerning the measured pressure might be reduced, since usually the external pressure transducer is either fixed at the holding device with is mounted at the bed or directly fixed on the pillow. The fixation of the LiquoGuard® pressure system directly at the patient allows for lumbar and ventricular application a continuous adaptation, the risk of measured pressure which is not corrected to the anatomical reference point of the patient is therefore minimized. In two patients, symptoms of intracranial hypotension relieved after changing the lumbar drainage from discontinuous to continuous manner.

The calculation of drained CSF volume gives further diagnostic information especially for diagnosis of critical situations such as slit ventricle syndrome and catheter occlusions. Furthermore, other therapeutically strategies might be modified using this parameter such as indication for CSF shunting and withdrawing the external ventricular drainage. Detection of CSF pulsation might indicate easily catheter occlusion and slit ventricle syndrome and offers easy and early additional information

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to the neurosurgical staff, since catheter occlusion can not be detected by a pressure sensor mounted at the tip of the catheter. The only limiting factor might be if air comes into the drainage which then might lead to deviations between calculated and measured CSF volume. However, since ICP curve will be dumped by air, ICP pressure pulsation will be reduced.

In conclusion, this new system offers new possibilities for neurosurgical patients for treatment in both, lumbar and ventricular application. The dual pressure sensor technique, independence to a dripping chamber and possibility to drain CSF and measure the CSF pressure simultaneously offers an additional safety and mobility for the patient.

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N. KLEMZ, B. LUTHER, P. KÖSTER, T. NOWAK, E. BERENDES

CONTINUOUS CONTROLLED LUMBAR SPINAL FLUID DRAINAGE FOR PPREVENTION OF SPINAL ISCHEMIA DURING THORACOABDOMINAL SURGERY OF THE AORTA

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"Der interessante Fall"
(Feature article)

Gefässchirurgie 2009 ***(publication: "Vascular surgery 2009")***
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Continuous controlled lumbar spinal fluid drainage for prevention of spinal ischemia during thoracoabdominal surgery of the aorta

Despite various therapeutic applications, attempts to substantially reduce ischemia associated neurological failures following thoracoabdominal aorta surgery have been unsuccessful. The challenge is to find better methods to determine and improve spinal cord perfusion. In addition to the use of shunts, left heart bypasses using pump systems, lowering body temperature, MEP monitoring, as well as clamp-and-repair techniques and inclusion of the spinal arteries in the reconstruction of the aorta, other suitable methods include fluid drainage systems such as the continuous closed variant (LiquoGuard) proposed.

Method

The current practice of lumbar drainage involves manual, irregular fluid withdrawal. The application of LiquoGuard by Möller Medical GmbH, enables for the first time, a continuous, pressure-controlled fluid drainage. Furthermore, in contrast to the established drop-chamber systems, this drainage system is closed and sterile (**Fig. 1**).
The fluid flow is controlled by a pre-programmed spinal pressure and a set maximum flow rate. Excessive drainage is avoided since underpressure never occurs. A pre-operative, time-consuming adjustment of the pressure transducer is not required since the sensor unit can be secured to the nape of the patient quickly and easily.

Case history

A 65-year old patient underwent surgery for a symptomatic thoracoabdominal aortic aneurysm Crawford Type III. A large, penetrating ulcer (PAU) on the right side indicated a high risk of perforation. A tubular prosthesis had previously been implanted as a result of an infrarenal abdominal aortic aneurysm. Due to the specific position of the TAA in the visceral segment of the aorta, an endovascular procedure was excluded.
The operation technique consisted in a left thoracoabdominal, extraperitoneal approach with an internal aorto-aortal shunt implantation. Resection of the aneurysm was performed by using a tubular prosthesis, with the inclusion of the spinal arteries TH 11 and 12, as well as all visceral arteries. Cooled, pharmacological rinsing perfusion was temporarily performed on an intestinal artery and a renal artery respectively. After successful reconstruction of the aorta, the internal shunt was removed and the thoracolaparotomy wound closed.
Prior to anaesthetisation, the patient received a thoracic peridural catheter to ensure analgesia. Another catheter was inserted in the L4/5 spinal region for lumbar drainage and incorporated with the LiquoGuard system. The drainage tube was fitted into the pump. The pressure sensor connector was connected to the pump and a zero balance performed. The interspinal pressure limit was set at 10 mmHg. The continuous flow rate was set at a mean value of 20 ml per hour and the application started. The system operated in a continuous and smooth manner throughout the duration of the surgery. Manual intervention was not required, thus ensuring that the system was permanently sterile, unlike conventional methods of manual fluid withdrawal via drop-chamber systems. Interspinal pressure peaks were particularly evident during aortic cross-clamping (**Fig. 2**). However, the pressure never exceeded 12 mmHg. The flow rate set avoided pressure peaks occurring from the outset.

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During the duration of the surgery, a total of 25 ml of fluid were drained by the LiquoGuard system without the need for intervention by the anaesthetist.

With a total drainage of 174 ml during the post-operative stage, the catheter was smoothly removed after 72 hours.
The patient indicated no post-operative neurological failure following a brief weaning stage. None of the feared side effects of lumbar drainage were noted.

Discussion

Spinal ischemia is a complication arising during thoracoabdominal aortic surgery. Over the past 25 years the incidence rate has ranged between 5 and 20% [7, 14]. Neurological failures such as sensorial deficit, paraparesis and paraplegia have resulted. As with so-called hybrid procedures, even modern techniques such as endoluminal stent-graft implantation in the treatment of thoracoabdominal aneurysmata (TAAA), constitute a risk of neurological failures, albeit to a lesser degree [2]. The paraparesis and paraplegia incidence rates are 4.2% and 8.5% respectively [21].
Often further complications arise during post-operative procedures, thus increasing patient morbidity. In particular, higher incidence in pneumonia and increased reintubation resulting from diaphragmatic respiratory impairment, are reported. Other examples include renal failure, urinary passage infections and major decubitus ulcers. The mortality rate with full paraplegia is recorded at about 20% [18]. Even in cases of anastasis, a complete recovery is the exception rather than the rule.
The protection of the spinal cord, therefore, is important during thoracoabdominal aorta reconstruction. The most common neurological safeguard is measuring the fluid pressure in the lumbar spinal canal and draining spinal fluid [17]. Since cross-clamping of the thoracic aorta causes increased pressure in the spinal canal, continuous lumbar drainage can reduce spinal cord compartment lesions. This increased intrathecal pressure is further strengthened by a secondary reperfusion-related tissue oedema resulting from a disturbance of the blood-spinal cord barrier [13]. The spinal cord oedema also impacts on the microcirculation. Spinal perfusion is influenced by the ratio of the spinal perfusion pressure to the tissue pressure in the osseous compartment.
Clinical data recorded in prospective randomised studies on the protection derived from spinal fluid drainage, indicate the neuroprotective advantages of spinal cord fluid drainage during and after thoracic aorta cross-clamping; these studies, however, have been repeatedly challenged [6, 8, 18]. Intraoperative spinal canal pressure monitoring is, therefore, recommended. In the event that the pressure limit of 15 mmHg is exceeded, fluid can be removed through a lumbar drainage in lying position in order to reduce the spinal pressure and raise the perfusion pressure in the spinal cord [3, 4, 12, 16]. The intraspinal pressure limit should not exceed 10 to 12 mmHg [4, 9]. Post-operative drainage monitoring is continued for another 72 hours in order to prevent a secondary pressure increase [1, 11, 17].
Temporary side effects and permanently manifest complications due to cerebrospinal fluid drainage are seldom reported in conjunction with thoracoabdominal aortic procedures. Catheter-associated meningitis (1.2%) and catheter fracture (1.8%) can be caused by the common intermittent fluid withdrawal in drop-chamber systems. Intraspinal haematoma (3.2%) and intracranial subdural haematoma due to excessive manual drainage (3.5%) are also reported [5, 10, 15, 20, 22]. From an anaesthesiological and legal perspective, therefore, indications in favour of lumbar fluid drainage are to be considered crucial [20]. In 2000, Coselli et at. [7] indicated a reduction in paraplegia and paraparesis of 80% in patients with thoracic aorta aneurysms where lumbar fluid drainage had been performed.

Conclusion

Fluid drainage within a sterile system (LiquoGuard) can minimise the incidence of temporary side effects and permanently manifest complications resulting from the particular surgical method, allowing for a broader application.

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Fig. 1 LiquoGuard

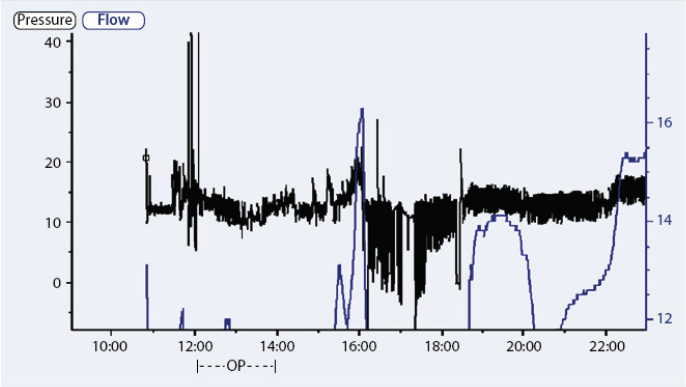

Fig. 2 Fluid pressure and flow during surgery and during the post-operative stage

Abstract

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N. Klemz · B. Luther · P. Köster · T. Nowak · E. Berendes

Continuous controlled lumbar spinal fluid drainage for prevention of spinal ischemia during thoracoabdominal surgery of the aorta

Abstract

Spinal ischemia is an unresolved problem in thoracoabdominal surgery of the aorta. As a result, neurological failures such as sensory deficits occur, as well as paraparesis and paraplegia. Therefore, protection of the spinal cord during thoracoabdominal surgery is a major challenge. The most commonly used method of neurologic surveillance is measurement of spinal fluid drainage and cerebrospinal pressure in the lumbar spinal canal. Complications such as meningitis or spinal catheter fracture can be caused by intermittent fluid withdrawal in the drop-chamber system. Further complications include intraspinal hematoma and intracranial subdural hematoma due to excessive manual drainage. So far, cerebrospinal fluid drainage systems have been manual and unbalanced. Using LiquoGuard (Möller Medical), continuous pressure-controlled cerebrospinal fluid drainage has been enabled for the first time. Furthermore, this drainage system is closed and sterile, in contrast to established drop-chamber systems.

Keywords

Spinal ischemia · Thoracoabdominal surgery · Lumbar drainage · LiquoGuard

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Conflict of interest: The author declares that no conflict of interests exists.

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AUTOMATICAL PRESSURE- AND FLOW-CONTROLLED VENTRICULAR CSF DRAINAGE LIQUOGUARD®: TWO YEARS OF EXPERIENCE WITH OVER 50 CHILDREN IN PEDIATRIC NEUROSURGERY AND EPILEPSY SURGERY

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Behandlungszentrum Vogtareuth
Schön Kliniken

Automatical Pressure- and Flow-Controlled Ventricular CSF Drainage LiquoGuard®: Two Years of Experience with over 50 Children in Pediatric Neurosurgery and Epilepsy Surgery

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Klinik für Neurochirurgie und Epilepsiechirurgie, Behandlungszentrum Vogtareuth

Introduction:
At the clinical centre Vogtareuth (Fig. 1), a department of neuropediatry as well as departments for neurosurgery and epilepsy surgery is in operation. The fields of pediatric neurosurgery and epilepsy surgery are cooperating very closely. Many of the jointly treated patients are suffering from complex forms of hydrocephalus, or need at least a transient post-surgical external CSF drainage. With the legacy open ventricular CSF drains using drip chambers, the handling was unsafe in many cases, in particular on the normal care station, and complications (e.g. overdrainage) occured in some cases (Fig. 2). To ensure better patient safety, we have been using the LiquoGuard®-System (Möller Medical), since 2006 in some test cases, and since 2007 systematically.

Fig. 1

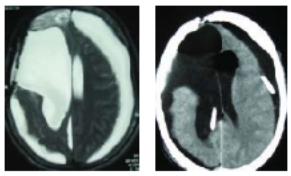

Fig. 2
After functional right hemispherectomy, a CSF overdrainage of about 200ml, caused by uncontrolled mobilization, led to a expanding hygroma on the opposite side. The hygroma left had to be treated by a subdural drainage.

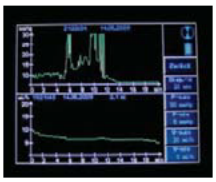

Fig. 3
History presentation (LiquoGuard®-System) of an artificial ICP increase, caused by screaming of the child (above).
The CSF flow remained constant throughout this phase. An overdrainage – as is common with legacy ventricular drains using drip chambers – did not occur.

Material and Method:
Since 2007, the common external CSF drains (drip chambers that have to be level-adjusted in relation to certain anatomical reference points) have been replaced by the LiquoGuard® system (Möller Medical) with almost all neuropediatric-neurosurgical patients. Particularly in epilepsy surgery, in connection with surgeries when a hydrocephalus condition was diagnosed, or resections of several cerebral lobes and extended opening of the ventricular system was required, this system was systematically used. Further application areas were verification of hydrocephalus diagnoses and external drains in connection with shunt infections and shunt-related complications. In total, the LiquoGuard® system was used on more than 50 children. We have analyzed and evaluated the data with regard to drainage-associated complications.

Results:
In none of the over 50 cases, the LiquoGuard® system caused any complications. Neither any overdrainage, nor any overdrainage-related complication that required surgical treatment, occurred. The advantages became even more visible, the more uncooperative, restless or mobile a child was. Neither coughing, crying/screaming (Fig. 3), unintended change of position, epileptic seizures or extreme mobility (Fig. 4) led to uncontrolled CSF losses. In these situations, had the child been treated with a drip chamber, a continuous supervision by nurses or parents would have been mandatory, since only the instantaneous closing of the drain would have prevented unintended loss of CSF.
With transient post-surgical use of the LiquoGuard® system, it was possible to remove the external drains earlier. The daily drained volumes were in some cases significantly lower, since no intended CSF losses came on top of the actually required CSF drainage volume.

Fig. 4
Ten days after vertical, parasagittal hemisperectomy with intrauterine media infarct and hydrocephalus, this girl was able to move about the hospital grounds by bicycle with active external CSF drainage and LiquoGuard® system (visible on the bicycle carrier).

Discussion:
Especially in the neuropediatric normal care station, the significant advantages of the LiquoGuard® system as compared to a drip chamber-based system were most obvious. Patient safety with a running external ventricular drainage was increased, while supervision and nursing effort was reduced. A continuous ICP measurement supplemented supervision, especially with children in the early post-surgical phase. Overdrainage-related complications did not occur. Besides patient safety, patient satisfaction was also increased significantly, since even longer mobile phases were possible with a running system and no complications.

Schön Kliniken. Die Spezialisten

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M. GELABERT-GONZÁLES, V. GINESTA-GALAN, R. SERNAMITO-GAREÍN, A.G. ALLUT, J. BANDIN-DIÉGUEZ AND R.M. RUMBO

THE CAMINO INTRACRANIAL PRESSURE DEVICE IN CLINICAL PRACTICE. ASSESSMENT IN A 1000 CASES

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Clinical Article

The Camino intracranial pressure device in clinical practice. Assessment in a 1000 cases

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Summary

Background. Intracranial pressure (ICP) monitoring has become standard in the management of neurocritical patients. A variety of monitoring techniques and devices are available, each offering advantages and disadvantages. Analysis of large populations has never been performed.

Patients and methods. A prospective study was designed to evaluate the Camino® fiberoptic intraparenchymal cerebral pressure monitor for complications and accuracy.

Results. Between 1992–2004 one thousand consecutive patients had a fiberoptic ICP monitor placed. The most frequent indication for monitoring was severe head injury (697 cases). The average duration of ICP monitoring was 184.6 ± 94.3 hours; the range was 16–581 hours. Zero drift (range, −17 to 21 mm Hg; mean 7,3 ± 5,1) was recorded after the devices were removed from 624 patients. Mechanical complications such as: breakage of the optical fiber (n = 17); dislocations of the fixation screw (n = 15) or the probe (n = 13); and failure of ICP recording for unknown reasons (n = 4) were found in 49 Camino® devices.

Conclusions. The Camino ICP sensor remains one of the most popular ICP monitoring devices for use in critical neurosurgical patients. The system offers reliable ICP measurements in an acceptable percentage of device complications and the advantage of in vivo recalibration. The incidence of technical complications was low and similar to others devices.

Keywords: Camino device; complications; fiberoptic device; intracranial pressure; ICP monitoring; zero drift.

Introduction

Continuous Intracranial Pressure (ICP) measurement forms part of the standard management of many patients with a wide range of intracranial disease. There are two systems to monitor intracranial pressure i.e., fluid-couples systems by placement of an intraventricular catheter, and non-fluid-coupled systems with a variety of devices developed over the last 20 years in which a miniature transducer is placed directly within the cranial cavity [29, 30]. The later group includes fibreoptic devices, the most popular of which is the Camino system. The system has been used widely in Europe and USA ever since Ostrup *et al.* first described it in 1987 [24]. Several experimental and clinical studies have been undertaken to evaluate accuracy, handling characteristics, and the complication rate of the Camino fiberoptic system [20, 23, 25, 27, 30]. Common complications of ICP monitors are infection, haemorrhage, and drift rate [30].

In our Hospital the Camino fiberoptic system for intracranial pressure monitoring has been extensively adopted in the last decade, in patients with severe intracranial pathology. The purpose of this study was to examine a consecutive series of 1000 patients in whom a ICP parenchymatous monitor had been placed in order to analyse the reliability, handling characteristics, and complication rate of the device in routine clinical practice.

Patients and methods

The present study was performed at the Hospital Clinic of Santiago de Compostela, a 700-bed University Hospital with a neurosurgical service for a population of approximately 950.000 in habitants. Between 1992–2004, 1000 consecutive patients had a fiberoptic ICP intaparenchymatous monitor placed. The ICP was measured with the Camino® intraparenchymal fiberoptic device (Model 110-4B), Camino Laboratories,

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San Diego, California). Data collected for all patients included age, sex, diagnosis, duration of ICP monitoring and complications. The ICP monitor was inserted either in the intensive care unit (ICU), or operating theatre (OT). The transducer was zeroed prior to insertion and located in the frontal region on the side of the pathology. The patient's head was aseptically cleaned with iodine povidone, and a small skin puncture was made approximately 2 cm anterior to the coronal suture in the mid-pupillary line using a twist drill before inserting the catheter into the brain parenchyma.

No prophylactic antibiotics were administered either preoperatively or during ICP monitoring. Antibiotics were administered if indicated for other reasons such pneumonia, abdominal surgery or urinary tract infections. Coagulopathy was defined by abnormalities in the partial thromboplastin time, prothrombin activity, or platelet count. A new area of haemorrhage adjacent to the probe on CT resulting from intracranial bleeding attributed to the device was evaluated as a complication.

A CT scan was performed in 922 patients after insertion of the fiberoptic system; the position of the tip was confirmed and occurrence of hematoma related to probe insertion was evaluated. In 547 fiberoptic catheter tips were removed in an aseptic manner and sent to the laboratory for culture.

In 624 patients zero drift was measured by monitoring the pressure signal when the probe was removed and after waiting 20–30 seconds. The recorded drift of each ICP system was documented. From these values, including negative and positive numbers, the actual mean drift was calculated; in the remaining 376 patients the zero drift was not recorded after removal because the device had been removed by the nurse or during the monitoring time as the device was momentarily removed for recalibration.

The data are expressed as mean ± SD for continuous variables and relative and absolute frequencies for categorical variables. Statistical analysis was performed using Student's t test and linear regression analysis. Differences were considered statically significant when $p<0.05$.

Results

From January 1992 to December 2004, 1071 consecutive Camino® intraparenchymal ICP probes were placed in 1000 patients. Sixty two patients received a second parenchymal fiberoptic probe and nine patients received a third parenchymal Camino device either due to mechanical complications (n = 49) or a new surgical intervention (n = 22). Sixty one per cent were male (611 males and 389 females). Average age was 45.6 ± 15.8 years (range 11 m–88 y), and the score on the Glasgow coma scale on admission ranged from 3 to 12.

Table 1. *Indications for ICP monitor placement*

Diagnosis	No. of cases	%
Traumatic head injury	679	67.9
Subarachnoid haemorrhage	113	11.3
Intracerebral hematoma	82	8.2
After surgery	82	8.2
Hydrocephalus	21	2.1
Arteriovenous malformation	8	0.8
Meningitis-Encephalitis	5	0.5
Others	28	2.8
Total	1000	100

The causes of the neurological disease requiring ICP monitoring are summarised in Table 1. Traumatic head injury accounted for 67.9% (n = 679), followed by 113 subarachnoid haemorrhage (11.3%), 82 intracerebral hematomas, 8 arteriovenous malformations. The fiberoptic ICP monitor was placed in the intensive-care unit in 754 patients (75.4%) and in the operating room in 246 patients (24.6%). The mean monitoring time was 184.6 ± 74.3 hours (range 16–581 hours) (Fig. 1).

Zero drift

In 624 patients zero drift was measured by monitoring the pressure signal when the probe was removed, zero

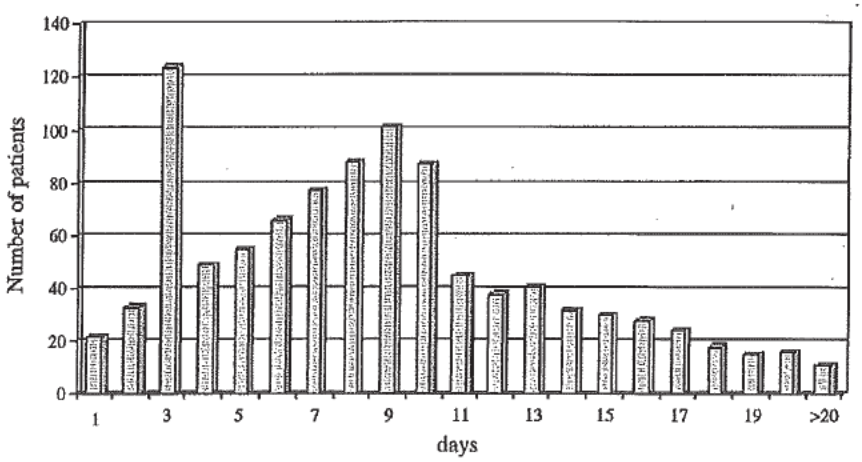

Fig. 1. Distribution of ICP monitoring duration (days)

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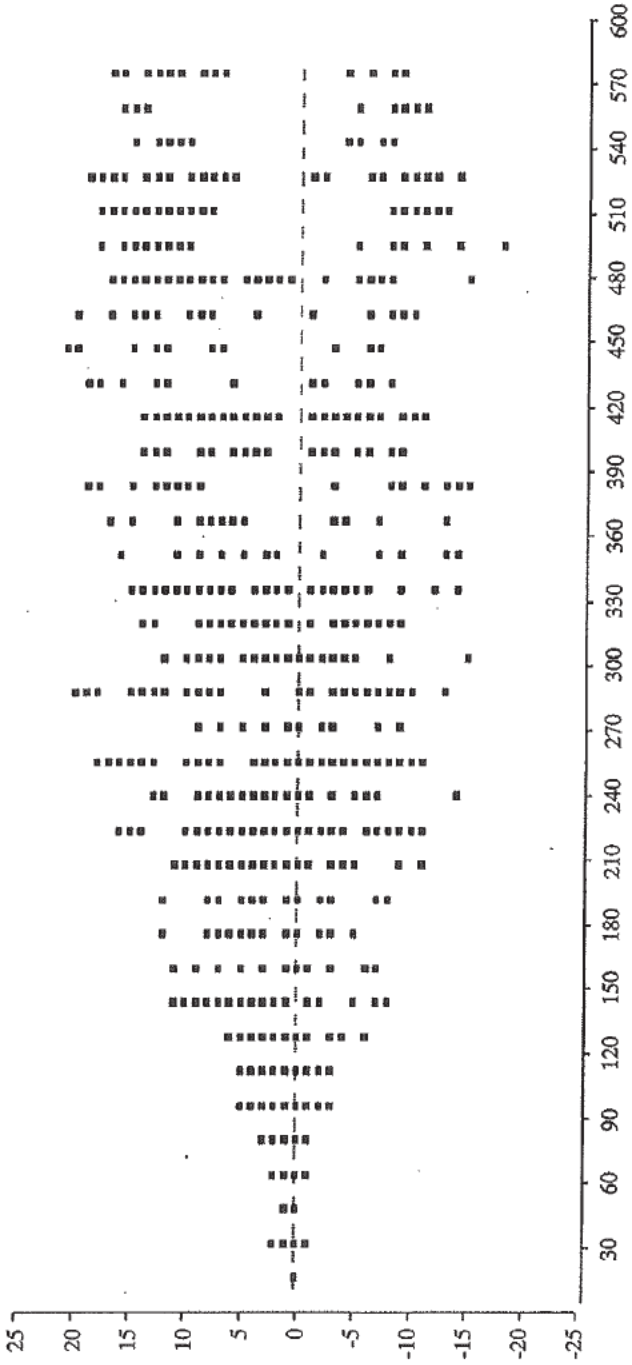

Fig. 2. Measuring time of the Camino devices versus actual drift after removal. The actual mean drift was 7.3 ± 5.1

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drift ranged from −17 to 21 mm Hg (mean 7.3 ± 5.1). In 322 sensors, a negative reading was obtained (mean 5.3 ± 3.8) ranging from −1 to −17. In 223 readings were positive (mean 8.1 ± 4.2) ranging from 1 to 21 (Fig. 2). Only 79 sensors (12.6%) showed no zero-drift (0 mm Hg reading) on removal, and mean monitoring time was 58.4 ± 8.6 hours (range 16–114 hours). No significant correlation was found between zero drift and monitoring time ($p = 0.316$), ($p = 0.211$), and ($p = 0.098$) for global, negative and positive drift.

Recalibration was performed in 94 fiberoptic devices, 11 devices were recalibrated twice during the monitoring period, of which 7 were infected.

Infection

Bacteriological analysis was performed in 547 probe tips, and cultures were negative in 91.5% of these (501 cases). Positive cultures were found in 8.5% (46 cases). Staphylococcus epidermidis was the main pathogen in this series, occurring in 22 of 46 cases (47.8%). In the remaining thirteen sensors, cultures were positive for Escherichia coli ($n = 9$), Corynebacterium ($n = 5$) (Table 2). No patients presented a cutaneous infection at the site of bolt insertion. No significant differences were found between patients who had more than one probe implanted. There was no statistical significance in the location of ICP monitor placement (OT or ICU) and the incidence of positive catheter tip cultures ($p < 0.45$).

Hemorrhagic complications: Abnormality in at least one coagulation parameter was observed in 87 patients (8.7%), and seven cases had a postoperative bleed (8%) but of no clinical relevance.

Bleeding rate in patients without coagulopathy was 1.9% (18/903). There were radiological findings in all of the cases but were clinically relevant in only 6 (0.66%) (4 intraparenchymal haemorrhage, 2 epidural haematoinas). The overall (including patients with and without coagulation disorders) bleeding rate was 2.5%.

Table 2. *Microbial pathogens isolated from the probe tips*

	No. of cases	%
Staphylococcus epidermidis	22	47.9
Escherichia coli	9	19.7
Corynebacterium	5	10.9
Staphylococcus aureus	3	6.6
Haemophilus influenzae	2	4.3
Klebsiella	2	4.3
Streptococcus spp.	1	2.1
Serratia	1	2.1
Pseudomona aeruginosa	1	2.1
Total	46	100

Table 3. *Technical complications in 49 cases*

Complication	Number	(%)
Breakage of the optic fiber	17	34.7
– During nursing or transport	10	20.4
– Patient activity	4	8.1
– For unknown reasons	3	6.1
Dislocation of the screw	15	30.7
Dislocation of the probe	13	26.5
– During nursing or transport	8	16.3
– Patient activity	3	6.1
– For unknown reason	2	4
Failure for unknown reasons	4	8.1
Total	49	100

Technical complications

Complications such as breakage of the optical fiber ($n = 17$) or dislocation of the fixation screw ($n = 15$) or the probe ($n = 13$) as well as failure of ICP recording for unknown reasons ($n = 4$) were found in 49 Camino® devices (4.5%). Most of these complications occurred during nursing manoeuvres, during transport of the patient to CT scan or patient activity (Table 3).

Discussion

ICP monitoring has been used in clinical practice for more than 4 decades, but evidence from randomized controlled trials in support of this intervention is lacking [31]. The first monitoring of intracranial pressure was described by Guillaume and Janny in 1951 using an indwelling intraventricular catheter attached to an external strain gauge transducer, amplifying system, and chart recorder [12]. Its use became routine after Lundberg's publication in 1961 describing accuracy in reading normal and abnormal intracranial pressure waves [18]. In the 1970's, subarachnoid screws, and subdural and epidural monitors were described and commonly used, when appropriate, in place of ventricular puncture [13].

Intraventricular pressure is considered to be the gold standard in ICP monitoring, and is the benchmark by which all others systems are compared [17]. Although ICP monitoring has become routine, there are no guidelines regarding the choice of intraparenchymal fiberoptic or and intraventricular catheter when monitoring is desired after traumatic brain injury [1]. The choice is

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at present dictated primarily by the surgeon's personal preference since both types of monitors offer advantages and disadvantages. The most accurate method of measurement i.e., placement of an intraventricular catheter, is now seldomly used due to its invasive nature and the risk of infection as well as the availability of fiberoptic devices that can be conveniently inserted in the intraparenchymal/subdural space at the patient's bedside [7]. The advantage of the fiberoptic monitoring device system is the ease of placement i.e., it allows direct measurement of brain tissue pressure in patients with compressed or dislocated ventricles in which placement of an intraventricular catheter would be difficult and eliminates several of the problems associated with hydraulic systems [24, 25, 30, 32]. The quality of pressure waveforms obtained is higher [25] and the absolute ICP value and amplitude are not subjected to damping or to the presence of air bubbles or blood clots within the catheter. The main disadvantages of the fiberoptic transducers are their cost and that drifts in calibration cannot be readjusted once in situ [25].

The Head Injury Management Guidelines published by the Brain Trauma Foundation in 2000 recommended intraventricular ICP measurement as the first-line approach to monitoring ICP "In the current state of technology, the ventricular catheter connected to an external strain gauge is the most accurate, low-cost, and reliable method of monitoring intracranial pressure (ICP). It also allows for therapeutic cerebrospinal fluid drainage" [5]. Despite the publication of these guidelines, fiberoptic intraparenchymal pressure monitoring remains popular given that it is reliable, easy, and quickly implanted. Extensive clinical and laboratory experiences using this system has been reported with optimum results in several trials [4, 9, 20, 24, 25].

Zero-drift

The drift of ICP probes is normally calculated as the difference between the initial and final pressure after given period of time; thus, it is one of the most important parameters since it reveals deviations from the patient's real pressure [8]. The nature of the drift of ICP probes is not fully understood and may be due to the inability to measure constantly the same pressure as a result of mechanical defects of the probe and the material used [22]. The manufacturer's specification for zero drift of the Camino device is ±2 mm Hg for the first day and ±1 mm Hg/d thereafter. Czosnyka *et al.* [8] confirmed these zero-drift findings in bench test studies, although they also reported, that the temperature drift of the device was significant (0.3 mm Hg/1 °C). In our study no correlation between the duration of monitoring and zero drift ($p = 0.316$) was observed, which is contrary to the findings of previous studies which showed a linear drift pattern in a positive or negative direction [6, 21]. However, probes have often been observed to exhibit a nonlinear drift pattern, and appear to reveal positive and negative drift consecutively hence the need for a more precise way to calculate the "drift index" during long-term ICP measurements [22]. Accordingly, the drift index consists of three parameters: 1) The percentage of measurements which involve a pressure change during a 10 day period; 2) The maximum absolute pressure deviation which occurs during the ten day period, and 3) The mean absolute pressure deviation during the 10 day period. In the Camino® device the median percentage of pressure change was 1.6% of; the maximum pressure change was upto the 6 mm Hg. The median values for the mean absolute pressure changes were: Camino®: 2.9 mm Hg, and the 10 days drift measurement was: 4 mm Hg (for the Camino®) [22].

Infection

The role of prophylactic antibiotics in preventing infection associated with intracranial pressure monitoring is not well defined. Prabhu *et al.* [26] in an extensive review of the literature analyzed the indication for prophylactic antibiotics in patients with ICP monitoring; the authors reviewed 85 relevant articles but most were retrospective, nonrandomized, nonblind trials, without adequate controls or patient numbers. Appropriate indications for prophylactic antibiotics have not been clearly established, whereas the indiscriminate use of antibiotics can theoretically results in infection from resistant organisms, anaphylactic reactions, increased bleeding time, and systemic toxicity. This study does not resolve the controversy regarding the role of antibiotics with ICP monitoring and questions the efficacy of administering antibiotics during this procedure. Nevertheless, the use of PAB should be determined in relation to the infection profile of each hospital in terms of the antimicrobial spectrum, bio-availability, side effects, and the antibiotic cost-efficacy ratio. Jacobs and Westerband [14] determined the safety and efficacy of prophylactic antibiotics in head-injuries requiring ICP monitoring, and observed that patients who received prophylactic antibiotics demonstrated statistically higher septic morbidity rates (78.6% versus 31.3%), and statistically

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higher pneumonia rates (57.1% versus 18.8%) compared with patients who did not receive antibiotics. The authors concluded that the administration of prophylactic antibiotics during ICP monitoring for head-injuries was unnecessary and potentially detrimental.

Haemorrhage

Haemorrhage depends on the compartment where the device is placed, and the existence of a coagulation disorder [20]. Other authors recommend that the coagulation disorder must be corrected before placing the probe, and if this is not possible, other less invasive types of devices such as an epidural probe should be used [16]. The discrepancy in the incidences of intracranial haemorrhages following the placement of an ICP monitoring device reported in the literature is considerable, ranging from (0–15.3%). However, most studies do not distinguish between large haematomas requiring surgical evacuation and small pinpoint haemorrhages detected incidentally only on imaging [3, 21]. In our series, we found a complication rate of 2.5% (25 patients), similar to that reported in the literature [4, 21], though only 6 cases required surgical evacuation.

Recently Davis *et al.* [10] studied the risk of haemorrhagic complications due to intracranial pressure monitors in patients with abnormal coagulation parameters, and concluded that in patients with coagulations disorders haemorrhagic complications after ICP monitor placement were infrequent and the use of fresh frozen plasma to correct coagulation parameters to "normal" is not supported by the study and delays monitor placement. A study on the safety of twist-drills in 1032 cranial perforations revealed that only four procedures (0.38%) caused clinically significant bleeding attributed to the twist-drill, all of which were managed conservatively without requiring surgical evacuation [19].

Technical complications

A total of 49 cases (4.5%) of technical complications were observed in the 1071 devices inserted. Our technical complication rate is acceptable when compared with other reported rates: 25.4% Schürer *et al.* [27], 23.5% Münch *et al.* [23], 17.8% of Bavetta *et al.* [2], and 13% Jensen *et al.* [15]. Fiberoptic breakage and dislocation usually occurs during nursing procedures or medical manouvering [28] and is usually detected by a sudden loss of functioning. Münch *et al.* [23] pointed out that the rigid fiberoptic cable sticking out of the head and the fixation screw are responsible for dislocation, accidental removal of the probe and breakage of the optical fiber.

In conclusion intracranial pressure measurement with the Camino intraparenchymal device offers reliable ICP recordings in the majority of the measurements. The mean drift of the system is acceptable, and similar to others devices. The system offers the advantage of recalibration in vivo in cases with suspected erroneous readings, and permits the relocation of the device through the same twist-drill without increasing the infection risk. When used correctly, the incidence of mechanical complications and the rate of infections are very low.

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Comment

This large study by Gelabert-González *et al.* demonstrates low infection and complication rates of Camino ICP transducers. It also examines the important question of drift in the zero point. Because this is set prior to implantation and cannot easily be checked or changed afterwards, any significant drift may cause inappropriate readings to be recorded. Zeroing and recalibrating transducers are often confused. It is extremely difficult to change the calibration of a device but re-zeroing (i.e. checking the transducer is measuring 0 mm Hg at atmospheric pressure) is difficult as it clearly increases the risk of infection.

The ease by which parenchymal pressure transducers can be inserted combined with low infection and complication rates adds to the evidence supporting the utility of such devices. However the zero drift characteristics may still be of concern to users. The data presented (Fig. 2) suggests than in patients monitored for less than 100 hours, at the end of the monitoring period the device did not drift more than ±4 mm Hg which is clinically acceptable. However for longer monitoring periods, high levels of drift, up to ±20 mm Hg, were found.

Although the authors present the results in terms of a drift index and conclude that the Camino device is reliable in the majority of measurements, this is not borne out by their results. Their data may suggest that for extended monitoring periods there are unacceptably high levels of drift that would cast doubt on the accuracy of the measurements. Douglas Miller was a great proponent of the idea that an inaccurate measurement was worse than no measurement at all. Perhaps we should remember this when monitoring ICP over extended periods with the Camino system.

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MULTICENTER CLINICAL ASSESSMENT OF THE RAUMEDIC NEUROVENT-P INTRACRANIAL PRESSERE SENSOR: A REPORT BY THE BRAINIT GROUP.

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MULTICENTER CLINICAL ASSESSMENT OF THE RAUMEDIC NEUROVENT-P INTRACRANIAL PRESSURE SENSOR: A REPORT BY THE BRAINIT GROUP

OBJECTIVE: The aim of this study was to evaluate the robustness and zero-drift of an intracranial pressure sensor, Neurovent-P (Raumedic AG, Münchberg, Germany), when used in the clinical environment.

METHODS: A prospective multicenter trial, conforming to the International Organization for Standardization 14155 Standard, was conducted in 6 European BrainIT centers between July 2005 and December 2006. Ninety-nine catheters were used. The study was observational, followed by a centralized sensor bench test after catheter removal.

RESULTS: The mean recorded value before probe insertion was 0.17 ± 1.1 mm Hg. Readings outside the range ±1 mm Hg were recorded in only 3 centers on a total of 15 catheters. Complications were minimal and mainly related to the insertion bolt. The mean recorded pressure value at removal was 0.8 ± 2.2 mm Hg. No relationship was identified between postremoval reading and length of monitoring. The postremoval bench test indicated the probability of a system failure, defined as a drift of more than 3 mm Hg, at a range between 12 and 17%.

CONCLUSION: The Neurovent-P catheter performed well in clinical use in terms of robustness. The majority of technical complications were associated with the bolt fixation technology. Adverse events were rare and clinically nonsignificant. Despite the earlier reported excellent bench test zero-drift rates, under the more demanding clinical conditions, zero-drift rate remains a concern with catheter tip strain gauge technology. This performance is similar, and not superior, to other intracranial pressure devices.

KEY WORDS: Intracranial pressure, Multicenter trials, Physiological monitoring, Technology assessment

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In the 1950s, the first practical method for the clinical monitoring of intracranial pressure (ICP) was developed, and not long after that, its clinical value was demonstrated by Lundberg (8, 10). However, despite nearly 50 years of experience with this technology, the accurate and reliable measurement of ICP in the clinical setting remains a challenge.

Catheter tip pressure sensors, which rely on the technology of miniaturization, are likely to cause less damage to tissue than larger, fluid-filled catheters. As there is no separation between the point of measurement and the pressure sensor, catheter tip sensors are not affected by hydrostatic pressure differences. However, because of the reliance on miniaturization of the sensors and the interconnecting technology, these devices are more prone to problems of robustness. Also, because the pressure sensor is at the tip of the catheter and its reference zero level cannot be checked after insertion, the technology must exhibit minimal in vivo zero-drift over several days of measurement. There are several catheter tip devices on the market which, although performing well in bench test studies, have exhibited unacceptable zero-drift, robustness, or both, in studies conducted in the clinical environment (3, 5, 13, 15–17, 19–21, 23).

To reduce the physical size of the strain gauge catheter tip, usually only a partial Wheatstone bridge (an electrical bridge circuit used to measure resistance) is used, particularly because of the difficulty of producing robust multiple electrical connections in the miniature catheter tip design. Recently, a new

ABBREVIATION: ICP, intracranial pressure

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technology has become available, the Neurovent-P (Raumedic AG, Münchberg, Germany), in which a full Wheatstone bridge is fabricated at the catheter tip together with integral miniature multiwire technology. This solution should, in theory, provide improved zero-drift characteristics. A recent 2-center study conducted in Germany studied the incidence of zero-drift, rate of placement-induced parenchymal hemorrhage, magnetic resonance imaging compatibility, and robustness of this new ICP probe (22).

As a prerequisite for a clinical trial, the BrainIT group conducted and reported on an independent bench test study of the Neurovent-P catheter, which confirmed the manufacturer's long-term zero-drift performance for this technology (4). The results of that study demonstrated that mean zero-drift, after 5 days, was very small, and long-term continuous recording of a stable pressure was very precise. The response in dynamic tests, i.e., the changes of pressure over a wide range, was excellent. The average bias of the Raumedic catheter compared with a known pressure is very small. However, controlled laboratory conditions can be a very different environment from the clinical setting, and although devices may perform satisfactorily in the laboratory, they also need to be evaluated in clinical use. The aim of this study was to evaluate the robustness and zero-drift of this technology when used in the clinical environment in a prospective multicenter trial.

PATIENTS AND METHODS

The present prospective multicenter trial involved 6 BrainIT (www.brainit.org) centers (Barcelona, Heidelberg, Monza, Newcastle upon Tyne, Uppsala, and Vilnius; see Appendix), where patients in whom ICP monitoring was clinically indicated were enrolled between July 2005 and December 2006.

This study conformed to the International Organization of Standardization 14155 Standard, "Clinical Investigation of Medical Devices for Human Subjects." The model used was one of an investigator-led study design with the BrainIT group coordinating center's host institution (Southern General Hospital, Glasgow, Scotland) acting as the study sponsor. The BrainIT group has a regional language-based coordination, data validation, and study monitoring infrastructure in place to provide the required trial monitoring.

The study hypotheses were that, during typical clinical use, Neurovent-P catheters: 1) maintain accuracy of calibration as measured by postremoval zero-drift and postremoval bench test calibration; 2) are robust, as measured by catheter/cable system failure rate; and 3) are easy to implant and set up, as measured by a structured survey questionnaire of neurosurgeons and bedside nurses involved in the implantation and use of the system.

The inclusion criteria were: 1) clinical indication for ICP monitoring using an intraparenchymal probe, in keeping with the local guidelines; 2) estimated monitoring time longer than 24 hours; and 3) minute-by-minute recording of ICP with a bedside data collection tool.

The exclusion criteria were: 1) age younger than 16 years, 2) no clinical indication for ICP monitoring, 3) coagulopathy, 4) expected monitoring duration less than 24 hours, and 5) no bedside data collection of ICP available.

Patients in whom an increase in ICP was suspected, satisfying the inclusion criteria, were monitored with an intraparenchymal pressure probe. All ICP probes were inserted through a frontal burr hole. The location was chosen according to local guidelines; in general, this was the right frontal lobe. The Neurovent-P probes were implanted either through the bolt kit or introduced with a twist drill and tunneled subcutaneously. A questionnaire was completed by the neurosurgeon after every implantation to collect information on the procedure. The probe was electrically zeroed to a patient monitor and implanted according to the manufacturer's specifications. The probe placement depth and side of placement were recorded. Minute-by-minute ICP data were collected together with the BrainIT core data as standard.

Recording of Adverse Events

During the course of the study, all adverse events and technical complications were recorded. Adverse events were defined as any undesirable clinical occurrence in a subject, whether it was considered device related or not, such as cerebrospinal fluid infection or cerebral hematoma. Cerebral hematomas were classed into 3 grades: small punctate hemorrhages or localized subarachnoid hemorrhages (I), larger bleeds that did not cause a new neurological deficit or required surgical evacuation but might alter ICP readings (II), and hemorrhages that caused a new deficit or necessitated surgical removal (III). Technical complications were defined as an event or device failure associated with no deviation from a patient's baseline health, such as measuring errors, probe dislocation or unplugging, and probe damage because of cable rupture or pronounced kinking of the sensor. We analyzed whether these complications occurred during nursing maneuvers, during transport of the patient, or for other reasons.

Data collection stopped when a clinical decision was made to remove the ICP monitor from the patient. On removal of the ICP catheter from the patient, the postremoval zero-drift was checked after a stable reading had been achieved.

After removal, all catheters were sent to Monza for bench testing. Using methods and laboratory equipment described previously (14), we tested the zero-drift and dynamic response of the system to changes of pressure in a stepwise fashion, from 5 to 20 mm Hg. Before starting each experimental run, we verified the recorded pressure value, and any sensors that were damaged after removal from the patient were discarded before bench testing. A progressively increased hydrostatic pressure was produced, starting at 0 and rising to 20 mm Hg.

Sample Size Calculation and Statistical Analysis

Evidence from previous work with the Raumedic ICP probe showed that zero-drift had been recorded as 0.2 ± 0.41 mm Hg initially, as 1.7 ± 1.36 mm Hg after monitoring was completed, and 0.6 ± 0.9 mm Hg after 5 days on bench testing (4, 22). To be able to calculate the failure rate, clinically defined as a zero-drift of ±3 mm Hg or more, it was necessary to observe at least 1 failure (1). The probability of observing a drift of ±3 mm Hg or more for different values of mean pressure and standard deviation were calculated. A sample size of 100 catheters would yield a 95% chance of including at least 1 failure if the standard deviation was 1.5, whatever the size of the mean drift, and a 95% chance of including at least 1 failure if the standard deviation was 1.0 and the mean drift was 1.3 mm Hg or more. Using this approach, we designed the study to collect data from 100 catheters. For the bench test studies, summary statistics reported include mean, median, maximum, minimum, standard deviation, and the 25th and 75th percentiles. The measured pressure for the dynamic tests was compared with the "gold standard" (hydrostatic water column). Splus 2000 software (Mathsoft, Inc., Seattle, WA) and SPSS software (Version 14; SPSS, Inc., Chicago, IL), were used to perform statistical analyses.

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TABLE 1. **Patient distribution among centers, percentage of bolt use, depth of introduction, site of introduction, and percentage of traumatic brain injury**[a]

Center	Patients		Bolt use (%)	Depth of introduction (mm)	Right frontal position (%)	Traumatic brain injury (%)
	No.	%				
Monza	28	28.3%	0	39.2 ± 8	24 (86%)	23 (82%)
Uppsala	25	25.3%	0	28.1 ± 1.3	20 (80%)	19 (76%)
Barcelona	23	23.2%	16 (76%)	46.8 ± 8	18 (78%)	19 (82%)
Vilnius	14	14.1%	0	20.7 ± 2	12 (85%)	14 (100%)
Newcastle	5	5.1%	5 (24%)	54 ± 1.1	5 (100%)	0
Heidelberg	4	4.0%	0	37.5 ± 1.6	2 (50%)	3 (75%)
Total cases	99	100%	21 (21%)	36.9 ± 1.3	81 (81%)	78 (78%)
P value			≤0.0001	≤0.0001	NS	≤0.0001

[a] NS, not significant.

RESULTS

Clinical Results

Population

Ninety-nine catheters were placed in patients, with a variable distribution between centers ranging from 4 to 28 cases/center (Table 1). Two catheters were not implanted because of technical problems (2 sensors were damaged by the surgeon during the procedure).

The main pathology was traumatic brain injury (78 patients, 78.8%), followed by miscellaneous pathologies (12 patients, 12.1%), subarachnoid hemorrhage (5 patients, 5%), and hydrocephalus (4 patients, 4%). The fixation bolt was used in 21% of the cases, with significant differences between centers. In 81% of the patients, the sensor was introduced in the right frontal lobe. The mean depth of placement into the parenchyma was 36.9 ± 13.6 mm, with significant intercenter differences. The mean duration of monitoring was 138.7 ± 118 hours (25th percentile, 50 hours; 75th percentile, 192 hours).

Preinsertion Zero-drift

Data were available from 76 catheters. The distribution of the values is presented in Figure 1. The mean recorded value before the probe insertion was 0.17 ± 1.1 mm Hg (median, 0 mm Hg; 25th and 75th percentile, 0 mm Hg).

Readings outside the range −1 to +1 mm Hg were recorded in only 3 centers on a total of 15 catheters (2 in Newcastle upon Tyne, 10 in Vilnius, and 3 in Uppsala; analysis of variance, not significant).

Complications at Insertion and during Use

Some centers pointed out difficulties in using the fixation probe at insertion and/or removal. Most of these incidents were recorded in the early patients: 1 probe was damaged by the surgeon before insertion, 1 defective cable was suspected, 3 probes were difficult to remove, 3 probes provided unreliable

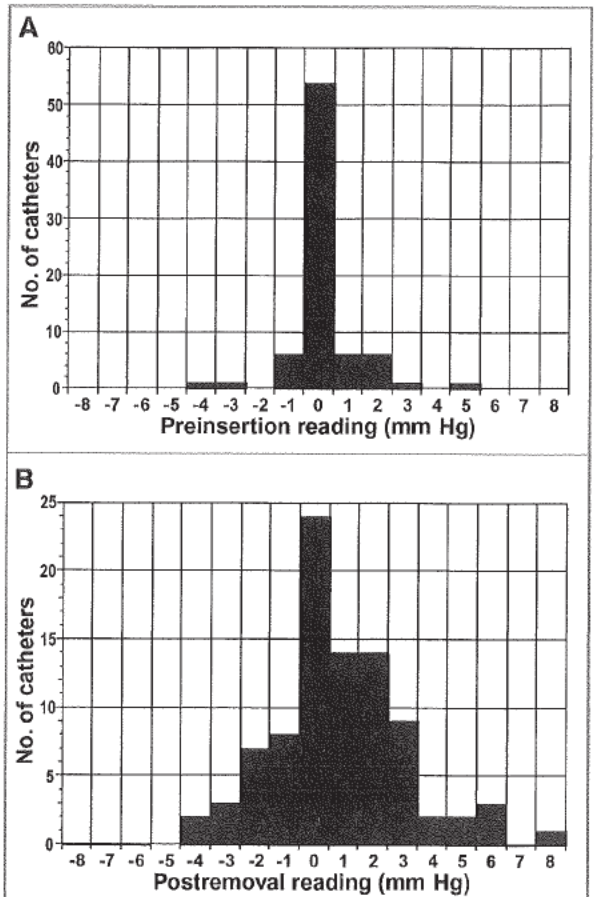

FIGURE 1. A, *graph showing distribution of the preinsertion values.* B, *graph showing distribution of the values at removal.*

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readings (checked with other systems), 5 probes had problems with the bolt, 2 probes were defective, 0 probes broke, 4 probes were dislocated (2 during surgery, 1 during nursing, 1 during radiology), 0 patients had central nervous system infection, and 2 patients had Grade I hematomas.

Postremoval Zero-drift

Data were available for 89 catheters, mainly because of damage during the removal phase that prevented the adequate recording of the postremoval zero reading. Distribution of the values is presented in Figure 1. The mean recorded value at removal was 0.8 ± 2.2 mm Hg (median, 1 mm Hg; range, −4 to 8 mm Hg; 25th percentile, 0 mm Hg; 75th percentile, 2 mm Hg). Statistically, but not clinically, significant differences were recorded between centers: Barcelona, 0.7 ± 1.7 mm Hg; Heidelberg, 2 ± 0 mm Hg; Monza, 0.7 ± 2.2 mm Hg; Newcastle upon Tyne, 1.2 ± 3.9 mm Hg; Uppsala, 1.7 ± 2.6 mm Hg; Vilnius, −0.3 ± 1.2 mmHg (analysis of variance, $P = 0.006$). Failures, defined as a recorded zero-drift of ±3 mm Hg or more, were identified in 22 cases. No relationship between failure and length of monitoring was identified (Fig. 2).

Bench Test Results

Continuous Readings at 0 to 20 mm Hg

Testing the recorded value after the application of a variable pressure, ranging from 0 to 20 mm Hg, the probability of a system failure, defined as a drift of more than 3 mm Hg, was estimated to range between 12 and 17% (Table 2).

Differences between Observed and Applied Hydrostatic Pressure

The box-and-whisker plot (Fig. 3) demonstrates the distribution of the differences between the observed and applied pressures at each of the applied pressure values and illustrates the many observations of more than 3 mm Hg (i.e., 2 standard deviations) from the applied pressure. To confirm whether this was because of a consistent drift across the applied pressure values in individual catheters, e.g., whether a catheter consistently recorded a value 4 mm Hg above the applied level, we investigated the difference between the observed readings of individual catheters at an applied pressure of 5 mm Hg and an applied pressure of 0 mm Hg, and so on. For each individual catheter, we would expect the difference in observed pressures to remain at 5 for each 5-mm Hg increase in pressure. Table 3 shows that this was not the case; for instance, a catheter might have an observed pressure of 11 mm Hg when the applied pressure was 10 mm Hg and an observed pressure of 19 mm Hg when the applied pressure was 15 mm Hg.

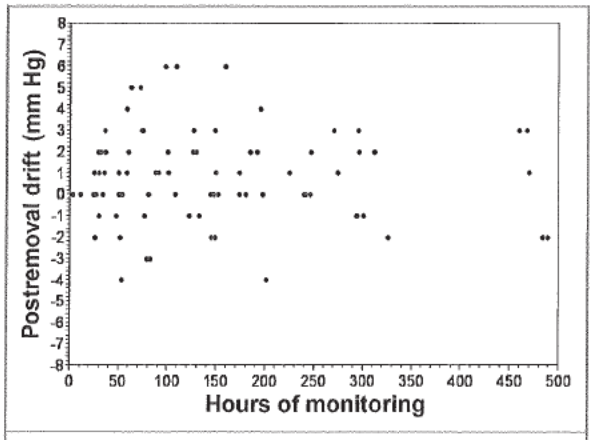

FIGURE 2. *Scatter plot of the recorded postremoval reading (mm Hg) and duration of monitoring (h).*

DISCUSSION

The accuracy and reliability of different methods of measurement for ICP remains a critical problem during management of acutely brain-injured patients, particularly of patients with severe head injuries in whom ICP monitoring is an accepted standard of care.

To guide therapy decisions, accurate measurement of ICP is essential. As the treatment threshold for increased ICP is low (20 mm Hg), relative to the physiological range of pressure that can be monitored with this technology (typically, 100 mm Hg), a measurement accuracy of 1 to 2% is required (16). For this reason, we predefined a failure as a reading of more than ±3 mm Hg. Use of systems with poor accuracy or unacceptably high zero-drift could lead to inappropriate treatment or, worse still, failure to treat when treatment is warranted.

The gold standard for ICP measurement remains the fluid-coupled ventricular catheter attached to an external pressure transducer. The advantage of this approach is that by using an externally mounted transducer, zero-drift and calibration can be checked and corrected, if necessary. This approach, however, is not without difficulties, especially in comatose head-injured patients, in whom the ventricle can be difficult to puncture; an additional risk of infection is reported with this type of catheter. For these reasons, catheter tip-mounted pressure sensor technology offers advantages. With this technology, pressure is measured at the tip of the probe, and consequently, ICP is measured directly in the parenchyma. Furthermore, this technology allows monitoring of patients in whom it is difficult to puncture the cerebral ventricles, and it avoids the problem of hydrostatic pressure differences. The main disadvantage of such catheter tip technology is that once placed into the patient, any zero-drift cannot be checked for or corrected. For this reason, it is critical that catheter tip devices are stable and robust and that their zero-drift characteristics remain within the known manufacturer's specifications.

The catheter tip systems most frequently used in the management of head-injured patients (Camino and Codman) do not allow pressure calibration to be performed in vivo, and so they cannot be corrected for inherent zero-drift after catheter placement. One of the potential advantages of the system we

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TABLE 2. **Pressure recorded during the bench test after the application of a variable pressure ranging from 0 to 20 mm Hg and estimate of the probability of a system failure**[a]

Pressure (mm Hg)	Mean	SD	U	Min	Max	Percentile			Drift	Probability of system failure[b]
						25	Med	75		
0	0.55	2.33	± 4.7	−7	6	0.0	1.0	2.0	0.55 ± 2.3	13%
5	4.83	2.44	± 4.9	−4	9	4.0	5.0	6.0	−0.17 ± 2.4	12%
10	10.04	2.56	± 5.1	1	15	9.0	11.0	12.0	0.04 ± 2.6	13%
15	15.07	2.65	± 5.3	6	19	14.0	16.0	17.0	0.07 ± 2.6	13%
20	20.28	2.94	± 5.9	7	25	20.0	21.0	22.0	0.28 ± 2.9	17%

[a] SD, standard deviation; U, uncertainty; Min, minimum value; Max, maximum value; Med, median.
[b] System failure is defined as a drift of more than 3 mm Hg.

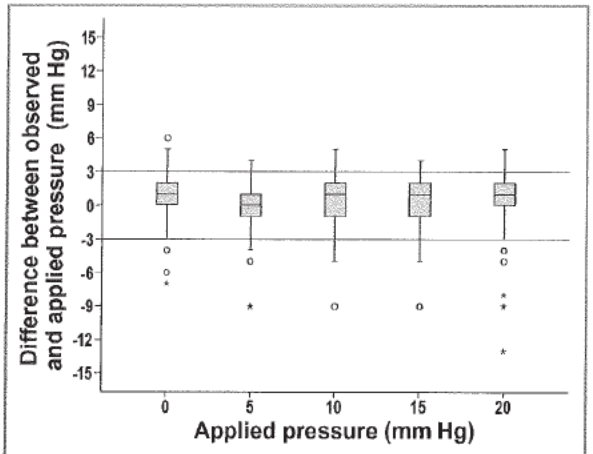

FIGURE 3. *Box-and-whisker plot (representing the 25th and 75th percentiles) showing the distribution of the differences between the observed and applied pressures at each of the applied pressure values, and the number of observations more than 3 mm Hg from the applied pressure.*

TABLE 3. **Bias data at different levels of pressure**[a]

Difference (mm Hg)	Mean ± SD (mm Hg)	No. >8 or <2
0–5	4.28 ± 1.63	6
5–10	5.20 ± 0.68	0
10–15	5.04 ± 1.18	3
15–20	5.20 ± 1.12	3

[a] SD, standard deviation.

tested is the incorporation of a full Wheatstone bridge into the catheter tip electronics. This technological improvement should enhance the zero-drift characteristics by reducing temperature sensitivity and the effects of non-pressure-related external strains. Until recently, this approach was only possible in the physically much larger external strain gauge systems. Through advances in miniaturization technology, it is now feasible to incorporate this technology into small catheter tip systems. Despite our promising bench test study results, further work was required to determine the performance of this measurement device in the clinical environment.

After these bench tests were performed, the next and most critical step was to conduct a trial of this technology in the more demanding clinical environment. The BrainIT group, as a multicenter collaborative group of neurointensive care scientists and clinicians, were well placed to design and conduct such a trial. All participating centers had great clinical experience with various ICP monitoring devices.

Issues Raised during the Multicenter Study

As in many multicenter trials, enrollment was slower than expected, and, because of local difficulties, some centers were not able to enroll the expected 15 cases. The cases are predominantly but not exclusively traumatic brain injuries, representing the use of ICP devices in other clinical conditions.

In this trial, there was no period of specific training or specific recommendations regarding insertion depth or whether to use the bolt or not. This could have an important influence on some of the problems detected in this study. In fact, a wide intercenter variability in the depth of probe placement was recorded across centers, ranging from 20 to 54 mm, with an average of 37 mm. These depths refer to distance from the end of the bolt or from the inner cranium. One of the helpful features of the Neurovent-P catheter is that number markings are recorded on its surface, thus making it easier to verify the actual placement depth. Unlike some bolts that have a physical stop, limiting depth of placement, this is not the case with the Raumedic bolt. It is surprising to find such a large intercenter variation, and perhaps this is in part a result of a lack of consensus or manufacturer guidelines for the depth of placement.

There were more technical complications reported than expected, with nearly 10% attributable to difficulties with the bolt fixation either on placement or removal. The bolt was difficult to remove in a number of patients, which could be an important problem in clinical use in countries where this is the preferred method of placement. However, bolts are not required by this device, and it can be easily implanted with a twist drill and safely tunneled.

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Adverse events were rare, with no infections and only 2 clinically nonrelevant hematomas. A higher-than-expected postremoval zero-drift was recorded and confirmed by postremoval bench test results. The probability of a catheter exhibiting a zero-drift rate of greater than ±3 mm Hg (failure) was pressure-dependent, with a 13% probability for low-pressure testing, which increased to 17% at a test pressure of 20 mm Hg. We consider this to be unacceptably high. We are unsure as to the root cause of the drift values outside this range, as they did not appear to be related to the center, physiological monitor, or any visible defect. A much larger study would be required to explore this aspect.

In general, the result of ICP measurement is only an approximation of the ICP value, and thus the ICP measurement result is complete only when accompanied by a quantitative statement of its uncertainty (6, 7, 12). We found that the postremoval uncertainty of the Neurovent-P catheter (Table 2) was within the limits ±4.7 to ±5.9 mm Hg (95% confidence interval). That uncertainty propagates to the uncertainty of clinical treatment decisions and to the uncertainty of the conclusions of ICP pathophysiology scientific studies. The challenge for ICP sensor manufacturers is to decrease that absolute ICP value measurement uncertainty to the clinically acceptable level of ±3.0 mm Hg or less.

CONCLUSIONS

The Raumedic Neurovent-P catheter performed well in clinical use in terms of robustness, with only a 2% complete catheter failure rate. The majority of other technical complications were associated with the bolt fixation technology. Adverse events in terms of infection or hematoma were rare and clinically nonsignificant.

At 13%, zero-drift rates of failure (defined as > 3 mm Hg drift) remain unacceptably high for this catheter. This is a particular issue with the Neurovent-P catheter, which provides no electrical means for adjusting any zero-drift identified before or during use. Despite the earlier reported excellent bench test zero-drift rates, under the more demanding clinical conditions, the zero-drift rate remains a concern with catheter tip strain gauge technology.

This performance is similar, but not superior, to that previously described in other articles on the clinical use of other solid-state and fiberoptic ICP devices (9, 11, 13, 15, 18–21). Nevertheless, in our opinion, this sensor has some clinical advantages over existing ones: its robustness is superior to traditional fiberoptic sensors, and it can be attached to any bedside monitor in the intensive care unit with a very simple interface.

APPENDIX

Investigators and Participating Centers

Barcelona, Spain: Juan Sahuquillo, M.D., Jorge Alberto de los Rios, M.D.; Heidelberg, Germany: Karl Keining, M.D., Janet Mattern, M.D.; Monza, Italy: Giuseppe Citerio, M.D., Davide Galli, M.D.; Newcastle upon Tyne, England: Iain R. Chambers, Ph.D.; Uppsala, Sweden: Per Enblad, M.D.; Vilnius, Lithuania: Saulius Ročka, M.D.

Disclosure

The BrainIT coordinating center (Southern General Hospital, Glasgow, Scotland) received a grant from Raumedic AG (Münchberg, Germany) to run the trial. Raumedic also donated all the disposables and catheters that were used in the study. None of the participants in the study received payment for the trial or for consultancy and/or advisory work, or honoraria for educational or other purposes, including for travel or other expenses. None of the participants hold stocks or shares in Raumedic.

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Acknowledgments

We thank all the staff at each of the participating centers for their time and help in collecting the data.

COMMENTS

Citerio et al. conducted careful postmarketing testing of the Raumedic Neurovent-P intracranial pressure (ICP) sensor. Novel design features had promised significant theoretical advantages of this technology, and laboratory testing had demonstrated lesser tendency toward zero-drift than other commonly used ICP devices. In practice, the device was quite robust, although superiority of performance could not be easily proven. With rigorous surveillance, problems were encountered in relation to bolt placement technique. And relevant zero-drift remained a frequent occurrence that was unrelated to duration of insertion. This affected the validity of ICP measurements in a significant fraction of cases.

Unfortunately, such careful studies are all too rarely undertaken after successful marketing of new devices, with diminished manufacturers' or champions' incentives to document real performance. And all too often, "equivalent performance" is sought "up front," which easily could reflect small sample size and type 2 error, whereas the advantages of new technology are accepted at face value on the basis of theoretical arguments. This study reminds me of Henri Poincaré's admonition in *La Science et l'Hypothèse*, more than 100 years ago, that "All generalization is a hypothesis. It ought always, as soon as possible, as often as possible, to be subjected to verification. If it does not stand this test, it ought to be abandoned without reserve. We do so with an ill humor. This ill humor is not justified" (1).

Issam A. Awad
Evanston, Illinois

1. Poincaré H: *Science and Hypothesis* [in French], 1906.

The authors have put together a very well-constructed, thorough, and transparent study of this promising ICP technology. Neurovent-P has the theoretical advantage of being a full Wheatstone bridge in the catheter tip, promising minimal to zero-drift, no adjustments after placement, ability to withstand a broad range of conditions, and thus improved accuracy for the patient and simplicity for the surgeons and nurses. In this study, the catheter seemed to be able to withstand the usually trying conditions of an ICU, provided real-time bedside recording, and demonstrated excellent preinsertion reliability. However, after removal, there were 22 cases in which the catheters displayed a 3 mm Hg or greater drift.

I am unclear on why there were significant differences in centers for the postremoval zero-drift measurement unless the bench test was flawed or the test was difficult to standardize owing to interobserver variability. There appeared to be few defects in the catheters. I agree with the authors, who stated that this technology is both accurate and robust, but, thus far, it is arguably no more reliable than our current fiberoptic standard. The aim should be to decrease the ICP measurement uncertainty below its current level.

Richard G. Ellenbogen
Seattle, Washington

This is an excellent contribution from the BrainIT group, a serious scientific multicenter neurointensive care study group from Europe that evaluated a commercial ICP monitor with due diligence. The authors found that the catheter performed well in clinical use with few adverse events, but zero-drift rate remained a concern. Overall, the authors felt that the performance was similar to that of other ICP monitors available. From the large number of detailed evaluations that were performed, we ought to be persuaded to believe them, although it is questionable whether we will switch from using current ICP monitoring devices, which are all fairly similar.

Neil Kitchen
London, England

The BrainIT group describes a well-conducted clinical evaluation of a new parenchymal ICP monitor. As one might perhaps expect, results during actual clinical testing were not as favorable as the previously reported results during bench testing. In particular, the zero-drift rate remains problematic. In future studies of this type, it might be interesting to compare different manufacturers' devices in a randomized (but, obviously, unblinded) fashion. Such a study design might allow determination of whether problems with a monitor are unique to that particular device, or whether all monitors at a particular institution have a high rate of problems (thus suggesting that difficulties are institution-specific). In the case of trials of ICP monitors, a comparison to ventriculostomy catheters should also be considered by study planners.

Alex B. Valadka
Houston, Texas

CUSTOMER SERVICE CONTACT INFORMATION

CNS Members: Call Sue Souders at: 301/223-2325.

Non-CNS Members: Call either 301/223-2300 or 1-800/638-3030.

Customer Service fax: 301/223-2400.

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JXG,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 13, 2013

Möller Medical GmbH
c/o Mr. Grant Geckeler
1612 Jenks Drive
Corona, CA 92880

Re: K121248
Trade/Device Name: LiquoGuard CSF System
Regulation Number: 21 CFR 882.5550
Regulation Name: Shunt, Central Nervous System and Components
Regulatory Class: Class II
Product Code: JXG
Dated: May 13, 2013
Received: September 16, 2013

Dear Mr. Geckeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K121248

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	BINOY J. MATHEWS BIOMEDICAL ENGINEER/SCIENTIFIC REVIEWER NEUROSTIMULATION DEVICES BRANCH DNPMD/ODE/CDRH U.S. FOOD AND DRUG ADMINISTRATION DATE: DECEMBER 12, 2013
Branch Chief Sign-Off	Quynh Hoang December 12, 2013 DNPMD/NNDB
Division Sign-Off	Joyce M. Whang -S 2013.12.13 17:17:24 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)…" Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe	Fixed a typo: Paragraph 1, final sentence, "We remind you,

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	Janicki	however; that device labeling must be truthful…" Replaced incorrect semicolon with a comma.

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Indications for Use

510(k) Number: **K121248**

Device Name: **LiquoGuard CSF System**

Indications for Use:

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure using pressure sensors and a pump, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure up to 75 mmHg and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

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5

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 13, 2012

MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248

Product: LIQUOGUARD CSF LIQUOGUARD CSF

Extended Until: 05/20/2013

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Pugh, Dominique *

From: Microsoft Outlook
To: grant@tpstech.com
Sent: Thursday, December 13, 2012 4:26 PM
Subject: Relayed: K121248 EXTENSION LETTER

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

grant@tpstech.com (grant@tpstech.com)

Subject: K121248 EXTENSION LETTER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

18

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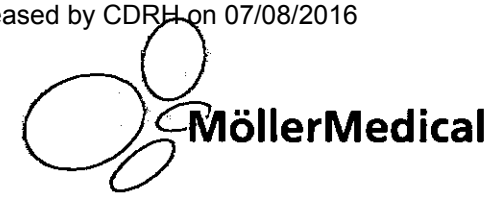
Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda · Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com



FDA CDRH DMC
DEC 13 2012
Received

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 11th, 2012

RE: 510(k) Number: K121248
Product: LIQUOGUARD CSF
Request for an extension of time for responding to FDA

Möller Medical GmbH is in receipt of FDA's letter dated November 20th, 2012 requesting additional information be provided in order to make a determination of substantial equivalence for the aforementioned 510(k) Premarket Notification.

At this time, we are requesting additional time in order to prepare our responses to the items in FDA's letter. Specifically, Möller Medical requests that our time to prepare and submit the responses be extended for additional 180 days.

Two copies of this letter requesting an extension of time are hereby submitted. The existence of this 510(k) Premarket Notification submission and request for extension are considered confidential information by Möller Medical GmbH, and we kindly request FDA consider it as such.

Please contact the undersigned if you have any questions. Thank you.

Sincerely,

Grant Geckeler , Esq.
Independent Consultant for Möller Medical GmbH
1612 Jenks Drive
Corona, CA 92880
Phone +1 714 312 6863
Fax +1 714 637 2460
Email: grant@tpstech.com

FB_002_004
2012-12-11_Time_Extension

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH

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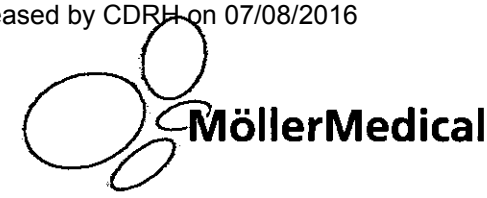

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DEC 13 2012
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Center for Devices and Radiological Health
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 11th, 2012

RE: 510(k) Number: K121248
Product: LIQUOGUARD CSF
Request for an extension of time for responding to FDA

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Please contact the undersigned if you have any questions. Thank you.

Sincerely,

Grant Geckeler , Esq.
Independent Consultant for Möller Medical GmbH
1612 Jenks Drive
Corona, CA 92880
Phone +1 714 312 6863
Fax +1 714 637 2460
Email: grant@tpstech.com

Sparkasse Fulda
BLZ 530 501 80 · Kto.-Nr. 40 014 403
IBAN: DE19 5305 0180 0040 0144 03
BIC (SWIFT): HELA DE F1FDS

Hypo Vereinsbank
BLZ 503 201 91 · Kto.-Nr. 8 600 228
IBAN: DE41 5032 0191 0008 6002 28
BIC (SWIFT): HYVE DE MM430

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IBAN: DE62 5308 0030 0801 6008 00
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Fortis Bank Niederlassung Deutschland
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IBAN: DE49 6005 0101 0004 5068 61
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HRB 5504 · Amtsgericht Fulda · UST-ID-Nr. DE 112 412 704 · Geschäftsführer: Peter Schrempp · Dr. Christoph Traxler

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

20

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Pugh, Dominique *

From: Pugh, Dominique *
Sent: Friday, November 23, 2012 10:42 AM
To: 'GGECKELER@GEOINC.ORG'
Subject: K121248 HOLD LETTER
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 23, 2012
GECKELER
GRANT
MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248

Product: LIQUOGUARD CSF LIQUOGUARD CSF

On Hold As of 11/21/2012
We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 23, 2012

MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248
Product: LIQUOGUARD CSF LIQUOGUARD CSF
On Hold As of 11/21/2012

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

* * * COMMUNICATION RESULT REPORT (MAY. 9. 2012 3:07PM) * * *

FAX HEADER 1:
FAX HEADER 2:

T 'SMITTED/STORED : MAY. 9. 2012 3:05PM

I. MODE	OPTION	ADDRESS	RESULT	PAGE
5072 MEMORY TX		9518932449	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 09, 2012

MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248
Product: LIQUOGUARD CSF LIQUOGUARD CSF
On Hold As of 5/8/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 09, 2012

MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248
Product: LIQUOGUARD CSF LIQUOGUARD CSF
On Hold As of 5/8/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed Under FDA request 2015-0257, Released by CDRH on 07/08/2016

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 25, 2012

MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248

Received: 4/25/2012

Product: LIQUOGUARD CSF LIQUOGUARD CSF

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Wednesday, April 25, 2012 2:21 PM
To: 'ggeckeler@geoinc.org'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 25, 2012
GECKELER
GRANT
MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248
Received: 4/25/2012
Product: LIQUOGUARD CSF LIQUOGUARD CSF

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Grayson, Giovanna *

From: Microsoft Outlook
To: 'ggeckeler@geoinc.org'
Sent: Wednesday, April 25, 2012 2:22 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'ggeckeler@geoinc.org'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K12/248
ME/DONE

Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda · Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

K14

MöllerMedical

FDA CDRH DMC
APR 25 2012
Received

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

April 16, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Traditional 510(k) Premarket Notification for LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**.

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis.

The **LiquoGuard CSF System** is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The **LiquoGuard CSF System** controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The **LiquoGuard CSF System** also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

The **LiquoGuard CSF System** consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Common Name:	External CSF Drainage System
Proprietary Name:	LiquoGuard CSF System
	Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification and Product Code:
21 CFR § 882.5550, "Shunt, Central Nervous System and Components", Class II, JXG

The Möller Medical **LiquoGuard CSF System** is substantially equivalent to the Central Nervous System devices "Integra NeuroSciences corporation (K030289, K032817)" and "Codman & Shurtleff, Inc. (K061568)" in terms of intended use, design, operating principles, and materials.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH

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Design and Use of the Device **LiquoGuard CSF System:**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002 _004
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GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

MöllerMedical

TRADITIONAL PREMARKET NOTIFICATION [510(K)] SUBMISSION

LIQUOGUARD CSF SYSTEM

Legal Manufacturer:
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1. Medical Device User Fee Cover Sheet (From FDA 3601)

The MDUFMA Cover Sheet is provided in front of the 510(k).

2. CDRH Premarket Review Submission Voluntary Cover Sheet

The CDRH Premarket Review Submission Cover Sheet is provided in front of the 510(k).

3. 510(k) Cover Letter

The 510(k) Cover Letter is provided in front of the 510(k).

4. Indication for Use Statement

The Indication for Use Statement is provided **Appendix 1**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5. 510(k) Summary

Submitter Information: Möller Medical GmbH
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Establishment Registration Number: 3006611221

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Name of Device:

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification: Shunt, Central Nervous System and Components, Class II, 21 CFR § 82.5550

Product Code: JXG

Substantial Equivalence:

The Möller Medical LiquoGuard CSF system is substantially equivalent to the CSF drainage systems listed below in terms of intended use, design, operating principles, and materials.

Integra NeuroSciences Corporation	K030289, K032817
Codman & Shurtleff, Inc.	K061568

Device Description:

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the “gold standard” for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF system consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF

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drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Intended Use:

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

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6. Truthful and Accuracy Statement

The Truthful and Accuracy Statement is provided in **Appendix 2**.

7. Class III Summary and Certification

Not Applicable.

8. Financial Certification or Disclosure Statement

Not Applicable (clinical study is conducted in Europe with a CE marked device).

9. Declarations of Conformity and Summary Reports

Not Applicable.

10. Executive Summary

10.1 Registration History

The LiquoGuard CSF System is CE marked since 2006. All over 180 devices are successfully placed on the European market without any incident.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device (see **Section 10.6**).

10.2 Indications for use

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

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10.3 Device description

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the “gold standard” for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF system consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

10.4 Predicate devices with same indication

The Möller Medical LiquoGuard CSF and the Integra LifeSciences (K030289, K032817) and Codman & Shrutleff (K061568) predicate devices listed in this application have the same indication.

10.5 Summary of substantial equivalence discussion

The LiquoGuard CSF drainage system is a tube system with integrated redundantly designed pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CSF drainage. The intrathecal CSF drain is used independent of the LiquoGuard CSF system, and the products approved for intrathecal CSF drainage can be connected to the LiquoGuard CSF system (but are not part of the system). The indication for insertion of intrathecal drainage will not be affected by using the LiquoGuard CSF system.

The control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing systems and the LiquoGuard CSF system. The measuring sensors are comparable and the effective mechanism and the function of the CSF extraction by means of a target value-controlled rotor pump in the LiquoGuard CSF system is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard CSF system offers comparable effectiveness to existing CSF drainage systems.

10.6 Performance Testing - Clinical

On April 8, 2009 representatives of Möller Medical and of the FDA met in Rockville to discuss the need of clinical data and the realization of a clinical trial. After consulting the FDA the following points were defined as guideline for the planed clinical trial:

- The clinical question is one of safety – efficacy is assumed based on the fact that the CSF draining is already a gold standard in trauma and neurosurgery.
- Clinical data is requested to answer the issue of whether or not the action of the LiquoGuard pump results in a significant increase in adverse events compared to the drip chamber (predicate device).

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- The clinical trial can be done by an observational study, as a control group historical data can be used.
- No scientific study will be necessary. To avoid any bias, it is sufficient to include all patients treated with the LiquoGuard in a facility over some period of time the data collection.
- The data can be collected in Europe.

On the basis of this guideline Möller Medical defined a study protocol and started the clinical trial in 2009 (please refer to **Section 20** for detailed information).

11. Device Description

11.1 Definition of drainage system

Cerebrospinal fluid (CSF) is drained from a patient using (i) a catheter placed in the third or lateral ventricle or lumbar subarachnoidal space, and (ii) a "drainage system" that removes any excessive CSF coming out of the catheter, and disposes of the fluid into a collection bag. Conventionally, the drainage system is a dripping chamber which works like a siphon or spill: any excessive CSF pressure leads to dripping inside the dripping chamber.

11.2 Product idea of the LiquoGuard CSF system

The key disadvantages of the conventional drainage systems are that they have no integrated alarm functions and that they are error-prone. A wrong cock position or a clogged/disconnected catheter can lead to under- or overdrainage. This problem is solved by the LiquoGuard CSF system that replaces the drainage systems above. It consists of (a) a tube set that is connected to the catheter just like the conventional dripping chamber. The tube set contains a dual pressure sensor measuring the pressure inside the tube at the end of the catheter. The other component (b) is an electronically controlled pump removing CSF as long as the measured pressure is excessive. The LiquoGuard CSF system detects many typically occurring and dangerous situations not caught by the dripping chambers, e.g. a sudden pressure drop by an accidentally extracted catheter, or a pressure staying constant for an extended period of time (which is unphysiological and may indicate a clogged/disconnected catheter).

11.3 Components of the LiquoGuard CSF system

The LiquoGuard CSF system consists of the LiquoGuard CSF pump and the LiquoGuard tube set.

11.3.1 LiquoGuard CSF pump

The LiquoGuard CSF main (see **Figure 1**) unit contains a peristaltic pump in which the tube set is inserted and connected for operation. It has a blue turning knob and three touch keys for user operation, a card slot to insert a memory card and a display to show pressure and flow values as well as a pressure and flow history. There are 5 light emitting diodes and a speaker for the audible alarms.

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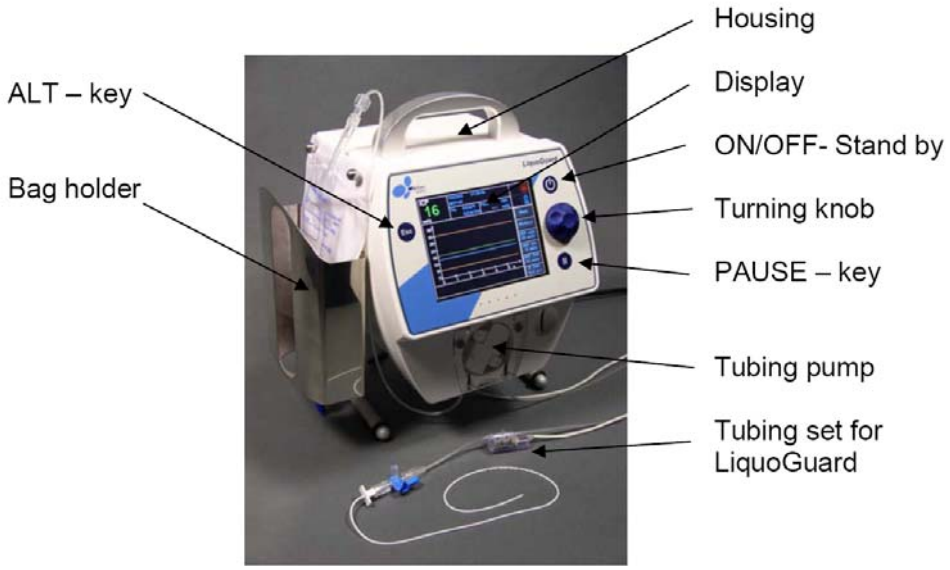

Figure 1: Front view of LiquoGuard CSF

11.3.2 Disposable tube set

The tube set consists of a polyvinyl chloride (PVC) tubing, luer locks, stop cocks, a drainage bag with a reflux valve, specially shaped plastic pieces to ensure correct insertion into the pump, and a pressure sensor housing with two piezo-resistant pressure transducers and a cable for connection to the pump. The tube set is only for use with the LiquoGuard CSF. Please refer to **Appendix 3** for the product materials and **Appendix 4** the packing contents.

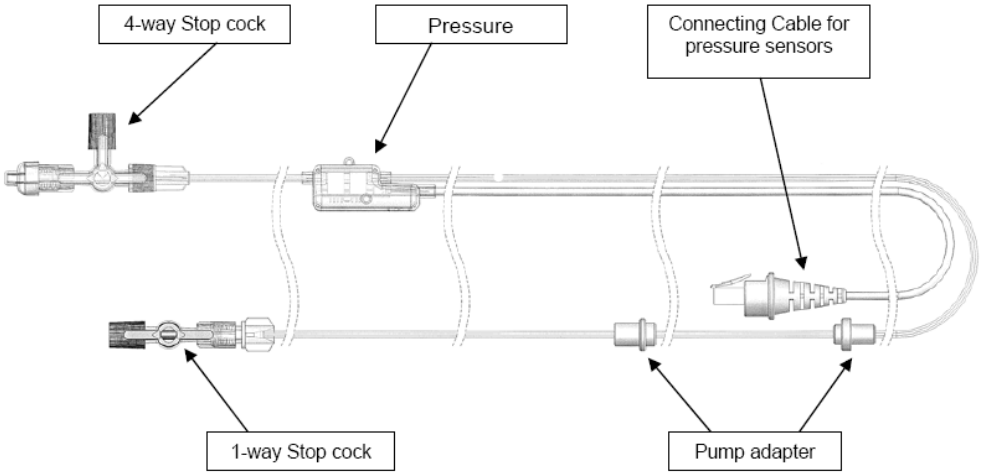

Figure 2: LiquoGuard tube set as schematic picture with its individual parts

The tube set exists in two variants which only differ in the length of the PVC tubing (1500mm and 2000mm). All components are exactly the same. The tube set is supplied as disposable sterile product.

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11.4 Principle of the LiquoGuard CSF system

The normal operation of the pump works as follows:

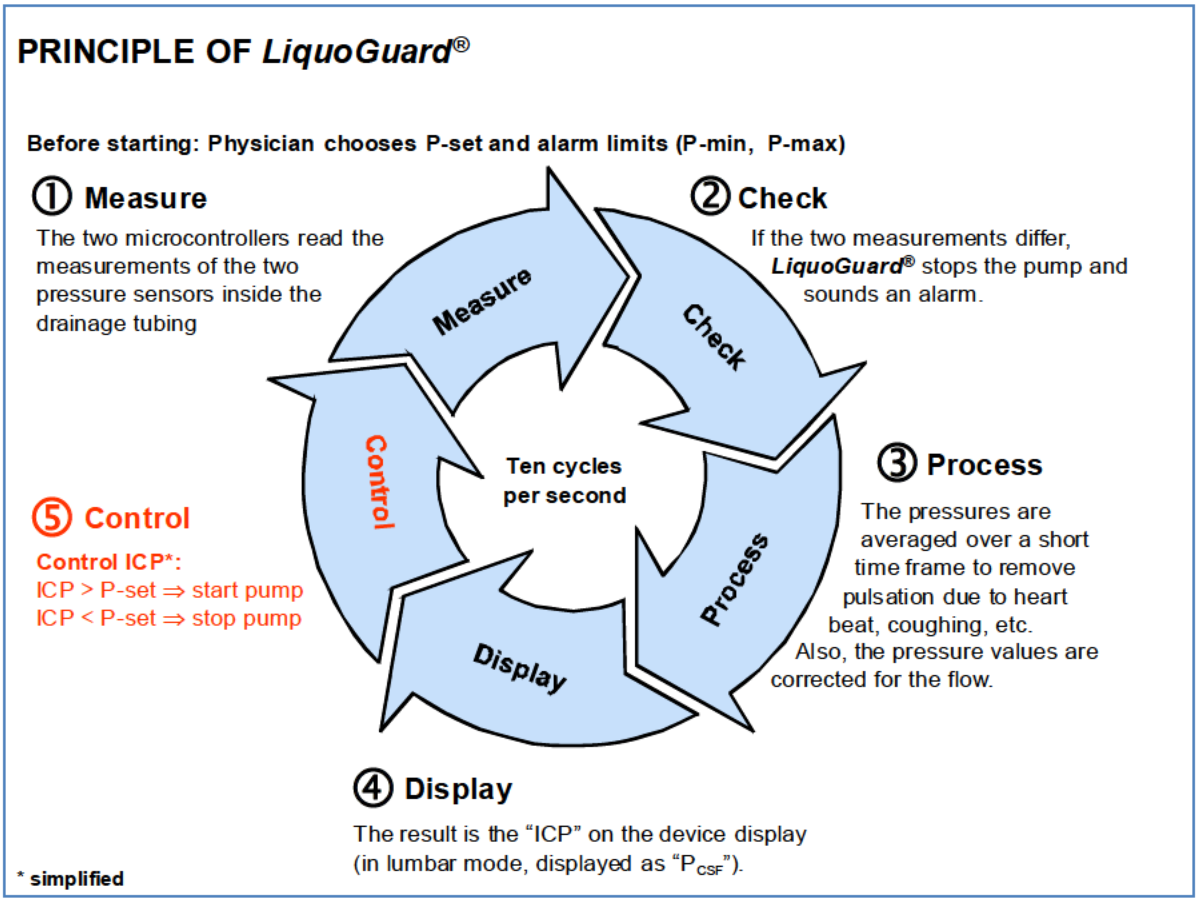

Figure 3: Principle of LiquoGuard

- Every 0.1s, read the measurements of two pressure transducers inside the tubing.
- Compare the two pressure values using the two microcontrollers of the LiquoGuard. If the resulting values differ by more than the combined tolerance of both sensors, assume that at least one of the sensors is malfunctioning: in this case, ignore all settings and all measured values, stop the pump, and sound an alarm.
- Otherwise, average the measured pressure value over the two pressure transducers and over a short time frame (configurable, standard setting 1s). The result is the CSF pressure shown on the device display – we call it simply ICP (intracranial pressure) in the following. The goal of this averaging is to remove the physiological pressure pulsations caused indirectly by the heart beat from the measurement.
- If <u>ICP is higher than P-set</u> (desired pressure, ordered by physician) by some small margin, operate the pump.
- If <u>ICP is lower than P-set</u> by some small margin, stop the pump.

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- Independently from P-set: if the measured pressure value (before averaging) is lower than the lower alarm limit, stop the pump.
- Independently from all settings: If measured pressure value (inside the tubing) is lower than 2 mmHg, stop the pump.

11.5 Details regarding the principle

11.5.1 Two microcontrollers

There are two microcontrollers. Each one has an analogue to digital converter and calculates the actual pressure inside the tube system. These values are communicated between the two controllers.

The system always displays the arithmetic average of the two measured values (the diagram only shows the master controller's pressure signal). If both values differ by more than 4 mmHg, an alarm is generated, as the system can't determine which value is the correct one. If the two values are within the valid range the average of the two sensors is used to control the pump.

A comment on the “small margin” mentioned above: this is needed to prevent the pump from starting/stopping too frequently. This small margin is called the “hysteresis”; it is a standard tool in all regulating devices that use only “on” and “off”-states, like switching a pump on or off. In the case of LiquoGuard, the hysteresis value is configurable and defaults to 0.5 mmHg.

A comment on the “lower alarm limit” mentioned above: The default value of the lower alarm setting is 0 mmHg. This setting can be changed by an order of a physician, however the allowed values are restricted to be above or equal to a minimum of -15 mmHg, which is a small negative value, far too small to tear off and aspirate brain tissue. To put this into perspective, note that negative ICPs of -50 mmHg and more occur physiologically in a healthy human being.

Detailing the difference between ICP and pressure in the drainage tubing: The pressure inside the tubing is equal to the ICP by the laws of hydrostatics, if there is a non-occluded liquid column between the ventricle and the pressure sensors. This is normally the case; therefore the measured pressure is displayed as "ICP" on the device. However, in the cases of catheter occlusion or collapsed ventricles (=closing of the catheter holes by brain tissue), the ICP can rise above the pressure inside the tubing. A drip chamber, working on hydrostatics alone, drains CSF depending on the pressure inside the tubing. The LiquoGuard does the same – it requires an excess pressure inside the tubing for pump operation. In the case of collapsed ventricles, the ICP may be high and yet no drainage will occur with both the drip chamber and the LiquoGuard. The effects of the two systems are thus substantially equivalent.

11.5.2 LiquoGuard CSF alarm system

The main safety advantage of the LiquoGuard CSF system over the passive dripping chambers is the sophisticated alarm system: there are many potentially hazardous situations in which LiquoGuard will call a nurse or doctor by audible and visible alarm signals. The following is a summary of all alarms offered:

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Pulsation alarm:

- o LiquoGuard CSF continuously monitors the physiological pressure pulsations caused by the heartbeat.
- o LiquoGuard CSF will sound an alarm if this pulsation is not present.
- o This is a check if the liquid column between the ventricle and the pressure sensors is present.
- o Possible reasons for this include catheter occlusion and collapsed ventricles (catheter holes covered by brain tissue).

Pressure alarms:

- o LiquoGuard CSF will sound an alarm if the pressure is higher or lower than the respective pre-selected alarm limits
- o LiquoGuard CSF will sound an alarm if the pressure remains constant for an extended period of time (Possible reasons include catheter problems with lumbar drainage)

Sensor cross-checking:

- o LiquoGuard CSF dual pressure sensor technology measures the pressure inside the tube with two completely independent transducers.
- o Even the cables are duplicate.
- o If there is any discrepancy between the two sensor readings, LiquoGuard will sound an alarm and shut the pump off as security measure.

Watchdog functionality:

- o The sensor information is processed by two completely independent microcontrollers (that have been programmed by two different software engineers).
- o These controllers read out the two pressure sensors and exchange their results via interprocessor communication.
- o LiquoGuard CSF will sound an audible and visible alarm and shut the pump off as security measure if there is any significant discrepancy of the data, or failure of the other controller to answer. The alarms are independent as well (different speakers and LEDs for each microcontroller).
- o This technology is similar to the safety concepts of avionics in airplanes or the redundancy of powerplants.

Battery alarm:

- o In mobile application, LiquoGuard CSF monitors the remaining battery time.
- o LiquoGuard CSF will sound an alarm if the battery is low.

11.5.3 Battery back-up

A rechargeable lead-gel battery is used as backup to ensure the system functionality for up to 3 hours while there is no mains power. The device has a charging symbol which goes down as the battery discharges. Before the battery is entirely depleted, an alarm will sound

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and the display will read “Battery empty, connect to AC”. After the battery alarm sounds, there is still 5-10 minutes of battery power remaining until the display goes off, at which time the alarm continues to sound for a few more minutes until the device deactivates.

Complete charging of an empty battery is approximately 8 hours.

Discharging time is getting shorter. For security reasons the rechargeable battery is replaced once a year during security checks. The device has to go into service every 12 months for checks on the security system, dual processor system, communication with pressure sensors, and battery.

11.6 Key Questions & Answers of previous 510(k) application

11.6.1 Over-drainage

In patients with elevated ICP but small/slit-like ventricles, the active removal of CSF may lead to further ventricular collapse and catheter occlusion with brain tissue or debris, necessitating catheter removal/revision with significant potential morbidity/mortality.

“The LiquoGuard does not work by “active removal of CSF”; over-drainage/aspiration is not possible. In contrast, this danger is present with the predicate device (drip chamber).

To clarify the principle of LiquoGuard: Although LiquoGuard is an “active” (electrical) device, it does not “aspirate”, meaning it never generates negative pressure. The pump only operates if the pressure *inside the tube* is excessive, i.e. necessarily positive (no “suction” or “aspiration”). This is equivalent to the drip chamber which drains only when the pressure inside the tube suffices to drive CSF up to the height of the drip chamber. Therefore, LiquoGuard drains CSF exactly when the properly adjusted drip chamber would, and LiquoGuard does not remove CSF under the types of conditions that a properly adjusted drip chamber would not. An “active” aspiration of tissue or debris is not possible by design, because the preset target pressure is always positive.

In contrast to the LiquoGuard System, a drip chamber can aspirate tissue and debris if it is adjusted at a level lower than the patient or if it falls to the ground. In these cases, the drip chamber can generate a negative pressure inside the catheter equal to the weight of the CSF column inside the tubing, reaching from the patient to the drip chamber. For example, with a CSF density of water (1 g/ml) and a drip chamber on the ground (1 m = 3 ft below the patient), this corresponds to a negative pressure of –10 kPa = –75 mmHg, clearly dangerous for the patient.

In practice, medical personnel can be very hesitant to report such incidents, but an example can be found in MAUDE report # 1221649-1996-00006. In the case cited there, the drip chamber fell to the floor, subarachnoidal bleeding and death of the patient followed. Another example is MAUDE report # 2648988-2003-00009, where a malfunctioning stopcock led to over-drainage of 200 cc. Many MAUDE reports mention leakages of drip chamber-based drainage sets, which may lead to accidental and unnoticed over-drainage.

With LiquoGuard, a leaking tube set, (or disconnected catheter, malfunctioning stop cock etc.) will be detected as soon as it lowers the patient’s CSF pressure level below the pre-set alarm level. Please see **Section 18** test reports 41 and 52, where the reliability of pressure alarms and the detection of disconnections are confirmed.

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In small/slit-like ventricles, the catheter holes may be covered by brain tissue which prevents drainage by any gravity-fed CSF drainage system. In this case, a drip chamber fails to drain and fails to notify medical personnel. LiquoGuard, lacking an excessive pressure in the tubing, fails to drain just like the predicate device. However, LiquoGuard will most likely either sound the "pulsation invalid" alarm or the "pressure too constant" alarm in this case. Please see **Section 18** test reports 42, 43 and 44, where we confirmed the reliability of these alarms as well as the alarm consequences of a catheter occlusion.

To explain the above mentioned alarms: Normally, the pressure pulsations caused by the heart beat are detected by LiquoGuard and can be seen on LiquoGuard's display, as long as the liquid column between ventricle and pressure sensor is complete. When the catheter holes are covered by brain tissue (or the catheter is occluded, etc.), this liquid column is interrupted and the measured pulsation is lost inside the tubing, where the sensors are positioned. As soon as LiquoGuard registers no pulsations, it sounds an alarm.

To summarize, LiquoGuard places no additional risks on a patient with small/slit-like ventricles. In contrast, drip chambers – when unattended – may well place such risks.

LiquoGuard does help to detect potentially deleterious situations because of its alarm features, whereas with a drip chamber, medical personnel are not alerted to potential problems by the device."

11.6.2 Under-drainage

Patients with elevated ICP may need 5-10 cc of CSF removal quickly to avert cerebral herniation, and a fixed setting of drainage may not allow this.

"We agree that there is a risk of under-drainage, but if this happens, it will not go unnoticed. As soon as the ICP (and with it the pressure inside the tubing) raises above the pre-set alarm level of LiquoGuard, the device will sound an alarm and thus call the attention of medical personnel to the patient's condition. (No such safety feature is present with the drip chambers.) Please see **Section 18** test report 41.

The drainage rate of LiquoGuard is pre-selected and can be set as high as 50 ml/h. It can be further adjusted up to 150 ml/h using a password-protected hidden menu. Should that not be sufficient – which can be noticed by a continued alarm – the three-way stopcock of the tubing set can be connected to another drainage bag to quickly allow removal of excessive fluid.

With drip chambers, a significant risk of accidental and unnoticed under-drainage exists; causes include catheter clogging, clogging of air vents, anti-reflux valves and other kinds of blockages. In this context, refer to MAUDE # 1226348-2007-00216 where a blocked anti-reflux-valve was followed by patient's death. An under-drainage situation cannot go unnoticed when using the LiquoGuard (see above)."

In patients requiring lumbar intrathecal catheterization for CSF diversion (which is usually performed to allow dural healing after surgery to prevent/fix CSF leak), under-drainage may prevent sufficient CSF removal that is needed for dural closure. This would put the patient at increased risk for wound infection/meningitis.

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"Especially in the cases of CSF leaks after surgery, LiquoGuard allows a very smooth and continuous drainage as the flow rate can be set to a certain rate and the device will continuously drain with this rate as long as the pressure is above a certain pre-set level.

In contrast, lumbar drainage with the predicate devices (drip chambers) is done via a very thin catheter, that can easily be occluded or squeezed and therefore lead to unnoticed under-drainage or via a nurse opening and closing the stopcock in order to get out the right amount of fluid drainage – which is difficult to control and can lead to pressure fluctuations which often cause headaches, nausea and vomiting for the patients.

Once the need for drainage is addressed, LiquoGuard offers the possibility of slowly and precisely adjusting the flow rate. This is difficult (if not impossible) with the drip chambers.

An under-drainage situation cannot go unnoticed when using LiquoGuard. Should the pressure rise above the pre-set alarm limit, LiquoGuard will sound an alarm; personnel will become aware of the problem; and adjustments to the flow rate (flush the catheter, etc.) can be made accordingly. Please see test report 41 of our original 510(k) submission."

12. Substantial Equivalence Discussion

The LiquoGuard CSF shares indications and essential design principles with the following predicate devices, which have been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created and the LiquoGuard CSF is substantially equivalent to the predicate devices. Please refer to **Appendix 5** for copies of the 510(k) summaries for these substantially equivalent devices and **Appendix 6** for the clinical evaluation according to MEDDEV 2.7.1.

Table 1: Substantial Equivalence Devices

Trade Name	510(k) Submitter/Holder	510(k) Number
Hermetic Plus External CSF Drainage System External Drainage Set	Integra LifeSciences Corp	K030289, K032817
CODMAN EDS 3 CSF External Drainage System	Codman & Shrutleff, Inc.	K061568

12.1 Indications for use

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

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12.2 Device design and working principle

A dripping chamber is a gravity-driven siphoning device. It basically functions as a spill, disposing of all fluid that rises higher in the tubing than the nozzle inside the chamber. In CSF drainage, this principle is being used to maintain a desired target pressure in the patient. Referring to Figure 4, the desired target pressure is defined at the Foramen of Monro (marked as a white F inside a red circle). Aligning the dripping chamber at a height Δh relative to the patient's Foramen of Monro, the fluid column inside the tubing creates, by Pascal's law, a pressure of

$$(1) \qquad P_{target} = \rho\, g\, \Delta h$$

at the Foramen of Monro. Here, ρ is the mass density of the fluid (CSF), and g is the gravitational acceleration (9.81 m/s^2). Equation (1) is a general law of fluid statics and correct unless the catheter or tubing is clogged or not completely filled between the ventricle and the dripping chamber.

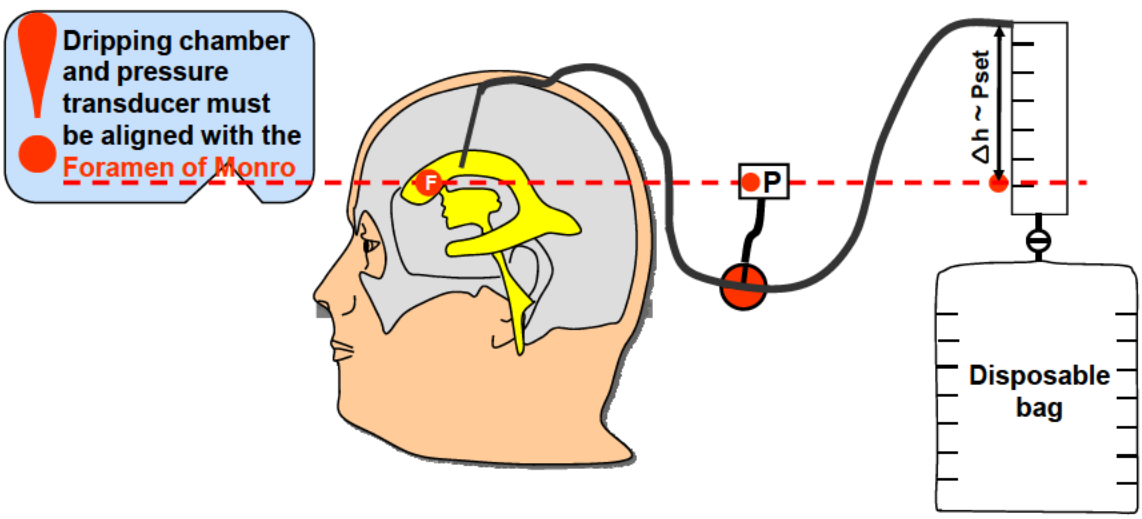

Figure 4: CSF drainage using predicate device (dripping chamber)

In the case of CSF drainage using the LiquoGuard CSF system (Figure 5), exactly the same Pascal's law states that the pressure at the Foramen of Monro must be *equal* to the pressure sensed by the dual electronic pressure sensors (box marked P in Figure 5) that are fixed outside on the patient's head at the height of the Foramen of Monro. This is again generally correct unless the catheter or tubing is clogged or not completely filled between the ventricle and the pressure sensors. LiquoGuard CSF uses its tube pump to reduce excessive pressure sensed at the pressure sensors, using the algorithm

If sensed pressure > P_{target}, then switch pump ON.

If sensed pressure < P_{target}, then switch pump OFF.

(slightly simplified).

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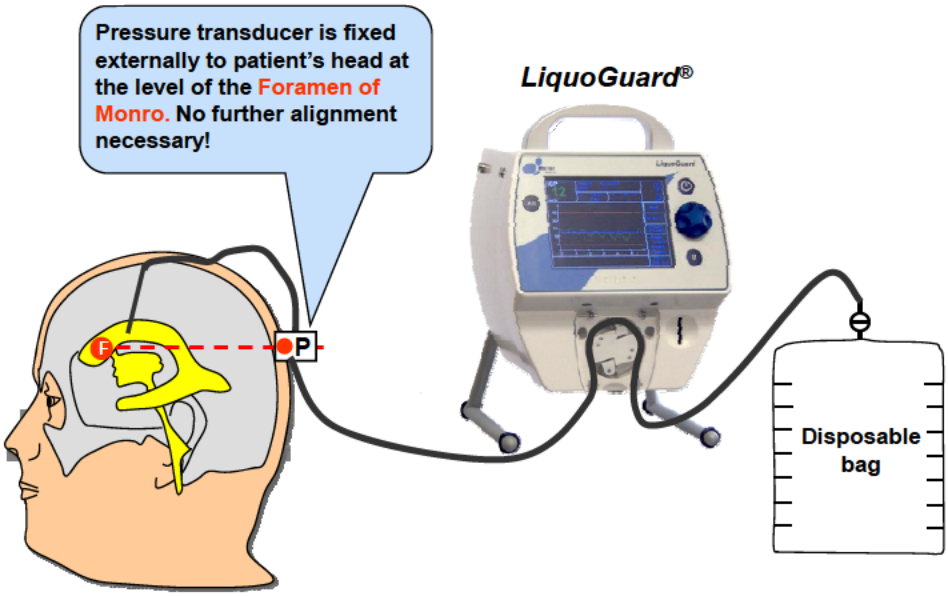

Figure 5: CSF drainage using LiquoGuard CSF

Note the similarity between the LiquoGuard CSF system and the predicate device (dripping chamber):

- Both devices function completely ignorant of the medical indication, the protein/blood content of the drained CSF (unless that content leads to clogging), or the attached catheter.
- Both devices make use of Pascal's law and thus depend on a completely filled, unblocked fluid column in the catheter and the tubing. However, while in the case of the dripping chamber the whole tubing (1000-2000mm length) has to be filled and unblocked, for LiquoGuard CSF only the small initial part of the tubing up to the pressure sensors (100mm) is relevant.

Note the key advantages of LiquoGuard CSF:

- The pressure is electronically sensed and documented.
- The pressure is used by the device to monitor the drainage process.
- The device does not have to be aligned in height, only the sensor.

These advantages translate into lower risks:

- Underdrainage can happen with the dripping chamber, e.g. when the air vent or tubing is clogged, or the height alignment of the chamber is lost by a repositioning of the patient. With LiquoGuard CSF, there is no air vent in the system, the relevant part of the tubing is much shorter (only the first 100mm to the pressure sensors are relevant), and no alignment is needed. Additionally, the pressure is constantly being

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monitored, and an alarm is signalled when the pressure leaves the pre-set safety boundaries.

- Overdrainage can happen with the dripping chamber, e.g. in the case of an accidental disconnection, or when the dripping chamber drops to the floor. With LiquoGuard CSF, overdrainage is simply impossible because the pump will stop whenever low pressure is sensed. Additionally, an alarm is signalled when the pressure leaves the pre-set safety boundaries.
- Catheter or tube clogging: The required fluid column has to be complete and unblocked starting from the ventricle only up to the sensors, which is only the catheter plus about 100mm of the LiquoGuard CSF tubing. In the case of the dripping chamber, the fluid column has to be complete and unblocked all the way from the catheter to the dripping chamber (1000-2000mm). Obviously, the chances of tube clogging increase with the length of the tubing. Additionally, LiquoGuard CSF monitors the physiological CSF pressure pulsations of the patient, and when these pulsations are lost, it sounds an alarm, indicating that something is wrong – possibly a clogged catheter.

LiquoGuard's pulsation alarm catches some of the dangerous situations not determined when using a drip chamber: As described above LiquoGuard CSF offers an additional safety feature which is unmatched by the drip chamber. The LiquoGuard CSF system continuously monitors the physiological pressure pulsations caused by the heartbeat. With suitable settings, the LiquoGuard will sound an alarm as soon as this pressure pulsation is not present. This will in many cases detect if the liquid column between the ventricle and the pressure sensors is indeed present, i.e. if catheter is not occluded or its holes covered by brain tissue in the case of collapsed ventricles. However, although the bench test results indicate that this alarm reliably detects catheter occlusions and collapsed ventricles, Möller does **not** claim that the pulsation alarm of the LiquoGuard will determine all the aforementioned medical situations and thus sound an alarm in all these conditions. It is merely a safety feature not matched by the drip chamber. The operation of the pump is in all cases equivalent to the drip chamber, the described pulsation monitoring and alarm function is just an additional safety feature.

LiquoGuard CSF cannot accidentally aspirate brain tissue: The pump measures the pressure **inside the tubing** and drains if **that** pressure is too high. In most cases, the pressure inside the tubing will be equal to the ICP by the laws of hydrostatics. The crucial point to note is that, if catheter occlusion occurs or the ventricles are collapsed such that brain tissue covers the catheter holes, the two pressures may be different. The LiquoGuard CSF system measures **inside the tubing** and will operate the pump only if it determines the pressure **inside the tubing** as excessive. The drip chamber does exactly the same – it drains if there is excessive pressure inside the tubing. Therefore, the two drainage methods are substantially equivalent. To aspirate brain tissue (which would be dangerous for the patient), a negative pressure **inside the tubing** would have to be induced by pump activity. The LiquoGuard CSF system never does that, because it is using exactly that crucial pressure **inside the tubing** to control the pump.

Patients with collapsed ventricles can drain less than 100ml/24 hours, no matter if a traditional drainage system or the LiquoGuard CSF system is being used. Therefore, a

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patient who has either system is at equal risk for intraventricular catheter occlusion. Since the LiquoGuard pump starts to drain CSF only in a positive pressure range, the system only drains excess pressure. This is comparable to a passive pressure valve system, such as the highly abundant implanted shunting systems which open in a positive pressure range. The LiquoGuard CSF system does not “suck out CSF”; “sucking” implies the generation of negative pressure in the tubing, which the LiquoGuard CSF system by design never allows to occur. Therefore, the LiquoGuard CSF system is equivalent to a drip chamber draining excess pressure by the principle of hydrostatics. All safety aspects of the drainage operation are therefore comparable to the predicate device of a traditional drip chamber mounted over the zero level of the patient (positive pressure).

In **traditional lumbar CSF drainage**, the volume of drained CSF is dependent on more than the pressure head of CSF and the level of drip chamber. It is dependent on:

a. Level of the head of the patient (positioning).
b. Level of the dripping chamber.
c. Diameter of lumbar drainage tube (small tube = less drainage).
d. Consistence of CSF (viscosity).
e. Passage of CSF.
f. Adaptation of dripping chamber to movement of the patient (e.g. patient stands up during drainage).
g. Intermitted occlusion of lumbar drainage due to compression e.g. by processi spinosi during retroflexion of the patient.
h. Absence of nurse during CSF drainage (system open).
i. Unnoticed disconnection of the lumbar drainage leading to high CSF outflow (which drains mostly into the bed).

This means that in several situations, uncontrolled CSF outflow can occur with traditional lumbar CSF drainage with high risks for the patient.

Patients with continued lumbar CSF drainage to a pressure of 0 mmHg may be at risk for cerebral herniation. Exactly this condition can easily and accidentally occur when using a conventional dripping chamber. This applies in particular to conditions f, h, i of the list above. In all these conditions, the traditional lumbar drainage offers **zero** safety against these risks. In contrast, the LiquoGuard safeguards against all three critical conditions:

If the patient stands up, pressure increases, but the sampling flow of the LiquoGuard CSF system (e.g. 10 ml/h or whatever the chosen value is) will remain unchanged. Contrast this to the drip chamber, which allows in this situation an unlimited (!) outflow of CSF, e.g. more than 200 ml within a few minutes depending on parameters a-e in the list above.

The LiquoGuard CSF system is able to drain CSF continuously over an extended period of time. With the drip chamber, however, a nurse has to count the drops and adjust the level of the dripping chamber. If the nurse leaves the patient even for some minutes, the flow rate can change quickly, endangering the patient.

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In this case, the LiquoGuard CSF system will detect a pressure drop to zero immediately due to the disconnection. This will lead to an alarm of the LiquoGuard CSF system. In contrast, the traditional lumbar drainage using a drip chamber does not offer any alarm system.

12.3 Summarizing

Many if not all risks leading to accidental, cerebral herniation in both systems (traditional drainage and LiquoGuard CSF) can be reduced or even eliminated by the LiquoGuard CSF system. There is no new risk introduced by the LiquoGuard CSF system.

The LiquoGuard CSF system is working equivalently to a drip chamber, with the additional safety that, using the LiquoGuard CSF device, a partial or intermittent catheter occlusion may be detected in many cases: In difference to the dripping chamber which must be an open system during drainage the LiquoGuard CSF system can measure the hydrostatic pressure inside the tube (drainage system) during drainage because the drainage system is closed.

The LiquoGuard CSF system behaves comparable to a traditional drainage system even in the case of a clotted catheter or collapsed ventricles.

12.4 Common components of LiquoGuard and predicate device

The Möller Medical LiquoGuard CSF system, along with the Integra LifeSciences and Codman & Shrutleff systems utilize sterile tubing sets, pressure sensors, and CSF drainage bags. The Möller external tubing set is made from polyvinyl chloride, the same material that the Integra and Codman external tubing sets are made of, along with numerous marketed I.V. administration tubing sets. The Möller Medical tubing set has two pressure transducers. The Integra tubing set also incorporates a transducer. Additionally, the Möller Medical, Integra and Codman systems all include CSF drainage bags.

By using the LiquoGuard CSF system, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in both systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement. Additional details for comparing these CSF Systems are contained in Table 2.

Table 2: Device Comparison

	Möller Medical	Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to	Externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a

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	Möller Medical	Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)
	reduce intracranial pressure.	subarachnoid space to a drainage bag in selected patients.	controlled rate based on differential pressure between the device and patient.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber
Height alignment of patient and device	Device can be positioned arbitrarily, only the pressure sensors need to be aligned	Alignment is critical because it controls the target pressure	Alignment is critical because it controls the target pressure
Device Adjusting Fluid Flow	LiquoGuard CSF peristaltic pump controlled by pressure at sensor location	None - fluid flow is not controlled or limited	None - fluid flow is not controlled or limited
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF system	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high * Pressure too low * Physiological pressure pulsation lost * Pressure remains constant for too long * Dual sensors deviate in	No integrated alarm functions	No alarm functions

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	Möller Medical	Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)
	readings (defective sensor) * Watchdog or main controller does not respond to each other's requests (device or software malfunction) * Battery low		

13. Proposed Labeling

13.1 Operating Manual

Please refer to Appendix 7 for a copy of the Operating Manual for the LiquoGuard CSF Drainage System. This operating manual contains diagrams, dimensions, tolerances and identifies the available accessories.

13.2 Package Labeling

Please refer to Appendix 8 for a copy of the labels for the LiquoGuard CSF. Please refer to Appendix 9 for a copy of the labels for the sterile LiquoGuard CSF Tubing Set, 1500mm and Appendix 10 for the copy of the labels for the sterile LiquoGuard CSF Tubing Set, 2000mm.

Note: All labeling for product to be marketed in the U.S. will meet the U.S. labeling requirements of 21 CFR Part 801.

13.3 Catalog Numbers

The catalog number for the LiquoGuard CSF System is provided below in Table 3.

Table 3: Catalog Number for the LiquoGuard CSF System

Product Names	Catalog Number
LiquoGuard CSF	00002563
LiquoGuard CSF Tubing Set, 1500mm	00002650, REF. 92007836
LiquoGuard CSF Tubing Set, 2000mm	00002911, REF. 92008568
Safety Cushion for Tubing Set	00002701
Attachment Clamp	00002672

14. Sterilization and Shelf Life

The LiquoGuard CSF Tubing Sets are sterilized using the EtO sterilization method at the following facility:

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Sterigenics
Kasteler Straße 45
Geb. G525 65203
Wiesbaden – Germany

The EtO sterilization process has been successfully validated in accordance with ISO 11135-1. In addition, the EtO residual analyze was performed according to ISO 10993-7 and all requirements were met.

The initial sterilization validation was performed in 2006 according to ISO 11135:1994 and ISO 10993-7:1995. To meet all requirements of the revised standards a re-validation of the sterilization was performed in 2010. The validation of 2006 and 2010 together fulfill all requirements of the ISO 11135-1:2007 and the ISO 10993-7:2008.

Please refer to **Appendix 11** and **Appendix 12** for the sterility validation reports of 2006 and 2010 for the LiquoGuard CSF Tubing Set.

The LiquoGuard CSF Tubing Set is packaged in a blister of PETG (700µm, medical grade), sealed with a Tyvek foil which is in accordance with ISO 11607-1. Proposed shelf life is 2 years - please refer to **Appendix 13** for the accelerated aging test report.

15. Biocompatibility

Please refer to **Appendix 14** for the biocompatibility testing according to ISO 10993-1 of the LiquoGuard CSF Tubing Set.

16. Software Validation

The software documentation is in accordance with FDA's May 2005 guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

16.1 Level of concern

The level of concern is, "Major Level of Concern", as failures or latent design flaws that could directly result in major injury or death to the patient or operator.

16.2 Software Description

The software controls the LiquoGuard CSF pump, which means, the operation with the keys and the display as well as the rotation of the motor are controlled by software.

The LiquoGuard CSF is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error.

16.3 Device Hazard Analysis

A device hazard analysis has been conducted on the LiquoGuard CSF pump. To mitigate identified risks, two pressure sensors and two microcontrollers are incorporated as a double

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check to ensure proper functioning of the pump. Additionally, the pump will give off an audible alarm in the case that the pump is not operating properly.

Please refer to Appendix 15 for the detailed Device hazard analysis for the LiquoGuard CSF including the software.

16.4 Software Requirements Specification

All software has major level of concern. Therefore, all functions are described in the verification and validation testing for the Möller Medical LiquoGuard CSF system. Please refer to Appendix 16.

16.5 Software Architecture Design

The high level software architecture design document which includes a detailed depiction of the functional units and software modules is provided in Appendix 17.

16.6 Software Design Specification

The software design specifications are summarized in the software detailed design documents. The SDS documents are listed in Table 4 below.

Table 4: Software Design Specification Documents

Software Design Specifications (SDS)	Appendix Reference
Serial communication interrupt	Appendix 18
Timer interrupt	Appendix 19
Watchdog communication	Appendix 20
Display	Appendix 21
Operation	Appendix 22
Alarm	Appendix 23
Motor control	Appendix 24
Data logging	Appendix 25
Patient monitor	Appendix 26
Measurement	Appendix 27
SD-Card	Appendix 28

16.7 Traceability Analysis

Traceability between system requirements and subsystem requirements is provided in Appendix 29.

16.8 Software Development Environment

The summary of the software life cycle development plan, including a summary of the configuration management and maintenance activities is provided in Appendix 30.

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16.9 Verification and Validation

Verification and validation of the LiquoGuard CSF have been conducted. Please refer to **Appendix 31** for the list of bench tests that have been conducted.

17. Electromagnetic Compatibility and Electrical Safety

The Möller Medical LiquoGuard CSF pump has been tested in accordance and meets the following electromagnetic compatibility and safety standards:

Relevant Directives:

93/42/EEC: Directive of 14 June 1993 concerning medical devices.

73/23/EEC: Directive of 19 February 1973 concerning low voltage, with modification of 93/68/EEC.

Electromagnetic Immunity and Emission:

DIN EN 60601-1-2, Publication date: 2002-10: Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility - Requirements and tests.

DIN EN 55011, Publication date: 2003-08: Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement (IEC/CISPR11:1997, modified + A1:1999 + A2:2002); German version EN5501:1998 + A1:1998 + A2:2002.

Copies of the Electromagnetic Compatibility reports for LiquoGuard CSF are included in **Appendix 32**.

18. Performance Testing – Bench

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

19. Performance Testing – Animal

Because the LiquoGuard CSF has the same indication for use as the predicate devices (external cerebral spinal fluid (CSF) drainage), and because all functions can be verified and tested in bench tests, animal performance testing was not deemed necessary based on the products risk assessment.

20. Performance Testing – Clinical

The LiquoGuard CSF has the same indication for use as the predicate devices (external

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cerebral spinal fluid (CSF) drainage), and because all functions can be verified and tested in bench tests, formal clinical performance testing was not deemed necessary based on the products risk assessment.

To present the safety of the LiquoGuard CSF System a clinical trial was started in 2009, 75 cases have been collected and are included in the study report. The LiquoGuard CSF system is CE marked in Europe since 2006 where the study was performed. Please refer to **Appendix 60** for the study protocols, the results and the discussion.

21. Others

The LiquoGuard CSF System is CE marked in Europe since 2006. The LiquoGuard CSF System is an innovation in the draining of CSF and some of neurosurgeons who are working with the LiquoGuard published their experience with the device. Please refer **Appendix 61** for some published reports.

- B.M. Hoelper “Clinical study report of a new pressure and volume controlled CSF drainage system (LiquoGuard)”.
- N. Klemz, B. Luther, P. Köster, T. Nowak, E. Berendes “Continuous Controlled Lumbar Spinal Fluid Drainage for Prevention of Spinal Ischemia during Thoracoabdominal Surgery of the Aorta”.
- Manfred Kudernatsch, Suleyman Nauros, Peter A. Winkler (Poster) “Automatical Pressure- and Flow-Controlled Ventricular CSF Drainage LiquoGuard®: Two Years of Experience with over 50 Children in Pediatric Neurosurgery and Epilepsy Surgery”.

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APPENDIX 1

INDICATION FOR USE STATEMENT

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E-Mail: info@moeller-medical.com Web: www.moeller-medical.com

March 26, 2012

Indications for Use

510(k) Number (if known): TBD

Device Name: LiquoGuard CSF System

Indications for Use:
The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 2

TRUTHFUL AND ACCURACY STATEMENT

Back to **List of Appendices**

Back to **Chapter 6. Thruthful and Accuracy Statement**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda · Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

April 04, 2012

Premarket Notification
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as general manager of Möller Medical GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Dr. Christoph Traxler, General Manager
(Typed Name)

4 APRIL 2012
(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

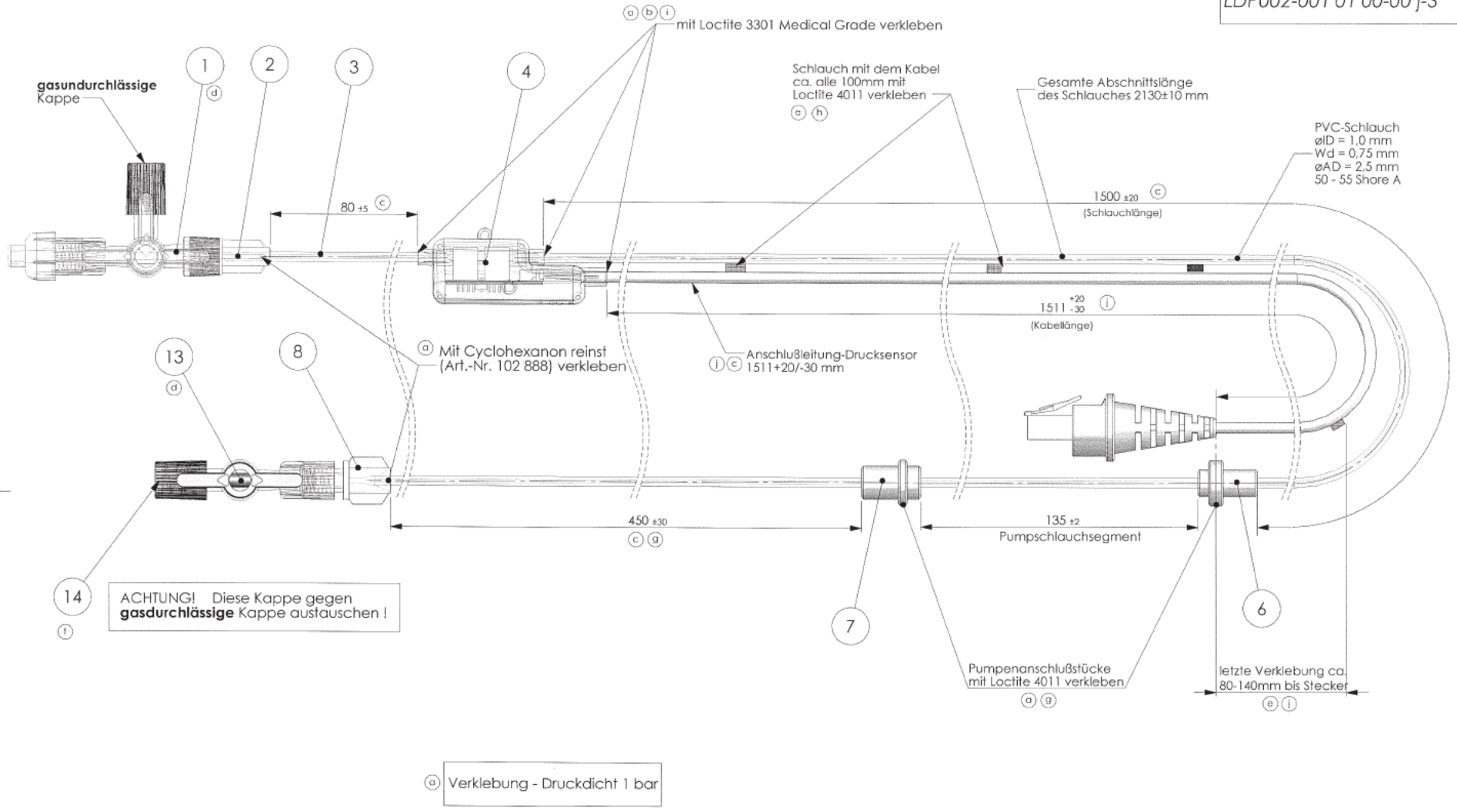
APPENDIX 3

PRODUCT MATERIALS
LIQUOGUARD CSF TUBING SET

(b)(4)
[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-001 01 00-00 j-3



MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 007 836	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1
							Gewicht: Volumen:
							Werkstoff: Werkstoff-Nr.:
							Halbzeug:
						Datum	Name
					Bearb.	16.12.05	LW
					Gepr.	31.03.08	
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j	geändert	KO 294	26.03.08	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.		
i	Kleber geändert	KO 268	19.06.07	LW			
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-001 01 00-00 0-3		Ers. für: LDP002-001 01 00-00 i-3

Schlauchset 1500 mm "LiquoGuard"

LDP002-001 01 00-00 j-3

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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E-Mail: info@moeller-medical.com Web: www.moeller-medical.com

MöllerMedical

Material of the LiquoGuard CSF Tubing Set (LDP002-001 01 00-00 j-3):

No.	Part	Material
1	4-way-cock (neutral)	Polycarbonate
2	Luer-Lock (male)	Glued with cyclohexanon
3	Tubing (2,5mm x 1,0mm)	PVC 50-55 Shore A
4	Housing of pressure sensors, including the pressure sensor and the connecting cable	Makrolon glued with Loctite 3301 Medical Grade, Freescale MPX2011DT1 for medical application, Polyurethane
6	Pump adapter (broad)	Makrolon glued with Loctite 4011
7	Pump adapter (small)	Makrolon glued with Loctite 4011
8	Luer-Lock (female)	Glued with cyclohexanon
13	1-way-cock (blue)	Polycarbonate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 4

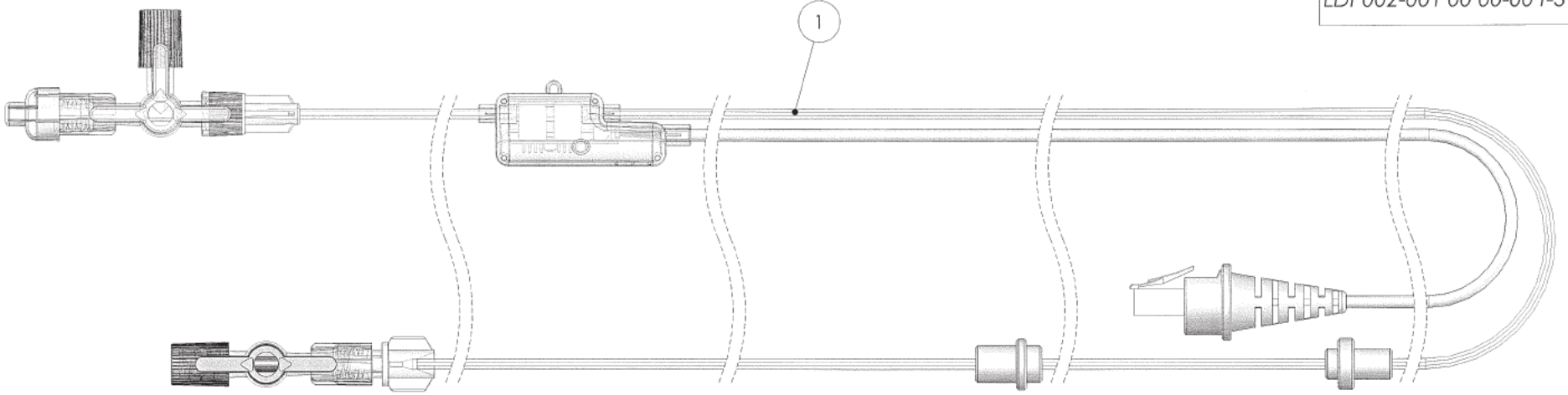
PACKAGING CONTENTS OF THE LIQUOGUARD CSF TUBING SET

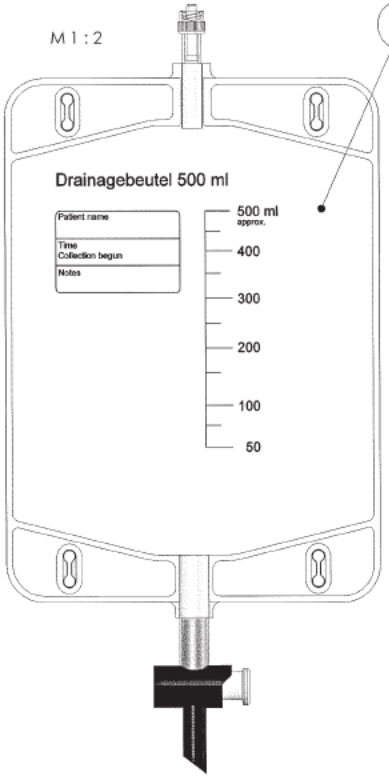
Back to **List of Appendices**
Back to **Chapter 11. Device Description**

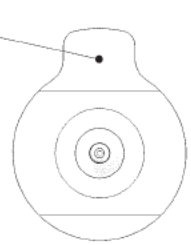
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

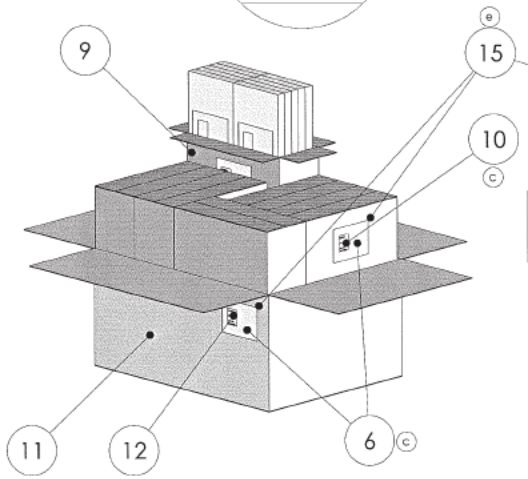
Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

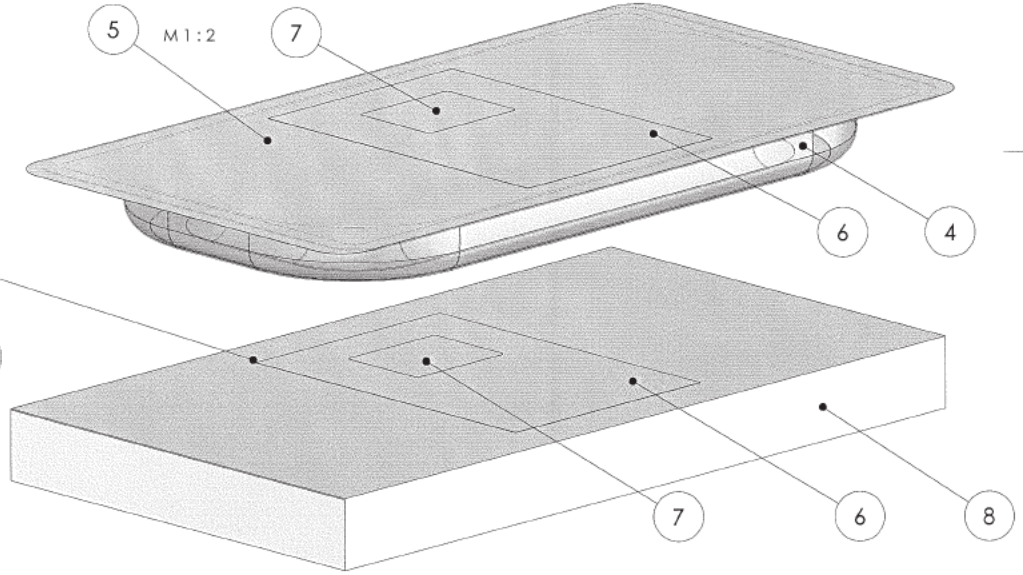
LDP002-001 00 00-00 f-3











d 13 Patientenaufkleber

d 14 Gebrauchsanweisung - Heft, mehrsprachig

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 00 002 650	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1 Werkstoff: Halbzeug:	Gewicht:	Volumen: Werkstoff-Nr.:
						Datum	Name	Schlauchset 1500 mm (VPE = 1 Stck.) "LiquoGuard" mit Zubehör / kpl. verp.	
					Bearb.	27.04.06	LW		
f	Pos. 6 geändert	KO3262	03.03.10	MÜ-De	Gepr.	03.03.10			
e	hinzu	KO 2694	19.07.07	LW	Norm				
d	hinzu	KO 2618	03.04.07		zul. Gewicht von: SYSTEM		04.03.2010 10:38:53		
c	Aufkleber geändert	KO 2563	06.02.07	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.			LDP002-001 00 00-00 f-3	Blatt 1 von 1
b	überarbeitet	-	04.07.06	LW					
a	überarbeitet	-	23.05.06	DE					
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-001 00 00-00 0-3			Ers. für: LDP002-001 00 00-00 e-3	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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Tel.: +49 (0) 661-94195-0 Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com Web: www.moeller-medical.com

MöllerMedical

Packaging of the LiquoGuard CSF Tubing Set (LDP002-001 00 00-00 f-3):

No.	
1	LiquoGuard CSF Tubing Set
2	CSF drainage bag
3	ECG-electrode (note: only used for attaching)
4	Blister (PETG), packaging
5	Tyvek, packaging
6	Labeling on packaging (LDP002-001 00 11-00 f-4)
7	Labeling on packaging with individual data (manufacturing date, LOT, shelf life)
8	Secondary packaging (cardboard)
9	Packing for 10 tube sets
10	Labeling on packaging for 10 tube sets
11	Packaging for 120 tube sets
12	Labeling on packaging for 120 tube sets
13	Labeling for patient data (LDP002-001 00 12-00 d-4)
14	Operating manual for tube set (30 004 036)
15	Indication button for EO Sterilization

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 5

COPIES OF THE 510(K) SUMMARIES FOR EQUIVALENT DEVICES

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Back to **Chapter 12. Substantial Equivalence Discussion**

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K030289

HERMETIC PLUS™
EXTERNAL CSF DRAINAGE SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K030289

Hermetic Plus™
External CSF Drainage System

510(k) SUMMARY

FEB 2 6 2003

Submitter's name and address:

Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Donna R. Wallace
Director, Regulatory Affairs
(609) 275-0500

Date summary was prepared:

January 24, 2003

Name of the device:

Proprietary Name:	Hermetic Plus™ External CSF Drainage System
Common Name:	External CSF Drainage System
Classification Name:	Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The Hermetic Plus™ External CSF Drainage System is substantially equivalent in function and intended use to the unmodified External CSF Drainage and Management Systems which has been cleared to market under Premarket Notification 510(k) K972994.

Intended use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure, to monitor cerebrospinal fluid, and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Device Description:

The Hermetic Plus™ External Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients. The systems connect to a ventricular or lumbar catheter via a luer connection to a patient line and ultimately to a drainage bag. The patient line is connected to a graduated burette that is then connected to the drainage bag. CSF can be collected and measured in the burette and subsequently emptied into the drainage bag by opening the stopcock placed in line between the burette and the drainage bag. An antimicrobial vent is included in the burette cap. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

antimicrobial vent used on the Hermetic Plus™ systems will allow better drainage of the CSF to the drainage bag and will resist occlusion after contact with CSF without the need for clamping the burette vent tube.

The Safety Locking Knob of the Hermetic Plus™ system will now contain a titanium screw component and the cord lock of the suspension cord has been changed to an all plastic component.

Safety

The Hermetic Plus™ External CSF Drainage Systems have been demonstrated to be MR safe* when used in the Magnetic Resonance (MR) environment.

*MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb. 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."

Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The systems have been tested for strength of bonded components, leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

Conclusion

The Hermetic Plus™ External CSF Drainage System is substantially equivalent to the unmodified External CSF Drainage Management Systems. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K032817

EXTERNAL DRAINAGE SET

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K032817

OCT - 6 2003

External Drainage Set

510(k) SUMMARY

Submitter's Name and Address:

Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France

Contact Person and Telephone Number:

Anne Bigeard
Regulatory Affairs Specialist
Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France
Telephone: 33 4 93 95 56 00

Authorized Agent in the United States:

Judith E. O'Grady
Integra LifeSciences Corporation
Sr. Vice President Regulatory, Quality and Clinical Affairs
311 Enterprise Drive
Plainsboro, NJ 08536, USA
Telephone: 609-936-2311

Date Summary was Prepared:

September 9, 2003

Name of Device:

Proprietary Name:	External Drainage Set
Common Name:	External CSF Drainage Systems
Classification Name:	Central Nervous System Shunts and Components JXG

Substantial Equivalence:

The External Drainage Set is substantially equivalent in function and intended use to the Unmodified External Drainage Set which has been cleared to market under Premarket Notification 510(k) K910853.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Intended Use:

The External Drainage Sets are intended for cerebrospinal fluid (CSF) drainage, sampling and collection.

Device Description:

The External Drainage Set is designed for cerebrospinal fluid (CSF) drainage, sampling and collection. The system connects to a ventricular or lumbar catheter via a Luer connection to a patient line.

The graduated cylinder of the External Drainage Set is attached to an IV pole and may be moved up and down to change positioning of the graduated cylinder by using the Velcro straps. CSF can be collected and measured in the graduated cylinder and subsequently emptied to the drainage bag by opening the stopcock placed in-line between the graduated cylinder and the drainage bag.

A hydrophobic vent filter is included in the graduated cylinder cap of the External Drainage Set. This vent filter allows air to enter the graduated cylinder to facilitate drainage from the graduated cylinder to the drainage bag while protecting the system from contamination.

Safety:

The External Drainage Set is provided sterile. The External Drainage Set has been tested for tensile strength of bonded components, pressure and leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids in compliance with the Needlestick Safety and Prevention Act, H.R.5178.

Conclusion:

The External Drainage Set is substantially equivalent to the unmodified External Drainage Set. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

K061568
CODMAN® EDS 3™
CSF EXTERNAL DRAINAGE SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

K061568

Codman
a Johnson & Johnson company

SEP 29 2006

510(k) Summary

Submitter: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person: Jocelyn Raposo
Regulatory Affairs Specialist II
Phone Number: (508) 828-3421
Fax Number: (508) 828-2777

Date Prepared: June 2, 2006

Proprietary Name: CODMAN® EDS 3™ CSF External Drainage System
Common Name: External CSF Drainage System
Classification Name: Central nervous system fluid shunt and components

Predicate Device: K902257 External Drainage System II
K910938 External Drainage System II
K954021 External Drainage System II

Device Description: The EDS 3 system is designed to collect cerebral spinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and the patient. Collecting CSF from the patient is performed in efforts to reduce elevated intracranial pressure (ICP).

Intended Use: Use of the EDS 3 system is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

Performance Data: The fundamental scientific technology of EDS 3 is the same as EDS II. Bench testing was performed for the EDS 3 system. The modified device was deemed acceptable according to the acceptance criteria; therefore, the safety and efficacy of the product was not affected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 6

CLINICAL EVALUATION ACCORDING TO MEDDEV 2.7.1

Back to **List of Appendices**
Back to **Chapter 12. Substantial Equivalence Discussion**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical evaluation for LiquoGuard

Literature route, acc. to MEDDEV 2.7.1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Author of the summarized clinical evaluation

Personal data

Dr. med. Bernd Manfred Hölper, born 8. February 1969 in Gießen, married to Dr. med. Dörthe Inge Hölper (neè. Beinroth), 2 children (Elisabeth Clara and Alexander Bernd)

Education and basic military servicet

1975 - 1979	Krofdorf-Gleiberg Primary School
1979 – 1980	Gießen Grammar School (Landgraf-Ludwig-Schule Gießen)
1980 – 5/1989	Ignaz-Günther-Gymnasium Rosenheim, Completion 5/1989 (University Entrance, average grade A)
6/1989 – 9/1990	Training as keyboard radio operator and telecommunications technician, Air Force in Pinneberg/Lengries

Tertiary Education

10/1990 – 3/1996	Medical degree at the Georg-August University in Göttingen
8/1992	Intermediate examination
3/1996	2nd part of the examination
4/1996 – 4/1997	Practical Year: Surgery and Internal Medicine at the Reinhard-Nieter Hospital in Wilhelmshaven and Neurology at the Nordwest Hospital in Sanderbusch
21. April 1997	Completion of medical studies with a "B" average.

Dissertation

2. 7. 1997	Granting of the Degree of a Medical Doctor at the medical faculty of the Georg-August University in Göttingen with the dissertation "Computer simulation and analysis of two artificial neuronal networks oriented to neurobiological models" (Supervision: Prof. Dr. H.-O. Reiber), Grade "A".

Function as physician in practical studies

5/1997 – 9/1998	Active as intern in the neurosurgical clinic of the Fulda Clinic for a duration of 18 months

Research in Richmond/Virginia USA

10/1998 –3/1999	Research at the Commonwealth University of Richmond, Virginia (USA), Neurological Surgery in Prof. R. Bullock and Prof. A. Marmarou's work group, research on intracranial pressure and cerebral metabolism

Function as assistant physician

4/1999 – 3/2005	Active as assistant physician in the neurosurgical clinic of the Fulda Clinic
2002	Awarded the scientific prize of neurological sciences
2001 - 2003	Course participant (European Association of Neurosurgeons)

Examination for specialist

9. 3. 2005	Recognition as neurosurgical specialist at the provincial medical chamber, Hesse

Function as Specialist

Since 3/2005	Active as neurosurgical specialist at the neurosurgical clinic of the Fulda Clinic.

Research focus

Intracranial pressure measurement and intracerebral metabolism in neurosurgical intensive care, evaluation of intracranial sensors (see author's publication index), evaluation of algorithms and assessment of medical data aided by artificial intelligence (neuronal nets), development of image fusion algorithms.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Scientific activity and author's publication index

Book (first author)

Hölper, B.M., Soldner F., Behr R.: Kompendium Neurochirurgie. proINN-Verlag, Rosenheim, 2006

Publications (peer review)

1. Hoelper BM, Reinert MM, Zauner A, Doppenberg E, Bullock R: rCBF in Hemorrhagic, Non-Hemorrhagic and Mixed Contusions after severe head injury and its Effect on Perilesional Cerebral Blood Flow. Acta Neurochir (2000) [Suppl] 76: 21-25
2. Hoelper BM, Soldner F, Choné L, Wallenfang T: Effect of Intracerebral Lesions Detected in Early MRI on Outcome After Acute Head Injury. Acta Neurochir (2000) [Suppl] 76: 265-268
3. Reinert M, Hoelper B, Doppenberg E, Zauner A, Bullock R: Substrate Delivery and Ionic Balance Disturbance After Severe Human Head Injury. Acta Neurochir (2000) [Suppl] 76: 439-444
4. Soldner F, Hoelper BM, Chone L, Wallenfang T.: Evoked potentials in acute head injured patients with MRI-detected intracerebral lesions. Acta Neurochir (Wien) 2001;143(9):873-83
5. Soldner F, Hoelper BM, Wallenfang T, Behr R.: The translaminar approach to canalicular and cranio-dorsolateral lumbar disc herniations.
   Acta Neurochir (Wien). 2002;144(4):315-20
6. Hoelper BM, Hofmann E, Sporleder R, Soldner F, Behr R: Transluminal Balloon Angioplasty Improves Brain Tissue Oxygenation and Metabolism in Severe Vasospasm after Aneurysmal Subarachnoid Hemorrhage: Case Report. Neurosurgery 2003; 52(4)
7. Hoelper BM, Soldner F, Lachner R, Behr R: Enhanced accuracy of MRI image fusion
   by defining a Volume of Interest. Neuroradiology 2003, 45(11), 804-809
8. Hoelper BM, Alessandri B, Heimann A, Behr R, Kempski O: Brain oxygen monitoring: In-vitro accuracy, long-term drift and response-time of Licox- and Neurotrend Sensors. Acta Neurochirurgica 2005, in press
9. Alessandri B, Hoelper BM, Heimann A, Behr R, Kempski O: Accuracy and stability of temperature probes for intracranial application. J Neurosci Meth 139 (2004), 161-165
10. Hoelper BM, Soldner F, Behr R: Fluoroskopie-kontrollierte Genauigkeit von rahmenloser Neuronavigation beim transsphenoidalen Zugang zu Prozessen der Sellaregion. In: Böker, Deinsberger (Hrsg): Schädelbasischirurgie. Acta Neurochirurgica Suppl (2004), ISBN 3-211-22324-X
11. Hoelper BM, Alessandri B, Heimann A, Behr R, Kempski O.: Brain oxygen monitoring: in-vitro accuracy, long-term drift and response-time of Licox- and Neurotrend sensors.Acta Neurochir (Wien). 2005 Jul;147(7):767-74.

Publications (abstacts)

1. Hölper B, Kurth C, Wieding JU, Schönle PW: Shift Invariance of a Heteroassoziative Self-Organizing Neural Network and its Stability after Deletion of Synapses; in: Göttingen Neurobiology Report 1994: proceedings of the 22nd Göttingen Neurobiology Conference 1994, Volume 2; hrsg. v. Elsner N, Breer H; Thieme-Verlag, Stuttgart 1994
2. Hölper B, Kurth C, Wieding JU, Schönle PW: Properties of a New Heteroassociative Self-Organizing Neural Network; in: Proceedings of the IASTED International Conference, Artificial Intelligence, Expert Systems and Neural Networks; hrsg. v. M.H. Hamaza; IASTED - ACTA PRESS, Anaheim 1994, 8 - 11
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Product name

LiquoGuard is a CSF drainage system, which is connected to an already existing intrathecal CSF drainage with the possibility to measure CSF pressure while simultaneously draining the CSF. The volume of drained CSF hereby depends on the CSF pressure measured by the system and on the maximum drainage volume defined by the operator.

Product manufacturer

The manufacturer of the product LiquoGuard and its set of consumables is Möller Medical GmbH & Co KG, Wasserkuppenstr. 29-31, 36043 Fulda, Germany.

Purpose

The LiquoGuard system consists of disposable consumables (CSF drainage system) and a control/pump unit. The purpose of the system is to measure CSF pressure in the CSF drainage system and to remove CSF at a determinable quantity via a surgically installed intrathecal CSF drainage, which was selected and installed by medical staff independent of the LiquoGuard system and whose indication does not depend on the use of the LiquoGuard system.

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Indications

Pathophysiological principles for the indication of intrathecal space puncture
The nervous system (brain, meninges) is surrounded by cerebro-spinal fluid (CSF) (6, 20). The production and resorption of CSF is in a stable balance (6, 10). Diseases or injuries to the nervous system or its surroundings e.g. hemorrhages, infections, tumors, cranio-cerebral injury or deformities can disrupt the balance between CSF production and resorption; a collection of CSF in the brain or in the meningeal area can then lead to increased pressure on the nervous system, which could lead to irreversible damage, severe permanent damage or even to death (1, 9, 10, 12-14, 18-20, 22, 24). In order to avoid this potentially life-threatening situation, CSF is drained to the outside (intrathecal CSF drainage) (7, 10, 13, 23). Analogue to this, lumbar CSF drains are used, which are not installed for the correction of a life-threatening situation, but serve the correction of a CSF fistula or the diagnosis of a chronic pathological collection of CSF (normal pressure hydrocephalus).(2, 3, 7, 15, 23)

"**Gold Standard" for the treatment of dysfunctional CSF circulation**
The essential basis for intrathecal CSF drainage is the installation of a drainage system in the CSF space. This is performed via ventricle drainage (usually consisting of silicon or polyurethane) or a stainless steel cannula (e.g. Duisburg needle) (7). Lumbar drainage is achieved by inserting a thin silicon catheter into the intrathecal space (2). Both procedures represent today's "Gold Standard" for intrathecal CSF drainage in dependence of the disease and therapy objective (10, 13). A CSF drainage system is connected to this CSF conductor, independent of the use of the LiquoGuard system. This CSF drainage system is either a system already established on the market or it may be the LiquoGuard system. All operative steps to install the intrathecal CSF drain must be carried out according to the respective indication, independent of the CSF drainage system used later.

Indication for temporary intrathecal liquor drainage
Fundamentally, the LiquoGuard system does not change the indication for intrathecal liquor drainage in any patient, nor does it influence the therapeutical concept, type of treatment, therapy objectives or therapy duration. The LiquoGuard system constitutes a liquor drainage system, whose most important characteristics comply to other liquor drainage systems on the market. Therefore the listed indications for liquor drainage must be understood in the broadest sense, without presupposing the use of the LiquoGuard system or a comparable liquor drainage system, as these systems are interchangeable with each other at all times without the need for a change in therapy or further surgery.

- **Communicating hydrocephalus:** This summarizes all clinical pictures in which liquor production is temporarily in disproportion to liquor resorption, usually during cerebral hemorrhage (subarachnoid hemorrhage, intraventricular hemorrhage), encephalitis and cranial-cerebral injuries. In most cases the cause is resorption dysfunction by obstruction of the Paccioni granulation. There is no alternative treatment to intrathecal liquor drainage for these clinical pictures.
- **Non-communicating hydrocephalus:** Liquor drainage is impaired by a partial or complete occlusion of the liquor draining paths. This may occur through masses (tumors, cysts, hemorrhage, congenital malformation) near

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the foramen Monroi, the 3rd ventricle, the aquaduct, the 4th ventricle or the foramen Monroi and the foramina Luschkae.

- **Therapy-resistant cerebral swelling:** The application of liquor drainage may be indicated in therapy-resistant cerebral swelling caused, for example, by cranial-cerebral injury, cerebral hemorrhage or subarachnoid hemorrhage or by cerebral swelling due to tumors, inflammation or hypoxia, in order to reduce intracranial pressure and to bypass trepanation (the removal of a cranial bone).

Treatment alternatives to CSF drainage

- **Endoscopy:** In a few cases of non-communicating hydrocephalus, endoscopic windowing (e.g. of the lamina terminalis) may be created to communicated with the external CSF paths. However, this is not indicated in all cases of non-communicating hydrocephalus, can only be performed by a few, specially trained neurosurgeons who possess the appropriate equipment (endoscope) and who are available at the required time. However, external CSF drainage cannot be replaced by endoscopic windowing for all clinical pictures of non-communicating hydrocephalus.
- **Therapy-resistant cerebral swelling:** After exhausting all medicinal forms of therapy, the removal of a part of the cranial bone can lead to effective relief of the intracranial pressure. The indication as to when external CSF drainage or cranial bone removal is performed depends on the primary disease, etiopathology, brain swelling dynamics, patho-physiological mechanisms, the patient's age, his overall condition, the prognosis and ventricle width and must be individually decided by the neurosurgeon. As the surgical risk of CSF drainage is considerably lower than that of cranial bone removal, CSF drainage at the appropriate medical indication and tenability is preferred to removal of cranial bone.
- **Shunt implantation**: As a shunt represents an implantable, permanent CSF drainage system and external CSF drainage represents temporary CSF relief, shunt implantation is no alternative treatment option to CSF drainage.

Contraindications

The contraindications do not apply to the use of a liquor draining system such as the LiquoGuard system, but to the application of intrathecal liquor drainage itself. As, however, liquor discharge is only applied in connection with liquor drainage, contraindications described below are in connection with the application of external liquor drainage only.

- **Absolute operative contraindications:** Coagulopathy, thrombocythemia.
- **Relative operative contraindications:** In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does the simultaneous intake of intrathecal antibiotics in the case of ventriculitis.
- **Indication for permanent liquor drainage:** If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculo-peritoneal shunt or a ventriculo-atrial shunt.

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PRODUCT DESCRIPTION

LiquoGuard system components
The LiquoGuard system consists of two components:

1. **Disposable tubing set:** CSF drainage system with male Luer lock connection (3-way cock) to connect to an already surgically installed intrathecal CSF drainage. Distal to the proximal Luer lock connection (3-way cock) is an attached pressure measurement device, in which two piezo-resistant pressure sensors, attached independent of one another, measure CSF pressure within the tube lumen. Both sensors are embedded in a die-cast component; a connection from the tube lumen to the outside does not exist. An attachment clamp is installed in the die-cast component enabling the attachment to a standard electrode with a press-stud. A cable anchored and connected to the pressure sensor electronics can be connected to a confusion proof socket in the LiquoGuard device. A compressible tubing system is distally integrated to the pressure sensors, which can be inserted into a rotor pump. A CSF collecting bag with a reflux valve is attached to the distal end of the tubing system via a 3-way cock.
2. **LiquoGuard device:** LiquoGuard consists of a casing with a transport attachment (bed, crossbeam, round rod) containing the dually installed evaluation electronics of pressure sensors, drive electronics for the rotor pump incl. the rotor pump, drive electronics for the monitor incl. the monitor, process electronics for input via keyboard and operating wheel, the internal power source (battery) incl. mains connection, the display for illustration of various values and data, alarm light emitting diodes, the loudspeaker for audible alarm emittance, the card slot for the insertion and removal of the memory card, the internal memory electronics and the connecting socket for external power supply as well as pressure sensors.

LiquoGuard system functionality
The CSF drainage system is inserted into the rotor pump by lifting the safety flap, whereby the arresting pins in the pump have been designed to be confusion-proof. After connecting the pressure sensor cable to the LiquoGuard device and after switching on the LiquoGuard device, zero calibration must be carried out on both pressure sensors. The CSF drainage system can then be connected to the previously and surgically installed intrathecal CSF drainage. Intrathecal CSF drainage is not a component of the LiquoGuard system; all approved intrathecal CSF drainage systems available on the market may be used. An indication for the installation of intrathecal CSF drainage does not depend on the use of the LiquoGuard system (consumable goods or LiquoGuard device). The housing with the integrated pressure sensors must be attached at the assumed CSF zero height. In the case of intracranial application an adhesive electrode is attached to the head near the audible tract, the external anatomic landmark of the foramen Monroi, in the case of intrathecal spinal application at the height of the proximal end of the catheter. In accordance with current literature, alignment of the zero point in intracranial application should be at the height of the foramen Monroi; the zero point in intraspinal application is at the height of the intrathecal catheter end (10). The casing with its integrated pressure sensors can be clipped to this adhesive electrode. Setting

Setting of therapy-specific parameters
A therapy during reclining CSF drainage is performed irrespective of the CSF drainage system only once CSF has been drained. In this respect CSF drainage

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under all clinical conditions is only required as of a positive intrathecal pressure. The height of the positive intrathecal pressure, as of which CSF is drained, depends on the disease and etiopathology and is determined individually by medical staff, entered as CSF target pressure into the LiquoGuard device via the suitable input interfaces and shown in the display. The pressure sensors continuously record CSF pressure. If the CSF target pressure is exceeded, the rotor pump is started. CSF is removed by the rotation of the pump, conveyed through the CSF drainage system and pumped into the CSF collecting bag. The pump stops once the pressure in the drainage system returns to the specified target pressure. This control keeps the patient's CSF pressure within a pre-defined range (predefined target pressure ± Hysteresis, resulting from the regulation, whereby the height of hysteresis is adjustable, e.g. 0.5 mmHg). As the closed measurement system enables continuous CSF pressure measurement, CSF drainage over and above the target pressure is not possible. The volume and speed of CSF drainage can be controlled by rotational speed and run-time of the pump. The CSF target volume parameter specified by medical staff is used in this respect. This parameter limits the maximum delivery rate and simultaneously defines the speed of CSF drainage. If the intrathecal pressure lies above or below the upper or lower CSF pressure alarm limit, an optical and audible alarm is triggered.

Diagnosis-specific parameters

The LiquoGuard system displays the diagnosis-specific parameter "intrathecal pressure" (ICP) and the drained volume of CSF.

- **Intrathecal CSF pressure:** After zero point calibration performed at startup of the disposable consumable articles, the two pressure recorders of the tubing set integrated into one casing are attached at foramen Monroi level. The CSF pressure column between the intrathecal catheter and the pressure sensors is the existing intracranial pressure. This pressure is not only the control pressure for the LiquoGuard's rotor pump but also represents the Gold Standard for determining intracranial pressure (10, 13). Further diagnostic and therapeutical measures depend on this measurement value. As each set of consumables can be used only once due to an internal electronic registration, repeat pressure measurement or one during application (with existing pressure) is not possible.
- **Drained CSF volume:** The diameter of the tube inserted in the rotor pump and the rotation of the rotor pump defines the volume of drained CSF. This volume is electronically displayed (ml/min, ml/h, ml/24h). The collecting bag also has a measurement scale which enables reading and controlling of the drained liquid volume. The drained CSF volume can indicate an imbalance between CSF production and CSF resorption. The therapeutical consequences may be a permanent CSF drainage (shunt) for the patient.

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Literature research on comparable products with the same purpose (including reasons of comparability)

Literature selection

External CSF drainage has been an established and standardized procedure in neurosurgery for many years, and beyond question in the entire current neurosurgical literature. As the LiquoGuard system does not represent a change in intrathecal drainage, its indication and therefore a possible increase in complications, generally acknowledged textbooks are used in literature evaluation with regard to CSF drainage effectiveness. Data sources for the creation of a literature overview were Medline, Pubmed, including the database of the National Center for Biotechnology Information (NCBI, www.ncbi.nlm.nih.gov) as well as library indexes on neurosurgical textbooks. Additionally, current convention reports of the Deutsche Gesellschaft für Neurochirurgie (DGNC) during the last five years were taken into consideration. Internet research via current search machines (yahoo, google) on intracranial pressure and CSF drainage was also carried out. Overview work from the most important and most renowned neurosurgical textbooks were used for citations on the topic of CSF drainage. Book articles were cited for respective questions regarding the accuracy of pressure sensors, which summarize numerous clinically recognized articles and were written by globally recognized specialists in their respective fields. As CSF drainage is an established, standardized method, book articles were mostly reverted to in connection with indication. Due to the utilization of large overview work published by different authors and various publishers worldwide, there is no indication that important, even negative literature was not used and would therefore distort literature research. No literature sources were explicitly excluded. Citations with an unfavorable or negative evaluation, which limit the use of the LiquoGuard system, are unknown. All used publications stem from recognized, scientific publications and were written by acknowledged experts. The objective of a literature evaluation is the illustration on the necessity of CSF drainage and the illustration of existing CSF drainage systems and pressure measurement systems, their technical details and compliance to the LiquoGuard system.

External CSF drainage

External CSF drainage is comprised of two systems: a catheter/cannula (intrathecal CSF drainage) inserted into CSF space and a CSF drainage system attached to this intrathecal CSF drainage (10, 17).

Intrathecal CSF drainage

The removal of CSF requires the surgical installation of an approved catheter or cannula into intrathecal space. This operative procedure is required for respective indications (subarachnoid bleeding, cerebral hemorrhage, brain tumors, inflammation of CSF paths, displacement of CSF-efferent paths due to tumors and swelling, cranio-cerebral injuries) and undisputed in the entire neurosurgical literature as well as life-saving in many cases.(1, 9, 10, 12-14, 18-20, 22, 24) Although the insertion of intrathecal CSF drainage is a prerequisite for using the LiquoGuard system, it does not change the indication of intrathecal CSF drainage due to its comparability with previous systems. All intrathecal CSF drainage catheters with female Luer lock connections approved for intrathecal CSF drainage, which can be connected to available CSF drainage systems, can also be connected to the LiquoGuard system. The use of intrathecal CSF drainage is in complete compliance and comparability with regard to the application of the system.

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CSF drainage system
All CSF drainage systems are connected to the intrathecal CSF drainage and serve the measurement of the intrathecal pressure as well as the removal of CSF.(10, 17)(10, 17) A CSF drainage system consists of various components which in their totality result in a functional system. These system components of systems established on the market are described below and compared to the LiquoGuard drainage system. The procedure is carried out under the same clinical condition, for the same clinical purpose of CSF drainage at the same part of the body on comparable patients (including age, anatomy, and physiology). CSF is identical; the same materials are brought into contact with the same human body fluids (CSF). Technically speaking, the identical version (Luer lock connection) with the same design exists if we compare the LiquoGuard system with existing CSF drainage systems.

CSF drainage tube system to pressure measurement system: All CSF drainage systems are connected to an intrathecal CSF drainage (10, 17). Current CSF drainage systems as well as the LiquoGuard drainage system consist of a transparent plastic tube system with an attached 3-way cock or an alternative CSF drainage facility. This applies to CSF drainage systems as well as to the LiquoGuard system; both systems are completely comparable with one another regarding this construction stage of the entire CSF drainage system. The tubing system is technically comparable, CSF drainage facilities (3-way cock) are identical, biological properties are appropriate (CSF) and clinical conditions (indication to remove CSF via connection (3-way cock) are the same.

Pressure measurement system
Pressure measurement in existing systems is conducted via a pressure sensor integrated into the CSF drainage system or connected to the lumen of the drainage system via a 3-way cock (10, 17). Correct intracranial pressure measurement requires that the tubing system is distally closed, as an open system cannot create pressure and the CSF will flow in direction of the open system (10, 17). The alignment of the pressure measurement system must be at zero point level (in the case of intrathecal intracranial application this would be the foramen Monroi (8)) in all systems (in previous CSF drainage systems as well as in the LiquoGuard drainage system). Display of pressure in previous systems was enabled by connection to the sensor system at a patient monitor, whereby the LiquoGuard system displays the pressure directly via the display integrated in the LiquoGuard device. Existing pressure measurement systems and the display of the measured pressure are based on the same sensor technology as the piezo-resistant LiquoGuard pressure measurement system (8, 21) and are therefore technically comparable as they measure the pressure of the same biological body fluid in the same clinically comparable patients.

CSF drainage tube system from pressure measurement system to CSF collecting bag
In established systems, CSF is transported to a droplet chamber or a collecting bag on the distal side of the pressure measuring system. To measure the intracranial pressure, the two existing CSF drainage systems must be distally closed to enable reliable pressure measurement. Once the pressure defined by medical staff has been

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reached, the CSF drainage system will be distally opened. Now CSF can drain via the drainage system into the collecting bag, whereby the drop-by-drop addition of CSF from the tubing system into the collecting bag must be set to the zero reference line (intracranial at foramen Monroi). The system must be opened distal to the external air so that the air displaced by inflowing CSF can escape within the collecting bag. Once CSF flow is suspended (target pressure is reached) the system is closed and pressure measurement is continued. Opening and closing intervals depend on the speed of the renewed intracranial pressure increase. In the LiquoGuard system CSF drainage occurs in analogue manner. The closing mechanism for the completion of correct intrathecal pressure measurement is carried out by the rotor pump instead of the 3-way cock or a crimp connection in the LiquoGuard system. If the measured intrathecal pressure rises to a pressure defined by medical staff (target pressure reached) the rotor pump is activated via its electronics and pump rotation leads to CSF removal with transportation of CSF to the collecting bag. If the pressure decreases to target pressure (analog to CSF flow suspension in existing systems), the rotor pump will stop and CSF drainage is suspended. Clinically, the same purpose is pursued under the same conditions, the same patient population and the same indication, i.e. the measurement of intrathecal pressure and the removal of CSF as of a definable pressure level. Both procedures therefore result in the identical clinical effect, the intrathecal pressure decrease as a result of CSF drainage. A biological comparability exists between the systems, as the same human liquid (CSF) is drained using the same materials. Technical comparability exists in the fact that both systems are primarily closed and remove CSF up to reaching a target pressure once a certain intrathecal pressure, measured with the same measurement technology has been reached. Whether CSF is drained by a positive intrathecal pressure via an overflow system (previous established systems) or via a rotor pump, is negligible, as further CSF drainage is prevented once the CSF target pressure has been reached. With regard to the function of the system there are no differences.

CSF volume control

Control of CSF to be drained is on a visual basis in existing system, by persons operating the system reading the CSF level within the collecting bag prior to CSF drainage, then opening the CSF drainage system and waiting until the appropriate CSF volume has drained into the collecting bag. The LiquoGuard system does provide visual control as an analog possibility, as an appropriately comparable scale has been attached to the collecting bag, but the calculation of CSF volume from the rotation of the pump and the diameter of the drainage tube inserted in the pump is more exact and simpler.

Illustration and measurement of CSF pressure and CSF volume

In existing systems, the pressure recorder is attached to the installed patient monitoring system in an appropriate stationary unit like arterial pressure measurement. The illustration of intrathecal pressure is then possible via this patient monitor. In the LiquoGuard system the intrathecal pressure is displayed in the LiquoGuard device itself. Furthermore, and unlike previous systems, the LiquoGuard system permits trend display of previously measured values and data storage (without patient information) onto a suitable memory medium, as well as data transfer to a patient monitoring system. Compliance is therefore given, but the LiquoGuard system provides additional functions.

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Alarm limits for ICP

In existing systems as in the LiquoGuard system, the upper and lower alarm limit of intrathecal pressure can be defined. Both systems activate a comparable visual and audible alarm once alarm limits are reached. In existing systems this is carried out via the patient monitor, whereas the LiquoGuard system has integrated alarm functions, whereby the alarm functions can also be activated via the connected patient monitor.

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Assessment criteria to prove the efficiency and safety of the product

The fact that intrathecal CSF drainage is applied in the same way by both the existing systems as well as the LiquoGuard system makes an assessment of intrathecal CSF drainage unnecessary. The efficiency of intrathecal CSF drainage is globally undisputed. It represents a routine procedure as therapy for intracranial pressure increase (1, 9, 10, 12-14, 18-20, 22, 24).

Expected effect of a CSF drainage system

The expected effect of a CSF drainage system consists of enabling sterile CSF extraction in identifiable quantities via an intrathecally inserted cerebro-spinal fluid drainage in case of intrathecal pressure increase beyond a certain threshold (target pressure) and when a pressure sensor is connected to be able to measure intrathecal pressure reliably by appropriate means ("Gold standard" for intracranial pressure measurement) (5, 8, 13, 21).

Both established systems and the LiquoGuard System make intrathecal CSF pressure measurement possible via integrated pressure measurement in the CSF drainage system. (7, 11, 21, 23) In order to enable pressure measurement, a pressure sensor must be integrated in the tube system or in the ventricle drainage region and zero-point calibration executed for both systems.

For intracranial pressure measurement in conventional systems, the tube system is closed distal to the pressure sensor. Only then does a closed pressure distal position exist, which can be used for intracranial pressure measurement. However, it is not possible to drain any CSF from these systems during this period. In the case of an intrathecal pressure increase in excess of a defined value, CSF extraction takes place by opening the system - for conventional systems by means of the differential pressure between the intrathecal catheter and the height of the distal CSF drainage system tube which leads to the CSF collecting basin. However, if the CSF drainage is open, reliable and correct pressure measurement for existing systems is not possible. Quantification of the CSF volume withdrawn is made visually for these systems, using a measurement scale which is attached to the CSF collection bag.

The LiquoGuard System records intrathecal pressure via the external attachment of pressure sensors at the level of the respective reference point. It is neither necessary to open nor to close the CSF drainage system because, if the target pressure is exceeded, CSF is withdrawn using the rotor pump and when target pressure is achieved CSF withdrawal stopped. As opposed to the existing systems, continuous intrathecal pressure measurement is possible, providing additional safety for the patient during CSF drainage as opposed to risks. The quantification of CSF withdrawn is also visual, using a measurement scale which is attached to the CSF collection bag. However, in addition, the amount of CSF withdrawn can be calculated using the number of rotations of the rotor pump and the tube diameter, providing two alternative methods for CSF quantification.

All in all, the use of the same correcting variables (target pressure, CSF quantity) and the same measurement systems (intrathecal pressure measurement via an externally attached piezo-resistant pressure sensor) for both systems (existing CSF drainage systems and LiquoGuard System) provide comparable effectiveness with regard to intrathecal pressure reduction and the quantity of CSF withdrawn.

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Assessment of the safety of CSF withdrawal

With regard to the period of CSF withdrawal, the quantity of CSF withdrawn differs between the existing systems and the LiquoGuard System.

The CSF quantity for existing systems during the course of time is dependent on the diameter and length of the CSF drainage system, the length and diameter of the intrathecal CSF drainage, the viscosity of the CSF, the height of the distal drainage system (target pressure), the ratio between the patient's CSF production and CSF absorption and the current prevailing intrathecal pressure. It is not possible to determine the CSF drainage amount exactly over the course of time using these systems as the additional times for the named factors cannot be determined (e.g. the CSF absorption rate). Therefore discontinuous CSF withdrawals are necessary, leading repeatedly to slow pressure increase (system closed) and quick pressure loss (distally open system). This can result in quick pressure loss in conventional systems, which can lead to an undesired quick pressure drop with the risk of an aneurysm rupture, especially in case of vascular malformation (aneurysm). Moreover for existing systems opening the system distally is dependent on the presence of a person who operates the drainage system closure mechanism. Hence intrathecal pressure can increase until the respective staff opens the system. As the controls of the rotor pump in the LiquoGuard system always depend on the currently measured intrathecal pressure and the respective target pressure, undesired fast changes in pressure and pressure reductions are impossible due to permanently controlled CSF drainage. There is no clinical indication for discontinuous CSF withdrawals, making continuous CSF drainage whilst maintaining the target pressure the therapeutic objective in all cases.

Moreover, it is also possible to quantify the exact CSF amount to be withdrawn over the course of time because, despite the unknown factors, the amount of CSF to be withdrawn depends on the diameter of the tube system and the rotational speed of the rotor pump and whether both influencing factors are known. The existing CSF drainage systems do not enable a time-based depiction of the CSF drainage amount. It is possible to read out the CSF amount in the drip chamber, however time-based references cannot be established in as far as the drip chamber is not emptied at very short time intervals, also restricting accuracy (low readout accuracy for low CSF amounts) (7). The CSF drainage system LiquoGuard enables highly precise measurement of the CSF feed rate with high time-based resolution, a balance for every hour or every 24 hours and depiction of the continuous feed rate. These parameters can be applied for controlling the pump (setting the maximum total feed rate per hour), not otherwise possible if using conventional systems without incurring personnel costs. This additional parameterization of the discharge flow with a time-based course may be of special significance for certain clinical pictures and concerns, in particular, withdrawal from ventricle drainage. In order to reduce the CSF feed rate, the height distance between foramen Monroi and the drip chamber of an open system is increased here. However this also means that pathological and thus high-risk high intracranial pressure might have to be tolerated. LiquoGuard can avoid this risk by reducing the CSF feed rate and increasing the upper alarm limit slightly, still maintaining CSF drainage, even if within a restricted scope.

Existing systems have a CSF collecting basin which must have an external opening via an air filter. Blocking up, unintentional or deliberate (e.g. whilst transporting patients) closure of the air filter hinders CSF drainage because the air must escape through the incoming CSF. By contrast, an external opening via an air filter is not required for the LiquoGuard System because the rotor pump transports the extracted

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CSF to the collection bag. In this way the risk of an unwanted insufficient CSF drainage can be considerably reduced using the LiquoGuard System. As the insertion of the LiquoGuard tube set in the rotor pump works confusion-proof in one direction, pumping in the opposite direction (distal to proximal) due to user error is not possible. Nonetheless, even if there is a rotor pump malfunction and the rotational direction of the pump is incorrect, the risk of danger to the patient is very low because only the CSF amount actually in the tube system is discharged retrograde and this can also occur in conventional systems in a similar manner if the distal end of the CSF discharge system is attached higher and due to the hydrostatic pressure CSF can run retrograde to the intrathecal CSF drainage. As the LiquoGuard System provides constant pressure monitoring, danger to the patient due to increased intrathecal pressure due to retrograde CSF flow can be ruled-out. This is not possible distally if conventional systems are used and CSF drainage is open. This means that by using the LiquoGuard System the risk of danger to the patient due to retrograde CSF flow is considerably lower than in existing systems.
CSF drainage is only possible when using existing systems when the ventricle drainage is opened, the 3-way cock is open and the air filter for the CSF collecting basin is opened (10, 17). Unintended closure of the CSF drainage system at any one of these points leads to a system occlusion which may remain unnoticed. In contrast, an occlusion of the LiquoGuard CSF drainage system is noticed as there is no CSF pulsation (occlusion proximal to the pressure sensors) or through an increase of the intrathecal pressure values (occlusion distal to the pressure sensors) auf. This leads to direct recognition of danger to the patient if the LiquoGuard System is used and the possibility to avert it, thus minimizing the risk of danger to the patient.
However, the systems used to date have had different disadvantages, caused physically with regard to the open system with an air filter when CSF drainage is desired. As conventional drainage is a distally open system (external pressure compensation is possible in the CSF collecting basin via an air filter), it is not possible to measure CSF pressure in a distally opened external tube system correctly (7, 21). CSF drainage is controlled using the height of the distal tube system which must always be set in accordance with the patient's height (7, 11, 17, 21). A change in the height of the intrathecal catheter in relation to the distal tube system inevitably causes a change to the differential pressure (target pressure) which remains unnoticed if distal CSF drainage takes place in the current systems. This means that the risk for the patient that either an uncontrolled high amount of CSF (differential pressure lower than wanted, distance between intrathecal CSF drainage and external drainage lower) or too low a CSF quantity (differential pressure higher than wanted, distance between intrathecal CSF drainage and external drainage higher) is drained. The LiquoGuard application can reduce this risk considerably because the pressure sensor attached externally to the patient at the height of the intrathecal catheter is carried along when the patient moves, thus averting any pressure changes. This formation not only decreases the amount of work for medical staff in its clinical application and daily routine - it also reduces the risk of incorrectly high or low CSF drainage.(4)

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Assessment of pressure measurement safety

Existing CSF drainage systems possess two varieties of pressure measurement with CSF drainage. The Gold Standard describes the attachment of a pressure sensor to the ventricle drainage and alignment at foramen Monroi level (10, 11). However, pressure measurement is only possible with a tubing system closed distal to the pressure sensor, this arrangement does not permit simultaneous drainage and pressure measurement (16). What is disadvantageous and risky to the patient is that an open system and therefore a deactivated pressure measurement does not guarantee the observation of a tube occlusion or a disconnection. The second variety permits measurement of brain pressure via a pressure sensor directly inserted in the ventricle system, attached at the tip of the ventricle drainage (16, 21). In this case the distal catheter part is open and permits CSF drainage. However, as simultaneous CSF drainage creates an open system, the value of the intraventricular pressure measurement is determined by the height of the drip chamber. Both systems currently available normally work with only one pressure measurement. This means that in case of a technical pressure sensor fault the measurements would lose their reliability, usually a technical redundancy for the safety of the patient does not apply. The CSF drainage system LiquoGuard permits simultaneous pressure measurement and CSF drainage in a closed system. All previously existing risks of unnoticed dysfunctional CSF drainage (disconnection, catheter occlusion) are therefore solved and lead to considerable improvement of patient safety. As this is a closed system, pressure measurement is possible with simultaneous CSF drainage. Simultaneous pressure wave analysis also permits statements on the functionality of ventricle drainage, which is also not possible with the pressure sensors attached to the tip of the ventricle drainage. As both pressure sensors as well as the device-internal processing are redundant in the catheter system, the risk of a technical error measurement as in previous systems can be virtually excluded, as a drift of both sensors in the same direction (positive/negative) in the exact same time resolution with identical amplitude can be classified as unlikely.

All pressure sensors require zero-point calibration before application. In this respect, existing systems do not differ from the LiquoGuard system. However, previous systems permit further zero-point calibrations, which denote two significant risks: 1. the system must be open to air, which promotes germ entry into the tubing system; 2. erroneous, subsequent zero-point calibration with adjoining liquid column can cause an erroneous, low pressure measurement, which can lead to erroneously low intrathecal pressure measurements. As zero point calibration in the LiquoGuard system can only be performed once during initialization of the system and as calibration is recorded in the sensory memory, a second, perhaps erroneously low calibration is impossible. This significantly increases patient safety.

Wrong attachment of the sensor in connection with the zero point (usually foramen Monroi) or unobserved detachment of the pressure sensor can lead to incorrect intrathecal pressure values. This could also lead to erroneous measurement of high intrathecal pressures resulting in CSF drainage. However, as the connection tube between CSF drainage and the pressure sensor is short, pressure difference is only marginal and has no significant influence. In contrast, the CSF collecting bag in existing systems can detach itself from the attachment clamp and fall to the ground. As the connection tube between intrathecal CSF drainage and CSF collecting bag is long, there is a risk of significant pressure differences, which could denote a hazard to the patient. This risk can be significantly reduced due to the technical properties of the LiquoGuard system.

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Safety assessment in CSF drainage occlusion

To ensure correct CSF drainage it must be guaranteed that the entire tubing system, starting at the ventricle catheter to the drip chamber, is not closed (e.g. by 3-way cocks, kinks in the tube, displacement of the inner tube lumen by blood coagulation, etc.) and that pressure balance in the drip chamber to the outside is guaranteed (air filter connected and not jammed, clamp at air filter open).(17) Air filter jamming in particular is difficult to recognize in previous systems, as an external visual inspection (all connections open) does not recognize malfunction and can only be noticed and corrected during air filter exchange or pressure measurement. Recognition of a situation potentially critical for the patient is not possible in previous systems. As pressure measurement is always simultaneously connected to drainage in the new LiquoGuard system, continuous pressure monitoring is possible. An occlusion proximal to pressure sensors is immediately recognized by the absence of the appropriate CSF pressure curve and an alarm is triggered. The occlusion distal to the pressure sensor system is measured by an increase in CSF pressure and an alarm is generated when the upper pressure limit specified by the physician is exceeded. In both systems the removal of a distal tube occlusion and a positive pressure difference between intrathecal pressure and target pressure to the achievement of the target pressure removes a comparable volume of CSF. All in all, the risk of an unnoticed system occlusion can be reduced by the additional measuring systems integrated in LiquoGuard and continuous pressure measurement during CSF drainage without creating additional risks in the application.

Safety assessment to maintain CSF target pressure

All previous systems are based on a distally open tubing system; the desired CSF pressure is set via height adjustment in the drip chamber of the CSF drainage (16, 21, 23). The problem is that when the position of the patient's head is changed (e.g. bed position, self-mobilization of the patient such as sitting up, turning, etc) the height of the drip chamber must be readjusted. If this is not performed, an undesired, large volume of CSF may drain (drip chamber too low in relation to patient's head) or too little CSF is drained (drip chamber too high). This results in serious risks to the patient, as overdrainage with reduced ventricle pressure may cause rupture of bridge veins and transtentorial herniation (clamping) (17). Too little drainage can cause increased CSF pressure and lead to pressure damage in the nervous system (22). The LiquoGuard CSF drainage system avoids these risks as follows: both pressure sensors are configured in such a way that they can be attached at the height of the patient's foramen Monroi by adhesive electrodes. Positioning of the height of the rotor pump and collecting bag is therefore completely independent of patient position. The pressure sensor follows all changes in the position of the head. However, this is only possible if the pressure sensors have been correctly attached to the head. As the proximal connection piece to the ventricle catheter is very short, the pressure difference in case of detachment and suspension in relation to previous systems (drip chamber falls to the ground) is limited. All in all, the system's independence from patient position leads to a significant reduction in risk to the patient and to much easier handling in the daily clinical application.

Safety assessment for disconnection during CSF drainage system application

The disconnection of the tubing system in all previous systems, occurring occasionally during permanent lumbar CSF drainage (patient removes proximal tubing system during change in position or disconnects it when disorientated) leads to spontaneous emptying of CSF to the outside with the risk of a negative CSF

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pressure (risk of herniation, hemorrhage) and CSF infection (no existing sterility, open CSF drainage serves as port of germ entry(17)). As permanent lumbar drainage is commonly applied in wards without a monitoring unit, the disconnection is only recognized after longer periods of time and after loss of significant CSF volumes(2)(17). The LiquoGuard drainage system can detect the problem immediately by measuring acute pressure reduction caused by disconnection in the catheter system and signal an appropriate alarm. The risk to the patient caused by unrecognized CSF drainage over longer periods of time is significantly reduced by the use of the LiquoGuard system.

Safety assessment for sterility of CSF drainage systems

For physical reasons, existing systems require an external system opening for CSF drainage. An air filter must be connected to the CSF collecting container, which can lead to cross-contamination. This risk can be reduced by using the LiquoGuard system, as it is a closed system and does not require the use of an air filter.
Existing systems can be reused contrary to the determination of suitability, whereas multiple use or re-sterilization in the LiquoGuard system is impossible due to single zero point calibration. This excludes the risk of unintentional multiple use of disposable products. All other consumable goods in contact with human body fluids are comparable to the LiquoGuard system and do therefore not denote any additional risk of infection.

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Summary

Verification of effectiveness

The LiquoGuard CSF drainage system is a tube system with integrated redundantly designed pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CNS drainage. The intrathecal CSF drain is used independent of the LiquoGuard system, and the products approved for intrathecal CSF drainage and pressure measurement can be connected to the LiquoGuard system. The indication for insertion of an intrathecal drainage will not be affected by using the LiquoGuard system. As the control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing systems and the LiquoGuard system, the measuring sensors are comparable and the effective mechanism and the function of the CSF extraction by means of a target value-controlled rotor pump in the LiquoGuard system is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard system offers comparable effectiveness to existing CSF drainage systems. Thus both systems similarly enable CSF drainage as a treatment up to target pressure in order to reduce intrathecal pressure, which makes it possible to treat intrathecal pressures leading to a perfusion deficit of the central nervous system. There is technically similar to standard shunt valves with regard to the automated pressure-related CSF flow control. Such devices usually work by tensioning a valve via a spring tension and can be adjusted from outside mechanically, magnetically or by any other suitable method, depending on the design. At a certain preset CSF pressure definable from outside, the valve opens and allows the CSF to flow, until the CSF pressure is below the preset pressure, causing the valve to close automatically (5, 7). This active pressure-controlled CSF drainage is realized in the LiquoGuard system in an analogue way.
By using the LiquoGuard system, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in both systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement.

Risk evaluation of the system

Intrathecal pressure measurement
In the LiquoGuard system, the technical requirements for pressure measurement are comparable to the existing CSF pressure measurement systems that work via a liquid column communicating to the intrathecal space. Both the positioning of the pressure sensors in the tube system as well as the orientation of the pressure sensor in relation to the intrathecal catheter is comparable. Contrary to other systems, however, the LiquoGuard system is designed such that the pressure measurement is performed twice, and in the event of measuring a differing pressure between both sensors, an alarm is activated enabling the malfunction of a sensor to be noticed immediately. Since a faulty measurement of the intrathecal pressure can pose a risk for the patient (excessive CSF pressure risking a compression and perfusion deficit of the CNS, insufficient CSF pressure risking a tensile stress on CNS structures

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leading to hemorrhages, vessel ruptures and shear injuries), the double measurement with mutual control of both pressure sensors allows the significant reduction of the risk of faulty pressure measurement in comparison to existing systems. The prevention of pressure equalization to ambient air pressure with already inserted systems, with the consequence of a wrong high or wrong low intrathecal pressure reading, further increases the safety of the patient in the LiquoGuard system.

CSF extraction
The LiquoGuard system, contrary to existing systems, allows continuous pressure measurement even during CSF extraction. Therefore, there are no further additional risks associated with using the LiquoGuard, but rather the risk of an uncontrolled CSF extraction under existing systems (wrong difference height set, patient moves during CSF extraction with open system, height of CSF drainage bag changes during CSF extraction, CSF drainage system is disconnected while drainage is in progress) can be significantly reduced by using the LiquoGuard system. Thus the risk of excessive CSF pressure risking a compression and perfusion deficit of the CNS, or of insufficient CSF pressure risking a tensile stress on CNS structures leading to hemorrhages, vessel ruptures and shear injuries can be reduced by using LiquoGuard. Hemorrhages (13, 17) caused by the application of intrathecal CSF drainage are not affected by the used CSF drainage system; there is no increased hemorrhage risk by using the LiquoGuard system. Other risk sources for the patient such as wrong catheter positions (11, 17) are also not related to the CSF drainage system and pose an independent risk that is neither reduced nor increased by using the LiquoGuard. .

Quantification of the CSF extraction volume
A comparable visual determination of the extracted CSF volume by reading the quantity of CSF on scales attached to the drainage bags, allows a basic CSF volume determination with both existing CSF drainage systems and the LiquoGuard system. Additionally, the LiquoGuard system can compute the extracted CSF volume by means of the number of rotations of the rotor pump and the tube diameter, thereby allowing not only a safety-relevant redundancy of the CSF volume determination, but also a quantification of the CSF volume in high time resolution.

Closed vs. open CSF drainage system: Existing systems allow reliable intrathecal pressure measurement with a closed CSF drainage system, and CSF drainage with an opened CSF drainage system. If the CSF drainage system is occluded distally from the pressure measurement (clogging of tubing system, tube closed by 3-way cock, clogging or closing of air filter at the CSF drainage bag) and the pressure measurement is not connected to the liquid column, a very high CSF pressure may build up without being noticed. This can lead to a severe risk for the patient, as it may result in a compression of the CNS with the danger of a perfusion deficiency. The risk of an unnoticed CSF pressure increase can be significantly reduced due to the continuous CSF pressure measurement with the closed system (LiquoGuard system), no air filter is required, and the CSF pressure measurement is possible simultaneously and independently from each other at any given time. The risk of a malfunction of the rotor pump control in the LiquoGuard system through a faulty pressure measurement is highly unlikely due to the double pressure measurement design.

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Disconnection and occlusion of the CSF drainage system

With existing systems in closed status as well as with the LiquoGuard system, during connected liquid column, any disconnection of the system with CSF leak can be immediately noticed due to a rapid drop in pressure at the pressure sensors below the lower pressure limit. Contrary to the LiquoGuard system, where it is possible to recognize a disconnection even under CSF drainage conditions, this is not possible with the existing systems under deactivated pressure measurement during CSF drainage. Here the danger is that CSF can leak out unnoticed in large quantities with the risk for the patient that due to insufficient CSF pressure there is a risk of tensile stress on CNS structures leading to hemorrhages, vessel ruptures and shear injuries. This risk can be significantly reduced by using the LiquoGuard system, without any identifiable additional risks for the patient. An occlusion proximal to the pressure sensors will lead to a suppression of pressure pulsations, which in existing CSF drainage systems can be visually displayed via a patient monitor connected to the pressure sensor, and in the LiquoGuard system both via a connected patient monitor as well as via the display of the LiquoGuard device. Contrary to existing systems, however, the LiquoGuard system is computing the pulsations and triggers an acoustic and visual alarm above or below defined alarm parameters. This will make the clinical staff aware of a possible system occlusion proximal to the pressure sensors. There are no other additional risks involved for the patient, but the risk of an unnoticed intrathecal pressure increase with the consequence of a compression and perfusion deficiency of the CNS can be significantly reduced by the LiquoGuard system in comparison to the existing systems. An occlusion distally from the pressure sensors will in both systems equally cause the CSF drainage to be suspended. With existing systems, this situation may remain unnoticed if the pressure sensor is not connected to the liquid column (e.g. by connecting the pressure sensors via 3-way cock). With the LiquoGuard system, a distal occlusion will lead to a measurable pressure increase, which will trigger an acoustic and visual alarm when the upper alarm limit for the CSF pressure measurement is exceeded. Therefore, the continuous CSF pressure measurement by means of the LiquoGuard affords a significant improvement of the CSF pressure monitoring with a decrease in the patient risk.

CSF system sterility

Handling the connection of the CSF drainage system to the CSF drain is comparable in all CSF drainage systems, here there are no identifiable additional risks by using the LiquoGuard. However, with an open system a bacterial contamination through the air filter might occur, which is not possible with a closed system (LiquoGuard). Additionally, the rotor pump prevents a CSF reflux from the tube/drainage bag system into the intrathecal space, which further reduces the infection risk. Any multiple use of the tube system with a possible germ contamination is virtually impossible due to the electronic protection and unique zero calibration of the pressure sensors. All in all there are no indications of any increased infection risk by using the LiquoGuard system; there are rather significantly less points of entry for a bacterial contamination of the system with the LiquoGuard system. Using the LiquoGuard system has no influence on the principle risk of an infection of the CSF drainage system (8, 17).

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Conclusion

It has been shown in the existing recognized literature that the CSF drainage is a recognized and established method in neurosurgery for many years for the diagnostic and treatment of patients with diseases of the CNS. The risks associated with the surgical insertion of a CFS drain are not depending on the CSF drainage system chosen and thus not on the use of the LiquoGuard system. The objective of intrathecal pressure measurement and CSF extraction is achieved both by existing CSF drainage systems as well as by the LiquoGuard system in comparable effectiveness. Contrary to existing systems, however, by using the LiquoGuard system, the risks of erroneous pressure measurement, sensor fault, and false pressure measurement by changing the reference height of the patient, unnoticed catheter occlusion and catheter disconnection as well as the infection risk can be reduced.

Biologically, the identical material is used for the drainage (CSF). Neither insertion technique, material nor the indications are influenced or altered by using the LiquoGuard. Therefore, there is no difference in the surgical risks for inserting the relevant ventricular or lumbar drainage when using the LiquoGuard. The intrathecal drainage is inserted with the identical patient population at the same place in the body (ventricular system, lumbar CFS system) (7, 13). The pressure measurement is performed by piezo-resistive pressure sensors that are established and described for the use in intracranial pressure measurement (10, 11, 21). Fundamental risks that do not depend on the method of CSF drainage and occur after insertion of a CSF drain (ventricular catheter, permanent lumbar drainage catheter) are described in major trials; these are infections (8, 17), hemorrhages (13, 17), wrong catheter positions (11, 17), occlusions (17), overdrainage (17).

The surgical procedures will not be changed in any way; also the indications for a surgical intervention remain unchanged. No material risk can be identified, as existing systems are made of comparable material and are used as soon as sterile catheter material becomes available.

In summary, from a functional point of view existing systems are identical to the LiquoGuard system (CSF drainage, pressure measurement), but the pressure-controlled CSF drainage via a rotor pump (LiquoGuard) offers a clear reduction of technical, application-specific and patient-specific risk sources, without generating new risk sources at the same time. All patient-relevant risks of usual systems can be significantly reduced by using the LiquoGuard. There is no additional risk to users or third parties..

Fulda, 23. August 2006

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Annex: Bibliography

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APPENDIX 7

OPERATING MANUAL FOR THE LIQUOGUARD CSF DRAINAGE SYSTEM

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US

LiquoGuard® CSF

Operating Manual

CE 1275

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The manufacturer reserves the right to make technical improvements.

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3 General Safety Instructions

3.1 Explanation of the safety symbols

Important information is marked in these operating instructions. This information is vital to exclude danger to patient and operating personnel, and to avoid damage or malfunction.

Achtung	Warning, important information
Gefahr	Caution! Hazard to patient or operating personnel
Hinweis	Information or help
	Application part BF
CE 1275	Conformity to medical guideline 93/42 EEC
~	Identification symbol for electrical and electronic devices
	Alternati ıg voltage
	Alarm signal deactivation switch AUDIO PAUSE
	Consult instruction for use
SN	Serial number
	Manufacturer
REF	Catalogue number
LOT	Lot number
	Date of expiration
	Date of manufacture
	Application range

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General Safety Instructions

STERILE EO	Sterilized using ethylene oxide
	Do not use if packaging is damaged
	Do not reuse
	Do not resterilize
MRI	Not for use in an MRI field
PHT DEHP	Contains or presence of phthalates
	Overall length

Each application of the unit is subject to precise knowledge of and compliance with these operating instructions. This operating manual does not replace the inservice of the user by the sales representative. The device must only be operated by qualified personnel or those with an equivalent level of knowledge and experience.

If components are used that do not correspond to the original parts of the manufacturer, the performance, safety and EMC behaviour may be impaired.

3.2 Manufacturer

The manufacturer can be regarded as being responsible for the safety, reliability and serviceability of the unit if:
assembly, upgrades, resettings, changes or repairs are only carried out by personnel who have been authorised to do so by the manufacturer. The electrical installation of the respective room complies to the appropriate requirements and the device is used according to the operating manual.

3.3 Precautionary duties of the operator

The operator is responsible for proper operation of this medical product.
Only qualified personnel may operate this unit. Operating instructions do not replace a proper inservice. Clinical application may only be performed by people who have been properly inserviced by qualified personnel.

The unit may not be operated if connected to power supplies whose soundness is doubtful. The supply voltage must match the details specified on the nameplate. Liquids must not penetrate parts of the device, which carry electrical voltage. Do not spray cleansing fluid into the memory card slot. Unplug the AC power cord prior to cleaning.

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3.4 Supplementary devices

Supplementary devices are not part of the unit's delivery scope:
Any additional equipment that is connected to the analogue and digital interfaces of the device must be proven to meet the requirements of the relevant EN specifications, (e.g. EN60601 for electrical medical devices). All device configurations must also satisfy the applicable version of the electrical system safety standard EN60601-1-1. Any operator connecting the additional devices is the system configurer and is therefore responsible for ensuring that the system safety standard EN60601-1-1 is upheld. In case of questions, please contact the manufacturer.

3.5 Single-use

Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.

3.6 Electro-magnetic emission

The ***LiquoGuard® CSF*** is suitable for operation in the stipulated electro-magnetic environment. The customer and/or operator of the ***LiquoGuard® CSF*** should ensure that it is used in one of the electro-magnetic environments described below.

Measurement of emitted interference	**Conformance**	**Guidelines for the electro-magnetic environment**
Emitted high-frequency interference acc. to CISPR 11	Group 1	
Emitted high-frequency interference acc. to CISPR 11	Class B	The ***LiquoGuard®*** uses HF energy exclusively for its own function. Its HF emittance is therefore very low and interference with neighbouring electronic devices is improbable.
Harmonic emittance acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emittance acc. to IEC 61000-3-3	Not applicable	

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3.7 Recommended safety distances

Recommended safety distances between portable and mobile HF telecommunication devices and *LiquoGuard®*			
LiquoGuard® is intended for operation in an electro-magnetic environment, in which HF disturbances are controlled. The client or operator of ***LiquoGuard®*** can assist in avoiding electro-magnetic disturbances by keeping to the minimum distances between portable and mobile HF telecommunication devices (transmitters) and ***LiquoGuard®*** - depending on the output power of the communication device, as stipulated below.			
Capacity transmitter power [W]	**Safety distance dependent on transmission frequency [m]**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

3.8 Electro-magnetic resistance

Resistance test	IEC 60601 - testing level	Conformance level	Electro-magnetic. Environment / Guidelines
Discharge of electro-static electricity (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should consist of wood or concrete or tiles. If the floor is covered with synthetic material, relative humidity should be at least 30 %.
Rapid transient electrical disturbances/ bursts IEC 61000-4-4	±2 kV for power lines ±1 kV for input and outtput lines	±2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Surge voltages Surges IEC 61000-4-5	±1 kV Normal mode voltage ±2 kV Common mode voltage	±1 kV Normal mode voltage ±2 kV Common mode voltage	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage IEC 61000-4-11	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	The quality of the supply voltage should correspond with that of a typical business or hospital environment. If the operator of the product demands continued functions even during the occurrence of power supply interruptions, we recommend the use of an uninterrupted power supply or battery.
Magnetic field for supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields for the net frequency should correspond with typical values as found in business and hospital environments.
Note: U_T is the AC supply voltage prior to application of the testing level.			

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3.9 Electro-magnetic resistance for non-life-supporting devices

Resistance tests/ Standard	IEC 60601-testing level	Conformance level	Electromagnetic environment / Guidelines
Conducted HF-resistance variable according to IEC 61000-4-6 Radiated HF-resistance acc. to IEC 61000-4-3	$3\ V_{eff}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	$3\ V_{eff}$ 3 V/m	Portable and mobile radio devices should not be used at a distance to the product, including lines, of less than the recommended safety distance, which is calculated according to the equation corresponding to the transmission frequency. **Recommended safety distance:** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{V_1}]\sqrt{P}$ for 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ for 800 MHz to 2.5 MHz with P as nominal transmitter power in Watt (W) acc. to transmitter manufacturer stipulations and d as recommended safety distance in meters (m). According to an on-site[a)] examination, the field intensity of stationary radio transmitters ought to be lower than the correlation level[b)]. Disturbances may occur in the environment of devices carrying the following symbol.

Notes:
NOTE 1 The higher frequency range applies to 80 MHz and 800 MHz.

NOTE 2 These guidelines may not be applicable in all cases. The diffusion of nominal electro-magnetic factors is influenced by absorption and reflection of buildings, objects and people.

[a)] The field intensity of stationary transmitters, such as radio base stations and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and TV transmitters theoretically cannot be predetermined accurately. An examination of the site should be considered in order to determine the electro-magnetic environment of the stationary transmitter. If the measured field intensity at the site, at which the product is used, exceed the above mentioned conformance levels, the product should be observed to prove the intended function. Unusual performance characteristics may require additional measures, such as changes to the alignment or position of the product.

[b)] The field intensity should be less than 3 V/m at 150 MHz to 80 MHz.

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4 Purpose

Möller Medical's ***LiquoGuard® CSF*** is a

- pressure controlled
- and / or volume controlled

tube pump for use in: monitored medical rooms in hospitals only.

The purpose of *LiquoGuard® CSF* with the tube set for *LiquoGuard®* REF.-No.: **92 007 836 (1500 mm/59.06 inch) or REF.-No.: 92 008 568 (2000 mm/78.74 inch) is the targeted pumping of CSF fluid.**

LiquoGuard® may not be used as an infiltration pump or infusion pump.

LiquoGuard® does not serve diagnostic purposes.

4.1 Indications for Use

The ***LiquoGuard® CSF*** system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The ***LiquoGuard® CSF*** system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The ***LiquoGuard® CSF*** system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

4.2 Contraindications

The contraindications do not apply to the use of a CSF draining system such as the ***LiquoGuard® CSF*** system, but to the application of intrathecal CSF drainage itself. As, however, CSF discharge is only applied in connection with CSF drainage, contraindications described below are in connection with the application of external CSF drainage only.

Absolute operative contraindications: Coagulopathy, thrombocythemia.

Relative operative contraindications: In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does simultaneous intake of intrathecal antibiotics in the case of ventriculitis.

Indication for permanent CSF drainage: If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculoperitoneal shunt or a ventriculo-atrial shunt.

4.3 Combination with other products

LiquoGuard® CSF may only be used in connection with Möller Medical's tube set for ***LiquoGuard®*** **REF.-No.: 92 007 836 (1500 mm/59.06 inch)** or **REF.-Nr.: 92 008 568 (2000 mm/78.74 inch)** , the tube set may only be used in connection with the ***LiquoGuard®***.

The tube set for ***LiquoGuard®*** REF.-No.: 92 007 836 or. REF-No.: 92

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008 568 is connected to a surgically implanted CSF draining catheter and does not come into contact with the body.
The tube set for ***LiquoGuard®*** REF.-No.: 92 007 836 or. REF-No.: 92 008 568 may only be connected to ventricular drainage catheters with an internal diameter of >= 1 mm (0.039 inch) and with lengths of <= 350 mm (13.78 inch) or lumbar drainage catheters with an internal diameter of >= 0.7 mm (0.028 inch) and a length of <= 800 mm (31.5 inch).

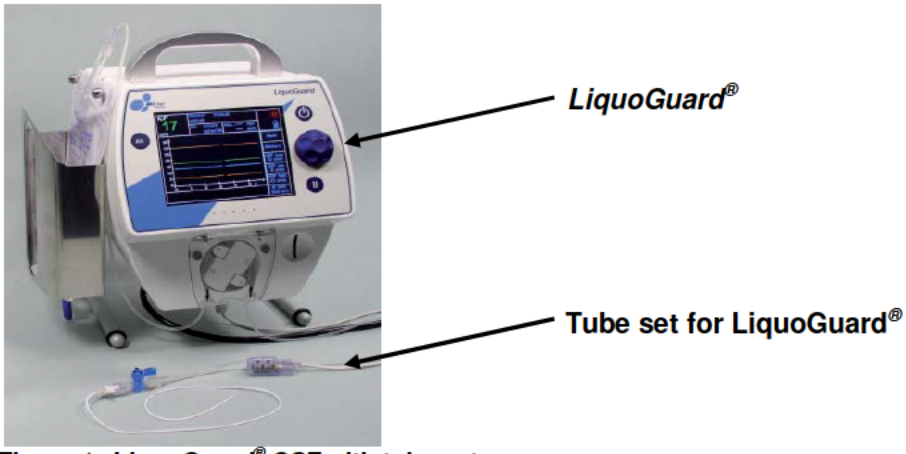

Figure 1: *LiquoGuard® CSF* with tube set

4.4 Patient population

The application may be considered for neonatal to geriatric patients.

4.5 Remaining risk

LiquoGuard® CSF is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error. The remaining risk for the patient exists mainly in the selection of parameters unsuitable for the patient or other application errors. The operator must be aware of this risk.
LiquoGuard® CSF does not serve diagnostic purposes.
For application during computer tomography (CT), the tube set may remain attached to the patient. ***LiquoGuard® CSF*** must be disconnected.

Application during Magnetic Resonance Tomography (MRT) or near an MRT device is prohibited.

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5 Set-Up and Installation

Ensure that the package has been delivered to you without damage. Please inform your sales representative immediately of any transport damage.

5.1 Unpacking the Device and Checking for Contents

Delivery of ***LiquoGuard®*** always consists of one carton. When unpacking ***LiquoGuard®***, ensure that no parts remain in the package and that all parts are present.

The delivery scope consists of (1 item each):

- ***LiquoGuard® CSF***
- AC power cord
- Operating manual

Every manipulation of ***LiquoGuard®*** requires exact knowledge and observance of these operating instructions. These instructions do not replace proper user training. Only qualified personnel may operate this unit. ***LiquoGuard®*** must be prepared according to cleaning guidelines prior to first application. For cleaning, use a mild detergent or disinfectant (e.g.: 70 % alcohol).

We suggest that packaging is retained for further use.
LiquoGuard® may only be shipped in the original packaging.

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5.2 Installation

Remove ***LiquoGuard® CSF*** from its packaging and place it on a suitable, steady surface.

LiquoGuard® CSF can be:

- safely positioned in a suitable, stable location.
- suspended on a 25 mm (0.98 inch) x 10 mm (0.39 inch) wall rail.
- or attached to an IV pole with a diameter of 25 mm (0.98 inch).
- or universally attached to various IV poles or the patient's bed with the attachment pole (accessory).

Observe the maximum tube length of 1.5 m/59.06 inch (REF.-No.: 92 007 836) or 2 m/78.74 inch (REF.-No.: 92 008 568) between catheter and ***LiquoGuard®***.

Figure 2: *LiquoGuard®* standing on base feet

Figure 3: *LiquoGuard®* - view from behind
Attachment system for wall rail 25 mm (0.98 inch) x 10 mm (0.39 inch)

Figure 4: *LiquoGuard®* - view from behind
Pole clamp

Insert the AC power chord into ***LiquoGuard® CSF*** at the lower side of the casing side and into a plug with connected protective earth conductors. Please observe the stipulated voltage values on the type plate.

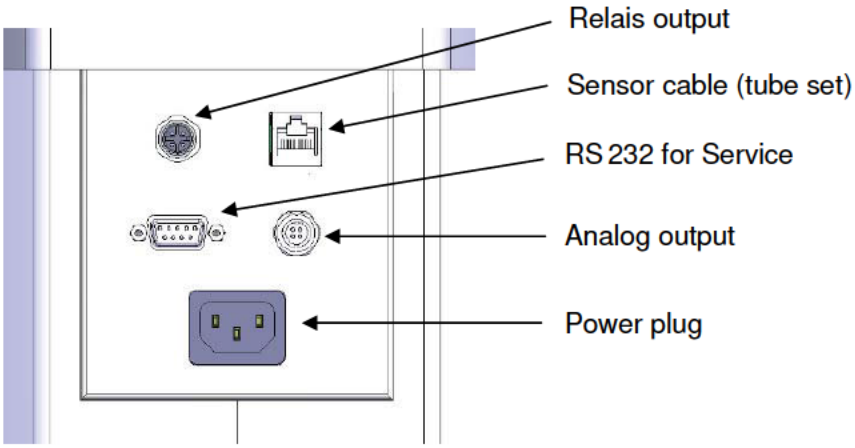

Figure 5: *LiquoGuard®* - View from below - Connections

The relay output can be used for an alarm connection to the device call system (frequently also known as the diagnostics call or nurse call). The function of this connection must be

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Set-Up and Installation

checked and validated in individual cases (Please Observe the prerequisites for Supplementary devices in Chapter 3.4 on Page 7).
This further alarm routing does not eliminate the need to control the patients. The alert notices from the ***LiquoGuard® CSF*** must be controlled in every case.

Connecting the AC power cord to ***LiquoGuard®*** puts the device into standby mode.

Further startup requires a tube set for ***LiquoGuard®*** by Möller Medical, **REF.-No.: 92 007 836** or **REF-No.: 92 008 568.**

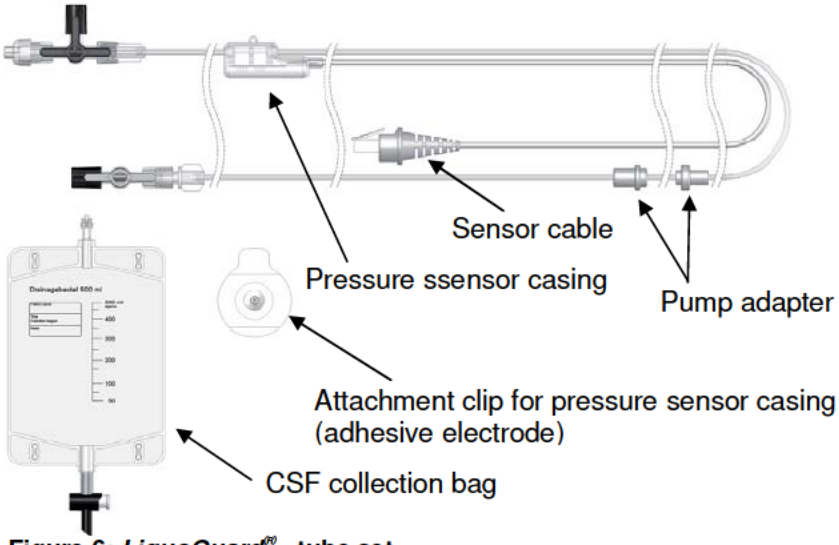

Figure 6: *LiquoGuard®* - tube set

To avoid false alarms, you should familiarise yourself with the alarm concept of ***LiquoGuard® CSF*** (see Page 15).

Please continue reading starting at page 30 for information on Application and operation.

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6 Alarm concept

The ***LiquoGuard® CSF*** alarm concept is designed in such a way that during correct operation the operator is always notified of alarm conditions by visible and audible alarms (i.e. an operator must always be within earshot and visibility range). ***LiquoGuard® CSF*** is equipped with a physiological and technical alarm condition. Alarm condition priority is stipulated with "HIGH Priority" for all alarm conditions. ***LiquoGuard® CSF*** creates visible and audible alarm signals. The alarm system is designed without self-regulating alarm signals.

6.1 Alarm system description

Terms and definitions

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm condition	Condition of the alarm system once it has determined a possible or real threat.	Excess of upper or lower alarm limit	
Alarm condition delay	Time between occurrence of an alarm condition either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), up to system determination of an existing threat.	See chapter 6.2	
Alarm limit	Limit value used by an alarm system to determine an alarm condition.	See chapter 6.2	Control panel
Alarm OFF	Condition of indefinite duration, in which an alarm system or a part thereof does not issue alarm signals	The user can set certain alarm conditions to OFF If these are not useful due to the condition of the patient. It is the responsibility of the user to set these consciously to OFF.	
Alarm paused	Condition of limited duration, in which an alarm system or a part thereof does not issue alarm signals	No possible setting	
Alarm presetting	Set of saved configuration parameters, including the selection of algorithms and initial values for the use of algorithms, which influence or change the effect of the alarm system.	N/A	
Alarm reset	Action performed by operator to cancel an alarm signal, for which there is no currently associated alarm condition.	N/A	

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Alarm concept

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm settings	Alarm system configuration including but not limited to: - Alarm limits - Properties of all conditions of alarm activation and - The values of parameter variables, which determine the function of the alarm system.	In some cases adjustable by user (see chapter 6.2)	
Alarm signal	Signal type created by the alarm system to display the existence (or the occurrence) of an alarm condition.	- Visible alarm signal - Audible alarm signal The audible alarm signal has an audio pressure level of 55dBA at a 1-metre distance	Visible impulse signal via red LED light in service screen. On-board sound emitter
Delay in alarm signal emittance	Time from start of alarm condition to emittance of alarm signal.	Depending on alarm condition, see chapter 6.2	
Audio OFF	Condition of unlimited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	settable	refers to all alarm conditions active at the time of key activation
Audio paused	Condition of limited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	Settable to a maximum of 180 minutes.	refers to all alarm conditions active at the time of key activation
De-escalation	Process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	No application	
Escalation	Process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	No application	
False negative alarm conditions	Missing alarm condition, if a valid triggering occurrence in the patient, in the device or in the alarm system has occurred.	Dual safety-Probability very low	
False positive alarm conditions	Existing alarm condition, if no valid triggering occurrence in the patient, in the device or in the alarm system has occurred.		
Information signal	Every signal, which is not an alarm or reminder signal.	Applies.	
Self-retaining alarm signal	Alarm signal which continues to emit after its triggering occurrence has been eliminated, until it is stopped with a deliberate operator action.	Does not apply.	
Non-self-retaining alarm signal	Alarm signal, which automatically stops if the associated triggering occurrence has been eliminated.	Applies.	
Physiological alarm condition	Alarm condition originating from a monitored, patient-related variable.	Applies.	
Technical alarm condition	Alarm condition originating from a monitored, device or alarm system-related variable.	Applies.	

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6.2 Alarm system overview

Alarm conditions	Pulsation frequency not correct	Lower pressure limit value undercut	Upper pressure limit value exceeded
Physiological alarm condition	Pulsation frequency too small (limit value)/ too large (limit value)	Measured pressure too low	Measured pressure too high
Technical alarm condition	n.a.	n.a.	n.a.
Alarm limit	Pulsations frequency (<=30) or (>= 180)	Lower pressure limit value (P-min) Adjustable by operator	Upper pressure limit value (P-max) Adjustable by operator
Alarm condition delay	Averaged value in 12 sec.	Filtered measurement value	Filtered measurement value
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	Not adjustable by operator Specified to 20 sec	Not adjustable by operator Specified to 20 sec
Alarm signal	Audible / Visible	Audible / Visible	Audible / Visible
Alarm signal description in display	Pulsation alarm!	Measured pressure too low	Measured pressure too high
Audio paused or Audio off	YES	YES	YES

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Alarm concept

Alarm condition	Pressure constant	Sensor defective or disconnected
Physiological alarm condition	Measured pressure too constant	n.a.
Technical alarm condition	n.a.	a) „Sensor defective“: Difference between the two sensors is too high b) „Disconnection“: cable can't be detected anymore
Alarm limit	standard 0.2 mmHg; adjustable by operator OFF or 0.1-2 mmHg	[illegible] sensors is > 4 mmHg
Alarm condition delay	12 seconds	a) „Sensor defective“: n.a. b) „Disconnection“: 3 Seconds
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	a) „Sensor defective“: specified to 20 Seconds b) „Disconnection“: n.a.
Alarm signal	Audible / Visible	Audible / Visible
Alarm signal description in display	Pressure too constant	Sensor defective or disconnected!
Audio pausedor Audio off	yes	no

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Alarm concept

Alarm condition	**Physiological alarm condition**	**Technical alarm condition**	**Alarm limit**	**Alarm condition delay**	**Delay in alarm signal emittance**	**Alarm signal**	**Alarm signal description in display**	**Audio paused or Audio off**
Battery empty	**n.a.**	**Voltage of battery too low**	**Internal device specification**	**n.a.**	**Not adjustable by operator Specified to 20 sec**	**Audible / Visible**	**Battery empty, connect to AC**	**YES**
Internal safety measures from hardware and software tests -dual safety- **These alarm condition or alarm signal descriptions are not displayed. In the case of such alarm conditions, *LiquoGuard®* must be checked by Service.**	**n.a.**	**Internal device assessments**	**Internal device specification**	**n.a.**	**Not adjustable by operator Specified to 20 sec**	**Audible / Visible**	**Device error x**	**YES**

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6.3 Inspection of alarm functions

Connecting the AC power chord to ***LiquoGuard® CSF*** results in a short peep tone and the two inner red diodes light up. This is a test for the emergency alarm (audible and visible).
A function test is also performed when ***LiquoGuard® CSF*** is activated. An audible information signal is created and the two external red diodes, as well as the central blue diode light up. The motor also starts up and the current software versions as well as the bus address are displayed for a short while.

6.4 Alarm system, dual safety

The path from pressure measurement by ***LiquoGuard® CSF*** to the alarm was designed according to dual safety aspects. This entails 2 sensors in the tube set, dual measurement value recording and processing, as well as various means of alarm emittance.
The two outer red LEDs are activated by ***LiquoGuard®***'s main controls. Alarm signals here (rapid flashing) are supported by displayed information. The audible signal in the main control is a trumpet call.
The two adjacent red LEDs are controlled by the monitoring system. They usually flash slightly delayed from the other LEDs at a slower rhythm.
If the monitoring system determines an error at the main controls, which does not issue an audible alarm, the monitoring system will issue an audible alarm in the form of a rhythmic beep with a fixed frequency. This condition is termed an emergency alarm. It can be cancelled by pressing the standby button three times. If the device returns to this condition repeatedly, the device should be checked by Service.
If a technical fault occurs during battery operation, the device may issue a continuous high-pitched tone. This is also an alarm signal. It can only be cancelled by reconnecting the device to the AC power. There is no other way to cancel this supply alarm.

Important:
The alarm system only refers to ***LiquoGuard® CSF*** itself. Possible signals from an external connected system do not release the operator from his duty to promptly and appropriately react to alarm situations signaled by ***LiquoGuard® CSF*** even if an external system should not display this alarm condition.

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7 Product description

7.1 *LiquoGuard® CSF* design

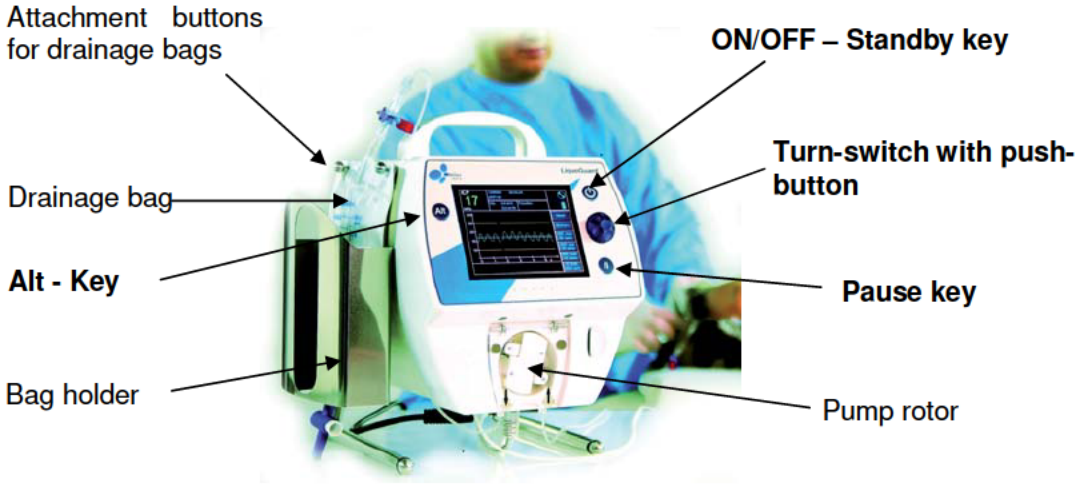

Figure 7: *LiquoGuard® CSF* - design

LiquoGuard® CSF is switched on and off with the **ON/OFF - Standby key**. All functions of the display control panel are set with the **turn-switch**.
You can change between pause mode and active mode of ***LiquoGuard®*** using the **pause switch**. The pump is switched off in pause mode. The **Standby-key** returns you to the next higher menu level from all sublevels. Pressing the **Alt-key** changes the menu items on the right display edge (see „Second selection menu“, page 25).

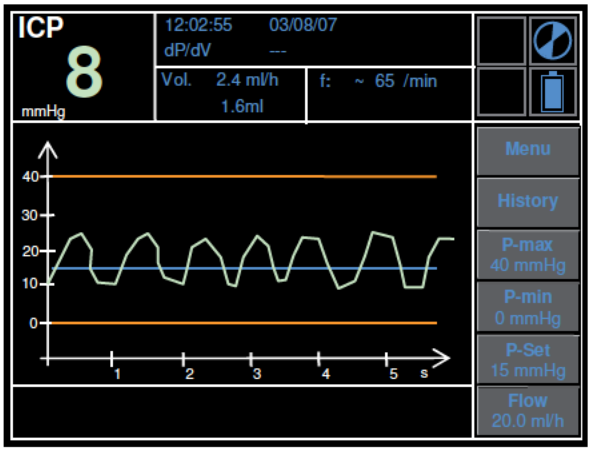

Figure 8: Display of the *LiquoGuard® CSF*

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7.2 Display fields

The monitor design of ***LiquoGuard® CSF*** is divided into display fields and display operating fields.
The **display fields** provide you with the following information:

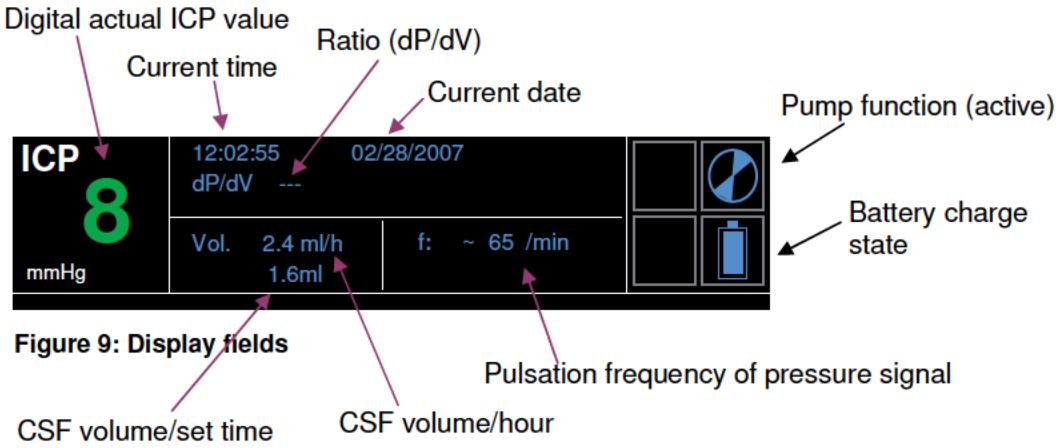

Figure 9: Display fields

7.2.1 Digital actual ICP value or actual P_{CSF} value [mmHg]

The digital actual ICP value/actual P_{CSF} value [mmHg] is the filtered pressure value [mmHg], measured by the pressure sensors. ICP: IntraCranial Pressure [mmHg]; P_{CSF}: Pressure of **C**erebro**S**pinal **F**luid [mmHg]

7.2.2 Ratio dP/dV [mmHg/ml]

Ratio of pressure to volume (Volume elasticity co-efficient, Compliance). This can only be displayed when at least 0.5 ml were pumped between pump start and pump stop and if this created a pressure difference of at least 2 mmHg.
Permanent compliance measurement requires hysteresis set to 1.5 mmHg (under: Sub-menu Extended application; (1) Hysteresis controller [mmHg]).
Note: Accuracy is not better than 20-30%.

7.2.3 Date/Time

These two fields automatically display the current date and current time. The current settings can be changed in the menu.
The date can be displayed in three formats:
DD.MM.YYYY, MM/DD/YYYY, YYYY-MM-DD, e.g.: 28.02.2007; 02/28/2007; 2007-02-28
Note: If the date/time was changed during an application, data (Date/Time) may appear twice or display gaps.

7.2.4 Pulsation frequency of pressure signal (f: ~ ---/min)

This displays the pulsation of the CSF recognised by the device. This recorded pulsation and the alarm conditions are integrated into the alarm concept of the ***LiquoGuard®***. The alarm limits are:

- Upper alarm limit → f >= 180/min
- Lower alarm limit → f <= 30/min

With sufficiently large fluid pulsation the pulsation frequency complies approximately with the pulse of the patient. In the ventricular mode, pulsation alarm is on by default and is an additional monitoring function to increase patient safety.

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It can however be de-activated if required, e.g.: in case of craniectomy/operative decompression: First press the alt key and the right display will appear with a menu containing 5 to 6 sub items (see page 25: “Second selection menu”), Then select "pulse" and set to "NO". The pulsation alarm remains de-activated until this is explicitly changed or a new application is started.
Pulsation recognition is not reliable for permanent lumbar drainage and is therefore not displayed. In this case alarms due to pulsation are not triggered.

7.2.5 CSF volume/hour (Vol. 0.0 ml/h)

This field displays the CSF volume per hour that has been pumped off. The value is always averaged to 15 minutes (adjustable in the system menu) and is updated every minute.

7.2.6 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h)

This field displays the CSF volume per "x" hours that has been pumped off. Variable „x“ can take values between 2 and 24 (steps of 2; see page 45 Duration of volume balance [h]) The value always displays the actual volume in this period. It is updated on an hourly basis. As long as the set balance time (e.g. 24 hours) has not been reached, the actually conveyed volume is displayed in ml. If this function is set to "OFF" in the system menu, the volume measuring function is active, i.e. balancing no longer takes place, and only the conveyed volume is displayed. This counter can always be reset to zero using the alt key and "Reset volume" (see page 25: “Second selection menu”).
Note: In the event that the tubing is changed more frequently for one individual patient without turning off the device, the entire balance will be continued until the end of its use so that the total quantity drained can be read at the end.

7.2.7 Battery charge state

LiquoGuard® CSF was designed for battery supplied operation for a maximum of 3 hours. A progressive decrease of battery capacity is an indication for a damaged battery (contact service). The display field Battery SOC indicates the current battery charge state during battery operation. During mains operation, a filling symbol indicates charging. A full symbol indicates a full battery. During battery operation the battery symbol is red and the blue LED flashes to show the operator that it is not connected to AC power.

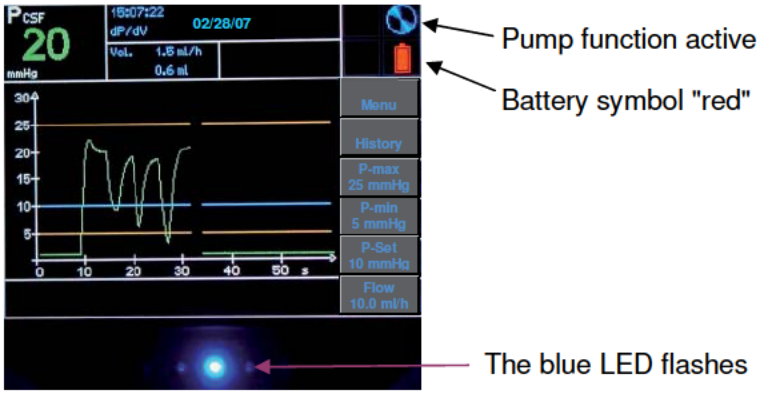

Figure 10: Battery charge state

Before the battery is entirely depleted it will sound an alarm and display: "Battery empty, connect to AC!“ The device must then be connected to AC power immediately. If this does not occur, the display will turn black after approx. 5-10 minutes and the alarm continues to sound for a few more minutes. The device will then deactivate until it is reconnected to AC power. Discharging the battery completely can cause permanent damage and thus should be avoided. Complete charging of an empty battery requires approximately 8 hours.

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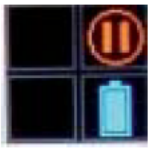
7.2.8 Pump function



If pump mode is set to "Pause", the pump will not work. To access the pump function you have to press the "Pause"-key.

Figure 11: Pump function - Pause

7.2.9 Graphic display of patient parameters

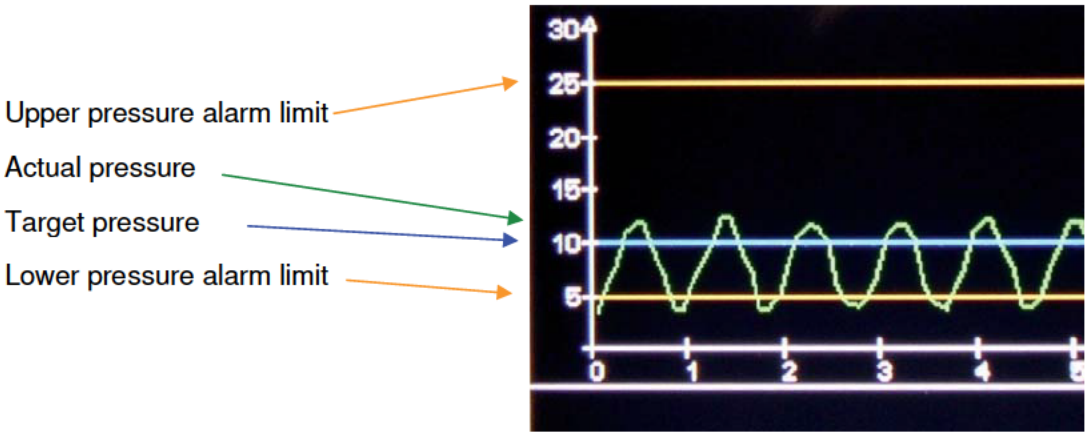


Figure 12: Display of pressure values

The upper pressure alarm limit (P-max) is the upper adjusted alarm limit for the alarm condition. The lower pressure alarm limit (P-min) is the lower adjusted alarm limit for the alarm condition.

7.3 Display operating fields

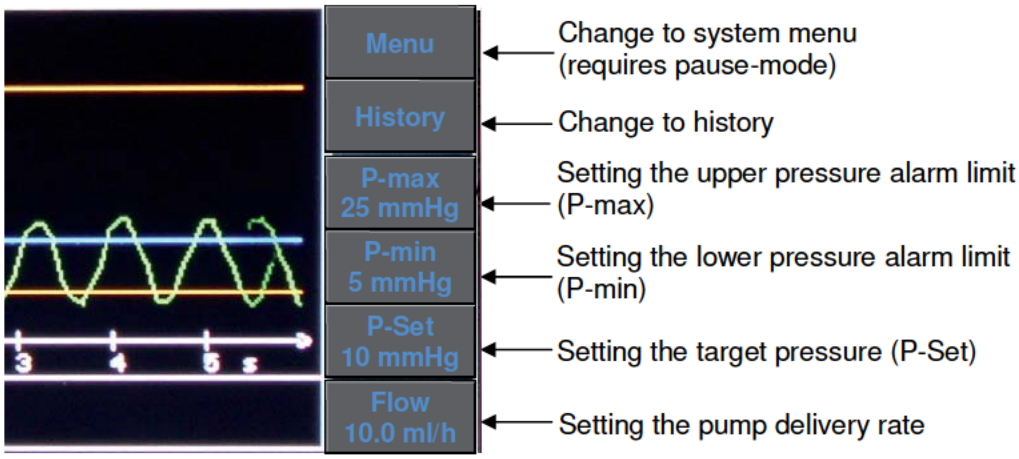


Figure 13: Display operating fields

The display control fields are selected via the turn-switch of ***LiquoGuard® CSF*** whereby the display control fields change their background color. The respective activated field is highlighted in light blue. Pressing the turn switch activates the selected display operating field and highlights it dark blue. By turning the turn switch changes can now be made in

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this field. Further depression of the push button activates the changes. (A text will appear in the display as a reminder: "Confirm changes with the wheel".) If the desired function is not confirmed within a preset time by pressing the turn switch, a timeout will occur. A negative confirmation tone is created (400 msec deep tone). In this case the originally set value is kept.

7.3.1 Quick reference guide - Setting/Changing of values:

1. Press the blue turn-switch. The “menu” field will now be highlighted.
2. By turning the switch you can move the illumination to the desired field.
3. By pressing the switch again, the highlighted field turns dark.
4. Now you can set the desired value. Important: You have to confirm this value by pressing the turn-switch again. If you forget to confirm, the new value will not be maintained and after a short interval the device will go back to the old value (operation timeout).
5. After confirmation of the new set value the field is highlighted again.
6. By turning the switch you can move the illumination again to another field.

Notes:

- If the switch is not touched for a short interval, there will be an operation timeout (no field is highlighted anymore) and you have to start at the beginning.
- By each short pressing of the Standby key you can go one step back.

To adjust the patient parameters please also read starting at Page 33.

7.3.2 Second selection menu

Pressing the Alt-key changes the menu items on the right display edge:

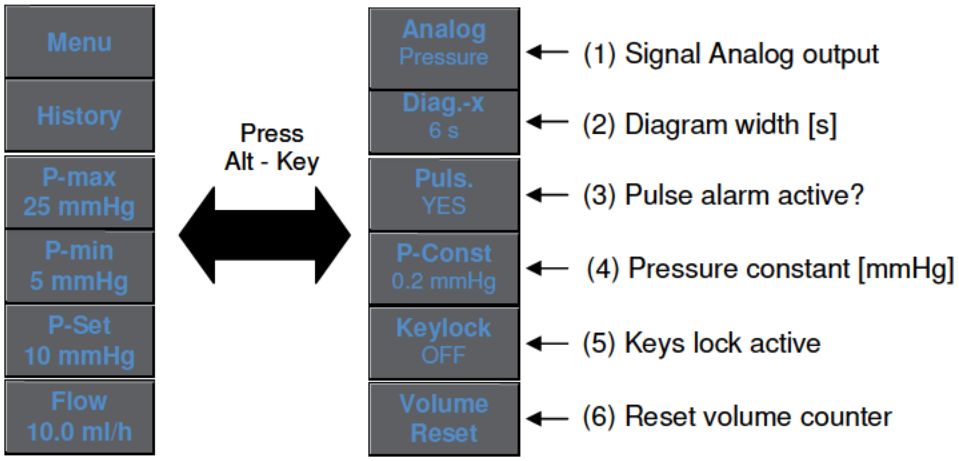

Figure 14: Second selection menu

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After the timeout period, which also applies for the system menu, you are returned to the standard key allocation as this contains the most information for the application.
Note:
If an audible alarm is active, pressing the Alt key will take you to the alarm pause selection (see page 38 Audio paused or Audio off). Therefore the Alt key has 3 levels, whereby only 2 are used without an alarm.

(1) Signal analog output

Meaning: Selection of the value to be issued via the analog output.

Possible parameter settings: Zero, Pressure, Flow

Note: The "Zero" setting serves offset correction purposes. The Pressure setting issues a value for pressure analog to the CSF-pressure measured by ***LiquoGuard® CSF.***
The same scale (20 ml/h correspond with 20 mmHg) can also be used to issue the pump flow corresponding to the history view.
This may be expedient as pressure regulation is active and if the pressure is consistent. Subsequently the quantitative size is the volume flow.

(2) Diagram width [s]

Meaning: The spread of the X-axis in the display diagram (Display) is stipulated by the Diagram Width (s).

Default value: 6 seconds (ventricular), 60 seconds (lumbar)
Minimum value: 6 seconds
Maximum value: 10 minutes

(3) Pulsation alarm active?

Meaning: Pulse recognition can be de-activated in the system menu, if patient conditions do not permit accurate measurement.

Possible settings: YES, NO (Default value: YES)

Notes:
- This parameter can only be set for ventricular application. The pulsation alarm is always de-activated for lumbar applications.

Attention: There is no reliable alarm function for catheter occlusions, catheter disconnections, or collapsed ventricles if the pulsation alarm is deactivated.

(4) Pressure constant [mmHg]

Meaning: A value of 0.2 [mmHg] means that the minimum pressure and the maximum pressure during the past 12 seconds (120 measured values) must differ by more or equal to 0.2 mmHg, so that no alarm is issued for "Pressure too constant". The alarm delay time of 20 seconds applies here, too.
The purpose of this function is to recognize a torn off/occluded catheter. The function is available for ventricular and lumbar drainage but not for the infusion test.

Default value: 0.2 mmHg
Minimum value: 0.1 mmHg (resp. OFF)
Maximum value: 2.0

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Product description

(5) Keys lock active [min]

Meaning: To prevent unintentional chages to the operating field parameters, "Keylock" can be set, so that ***LiquoGuard® CSF*** creates a keys lock after a certain inactive period. By default this function is set to OFF.

Default value: OFF
Minimum value: OFF (keys lock inactivated)
Maximum value: 60 minutes

Figure 15: Keys lock active

Symbol for active keys lock

If the keys lock is active, a key will appear in the display and no further settings can be performed via the operating field. The key lock is deactivated by pressing and holding the "**Alt key**" for 2 seconds. The lock is automatically re-activated if the preset time has lapsed without key activation.
Note: the keys lock is automatically de-activated every time an audible alarm signal is sounded. This also applies for the opening of the lid, if the question appears: "Interrupt application?".

(6) Reset volume counter

The volume counter is reset to zero when confirming "Volume reset".

Note: The key "Volume reset" is only active if "Duration volume balance" is set to "OFF" in the system menu.

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7.4 Technical Data

Order number:	**00 002 563**
LiquoGuard® dimensions:	Length x Width x Height: 280 mm x 210 mm x 315 mm (11.02 inch x 8.27 inch x 12.4 inch)
Weight:	approx. 4.8 kg (10.58 lb)
Electrical supply: Voltage 100 – 240 VAC (alternating voltage)	
Frequency	50 – 60 Hz
Current consumption	0.5 – 0.2 A
General characteristics:	
Operating conditions: Temperature Humidity	 +10 °C to +40 °C (+50 °F to +104 °F) 30 to 75 % rel. humidity
Transport - storage conditions Temperature Humidity	 -10 °C to +50 °C (+14 °F to +122 °F) less than 90 % rel. humidity
Protection category	IP 20 - ***LiquoGuard® CSF*** IP 20 - Tube set for ***LiquoGuard®***
Pump rate	1 ml/h to 120 ml/h (variably adjustable)
Flow rate accuracy	± 15 %
Pressure range	-15 mmHg to +75 mmHg
Accuracy of pressure sensors (according to data sheet)	 ± 0.5 mmHg
Display accuracy of system	± 2 mmHg
Application temperature range	+10 °C to +40 °C (+50 °F to +104 °F)
Relay output:	pure switch output for extra-low voltages of 25V AC / 60V DC, Current limitations: 3 A
Output signal of analog interface: Direct connection	 5.9 mV/mmHg (Tolerance: ± 12 mV or ± 10 % *)
With TruWave adapter cable	33 µV/mmHg (Tolerance: ± 66 µV or ± 10 % *) *The highest value is valid respectively.

<u>Attention</u>: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

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7.5 Recurring inspections

LiquoGuard® CSF must be subjected to safety inspections at least every 12 months. Documents on safety inspections can be requested from the manufacturer.

In addition to the safety inspections, further maintenance of the *LiquoGuard® CSF* is required in order to verify measures for the dual safety of the device.

Maintenance must be conducted by a maintenance center approved by the manufacturer. Information on maintenance can be requested from the manufacturer`s service division (see page 52). Enter safety inspections into the equipment log book and document inspection results. If the device is not fully functional or safe to operate, it must be repaired immediately by device service personnel. The safety inspections and technical measurement checks can be performed by the Service department of Möller Medical service@moeller-medical.com.

7.6 Dimensions, weight and transport information

LiquoGuard® CSF dimensions with packaging:	Length x Width x Height: 580 mm x 430 mm x 415 mm (22.83 inch x 16.93 inch x 16.34 inch)
Weight:	approx. 8 kg (17.64 lb)
Transport and storage conditions	
Temperature:	-10°C to +50°C (+14°F to +122°F)
Humidity:	less than 90 % rel. humidity

When transporting, do not stack more than 3 cartons above one another.

The external packaging is a folding corrugated cardboard box. The internal packaging is made from polyethylene foam rubber.

The packaging material is highly flammable and represents a fire hazard. Keep away from naked flames and do not smoke!

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8 Application and operation

LiquoGuard® CSF may only be switched on if power supply is conveyed via power input. The ***LiquoGuard®*** is ready for operation once the **ON/OFF – Standby – button** is activated. ***LiquoGuard®*** starts with a recognition signal and the current software versions as well as the Bus address are displayed for a short while.
Note: The emergency alarm is tested when ***LiquoGuard®*** is plugged in. This means you will have to hear a short beep. A function test is also performed when ***LiquoGuard®*** is activated (see page 20 "Inspection of alarm functions").

As a first step the subsequent display screen will appear.

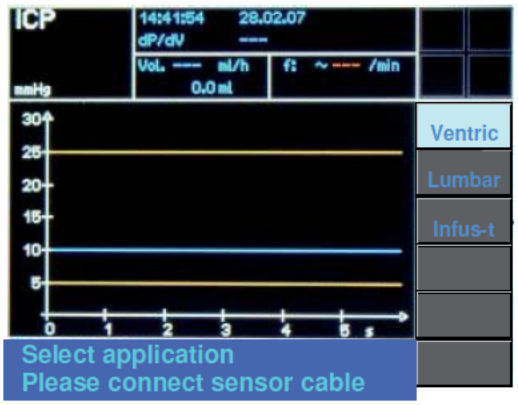
Should you not have written the data from the last patient to the memory card, this procedure can be carried out now (confirmation with the turn switch). All existing data is fully deleted once a new tube set is connected.
(This step can be skipped by activating the alt key or the standby key.)

Figure 16: Write data to memory card?

Select the desired application in the next step:

- **Ventricular drainage (Ventric)**
- **Lumbar drainage (Lumbar)**
- **Lumbar infusion test (Infus-t)**

Please read page 36 (Ventricular drainage) or page 37 (Lumbar drainage) or as of Page 54 (Option: Lumbar Infusion Test).



Turn the turn-switch to move the highlight to the desired field. Press the turn-switch to confirm the desired application.
(By pressing the "Alt" key or the "Standby" key the device is switched off.)

Figure 17: Select application

The following steps apply only to the following applications: Ventricular drainage or lumbar drainage. An additional software upgrade is required to run the device application option

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of "lumbar infusion test". This special application is described in detail in Chapter 12 (Option: Lumbar Infusion Test) as of Page 54.

8.1 Connection of the tube set

Please be sure to see that the following procedures are carried out:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.
2. Connect the tube set to the drainage bag and fasten the drainage bag to the holder provided

Note: Insert the drainage bag into the top of the bag holder at the ***LiquoGuard®*** (see Page 21, Figure 7).The drainage bag is freely suspended by the upper attachment buttons at the bag holder.

3. Insert the tube set into the pump: Ensure that the connecting pieces are correctly seated in the guides. Turn the pump rotor counter-clockwise by three rotations. Check whether the pump tube was correctly threaded.

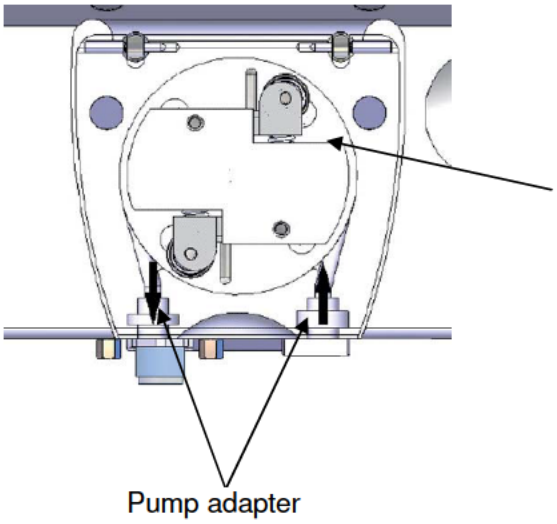

Figure 18: Pump rotor

As a first step you open the front cover of the pump and insert the tube set with the pump adapters into the pump receptacles.

Then thread in the pump tube by manually rotating the pump rotor to the left, threading via this rotor edge.

Manually turning the pump rotor counterclockwise for at least three rotations ensures that the tube is not jammed anywhere.

Then close the front cover.

4. Turn the stop cock of the 4-way manifold by 180° flow direction from the pump to the catheter… and remove the protective cap on the catheter side.

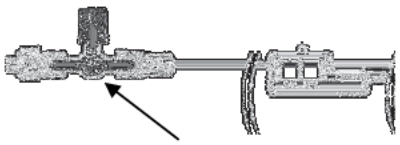

Figure 19: Stop cock setting before the application

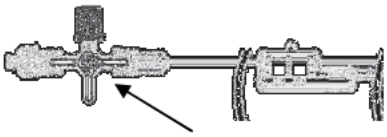

Figure 20: Stop cock setting during the application

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5. If you haven't done it yet: Connect the sensor cable to the ***LiquoGuard®*** (connection under the device).

Figure 21: Connect sensor cable to pump

Notes:

- In the event that a tube set had previously been attached, the point concerning "connect the sensor cable to the pump and wait" will be skipped, since the device will automatically recognize the tube set.
- Should you select a tube set that is unsuitable or which has already been used, the following message will appear: "wrong tube set for this application" and/or "please change the tube set". In this case, disconnect the tube set from the device. The following message will then reappear: "Sensor cable - connect to the pump and wait". Either connect a tube set which is suitable for the selected application or go back a step using the ESC key, in order to select an application for which the tube set is suitable.

6. Connect the catheter to the tube set (Please observe page 10 "Combination with other products").

7. Use the adhesive electrode (attachment area depends on application, see Pages 36/37) to attach the pressure sensor housing to the patient. Follow the display to do so:

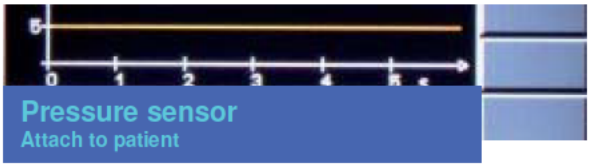

Figure 22: Attach pressure sensor

Until this point in time, the tube set can still be disconnected, use the "Esc" key to return to the beginning step-by-step. The tube set is not yet marked as being used.
As soon as the catheter and the pressure sensor are connected to the patient and this is verified by activating "Okay", the tube set is marked as used and can no longer be employed for a new application. A brief notice appears stating, "Connect sensor cable to the pump and wait", whereby the device checks to see whether the sensor cable is actually connected. At this point the alarm function will activate and the device is put into normal operating mode.

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Notes:

- During all steps observe also the instructions displayed on the ***LiquoGuard®*** and always adhere to the prescribed sequence of steps.
- After you have connected the tube set to the catheter, attached the pressure sensor housing to the patient and confirmed with "OK", ***LiquoGuard®*** electronically marks the tube set as used and it cannot be used again.

ATTENTION:

To avoid possible CSF reflux, always close the 4-way stop cock between the tube set and the catheter before removing or replacing the tube set.

The tube set must be replaced after a maximum of 120 continuous operating hours.

Attention: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

8.2 Setting of patient parameters

Setting of patient parameter target values is carried out via the display control fields, as described as of page 24. For LiquoGuard there are 2 target value settings for application as well as 2 safety settings for the alarm limits:

Setting the patient parameters may only be carried out by qualified personnel.

8.2.1 P-max:

P-max (mmHg) is used to set the upper alarm limit for **LiquoGuard®** alarm conditions. If the filtered actual ICP value is higher than the upper pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 25 mmHg
Minimum value: limited by P-Set
Maximum value: 75 mmHg

8.2.2 P-min:

P-min (mmHg) is used to set the lower alarm limit for ***LiquoGuard®*** alarm conditions. If the filtered actual ICP value is smaller than the lower pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 0 mmHg
Minimum value: -15 mmHg
Maximum value: limited by P-Set

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8.2.3 P-Set or P-Stop

During ventricular application **P-Set** (mmHg) is used to set the target value for pressure regulation. If the filtered actual ICP value (mmHg) reaches a pressure higher than **P-Set**, the ***LiquoGuard®*** pump is activated and pumps off the CSF. Pumping continues until the filtered actual ICP value reaches a pressure value lower than **P-Set**. The symmetrical hysteresis value (standard 0.5 mmHg) of this regulation is adjustable in the menu.
During lumbar application **P-Stop** (mmHg) is used to specify the value under which the pump no longer conveys.

Default value:	15 mmHg
Minimum value:	2 mmHg or limited by P-min
Maximum value:	limited by P-max

8.2.4 Flow

Flow sets the pre-selected flow rate of the ***LiquoGuard®*** pump (ml/h). Therefore pumping of the CSF can be influenced by time.

Default value:	20 ml/h
Minimum value:	1 ml/h
Maximum value:	50 ml/h (ventricular application)
	20 ml/h (lumbar application)

Notes:

- When starting a new application (by switching on the device), the parameters are always automatically reset to the standard values.
- In the event that an application is interrupted or when a tube set is renewed (without turning off the device), the parameter values last used will remain set.

Default values:

- **P-max: 25 mmHg**
- **P-min: 0 mmHg**
- **P-Set: 15 mmHg**
- **Flow: 20 ml/h**
- **Pulse alarm: "ON"; coupled to: Filter time Control 1.0**
- **Pressure constant : 0.2 mmHg**

ATTENTION:

An adjustment of the standard values may only be carried out by specialists.
Before every use, the user should check to see whether the momentary settings are suitable for the patient!

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8.3 Short checklist

After attaching the tube set and setting all patient parameters, ***LiquoGuard® CSF*** works independently. Before letting the system work independently you should review the following short checklist:

- **Is the tube set correctly inserted in *LiquoGuard®*?**
- **Are the catheter and drainage bag connected correctly?**
- **Are the stop cocks of the tube set in the correct position for the application?**
- **Are the set patient parameters correct?:**
  - **P-Set or P-Stop - *Pressure setting parameters***
  - **Flow - *Pump delivery rate settings***
- **Are the set alarm limit values correct for the following alarm conditions:**
  - **P-max - *upper alarm limit value for the alarm condition***
  - **P-min - *lower alarm limit value for the alarm condition***
- **Is the pulsation alarm activated?**
- **Is the "Pressure constant" alarm activated and properly set?**

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8.4 Ventricular drainage

During ventricular drainage, ***LiquoGuard® CSF*** functions as a pressure controlled tube pump. Adjustment specification here is **P-Set.** The pressure housing must be attached at the height of the Foramen Monro. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore the position of the sensor at the head must be considered when evaluating pressure values.

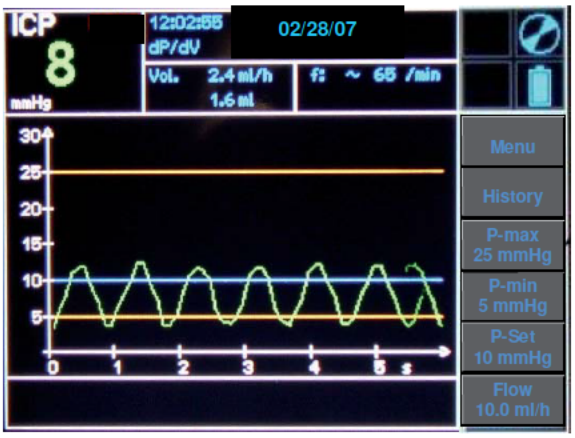

Figure 23: Display setup during ventricular drainage

There are 4 physiological alarm limits during ventricular drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)
- **Measured pulse frequency invalid** (f <= 30/min - fixed limit value)
- **Measured pulse frequency invalid** (f 180/min- fixed limit value)

ATTENTION:
In both important cases of catheter blockage and collapsed ventricles it is usually the case that the pulse can no longer be measured, which triggers an alarm - if activated!

By default, pulsation alarm is set to on. It is an additional monitoring function to increase patient safety (see page 22: Pulsation frequency of pressure signal (f: ~ ---/min)).

It would be expedient to deactivate pulse recognition in the system menu, if patient conditions do not permit accurate measurement. As an indication to the operator that pulse recognition is deactivated, the system displays “(f:)" instead of “f:“.

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8.5 Lumbar drainage

During lumbar drainage, ***LiquoGuard® CSF*** functions as a volume controlled tube pump. The specified setting here is the pump flow rate (**Flow**). During lumbar drainage, pulse recognition is deactivated, the time axis is set to 60 seconds by default and P-Set becomes P-Stop (see page 34, P-Set or P-Stop).
The pressure sensor housing should always be on or slightly below the level of the catheter end in the spine. Ask the patient about his sleeping behaviour. Patients sleeping on their sides should have the pressure sensor housing attached to their backs. Patients sleeping on their backs should have the pressure sensor housing attached to their sides. A safety cushion (available as an accessory) can be applied to avoid pressure pains. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore avoid that the patient lies on the side, at which the sensor is attached.

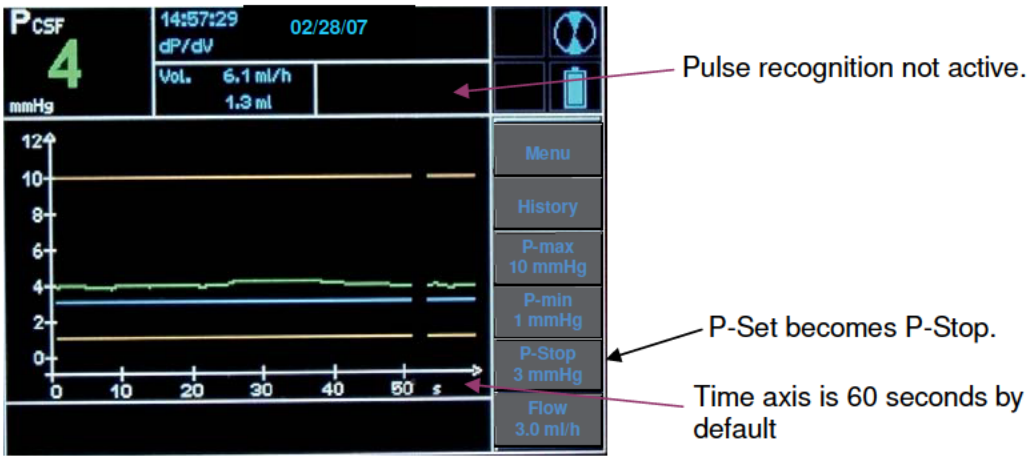

Figure 24: Display setup during lumbar drainage

There are 2 physiological alarm limits during lumbar drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)

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8.6 Audio paused or Audio off

In case of an alarm condition, the alarm signals are created with a 20 second delay. The alarm condition is also displayed. In case of multiple alarm condition these are displayed alternatively. (In the example contained in Figure 25 "Measured pulse frequency invalid!" alternates with "Measured pressure too low!".)
Additionally a key menu with 4 options appears on the right hand side of the display: Audio Pause 20 min (duration settable in system menu), Audio Pause 60 min, Audio Pause 180 min and Audio off.

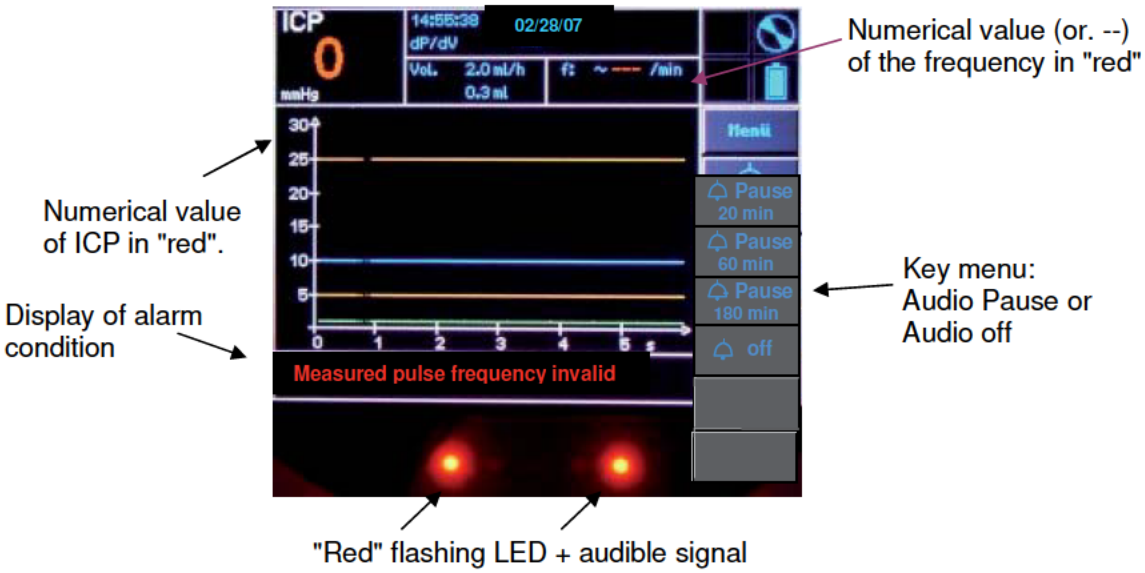
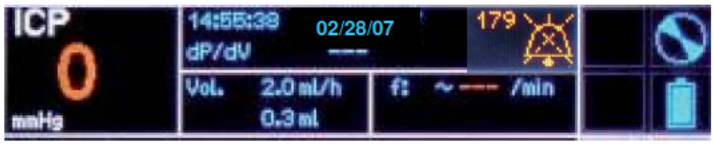


Figure 25: *LiquoGuard® CSF* in alarm mode

The *LiquoGuard® CSF* alarm system cannot be deactivated. The function "Audio paused" or "Audio off" can create a condition in which no audible alarm signal is emitted.



Use the turn switch to select the desired bell (Audio Pause 20 min, Audio Pause 60 min, Audio Pause 180 min or Audio off) and press the turn switch to confirm the function "Audio paused" or "Audio off". This condition is displayed by a crossed out red bell. The remaining duration in minutes is displayed on the left hand side (see Figure 26). In the case of "Audio off" it displays "OFF".

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"Audio paused" and "Audio off" refer to all alarm conditions active at the time of key activation.
In the case of the 3 audio pause time, the cancellation of the alarm condition does **not** lead to the cancellation of "Audio paused". In the case of "Audio off" the cancellation of the alarm condition does lead to the cancellation of the condition "Audio off".

Example:
- Alarm due to low pressure and pulse
- Audio Pause 20 min was pressed
- Both alarm conditions are cancelled and return (within 20 minutes) → Audio Pause remains constant
- Pressure rises to overpressure alarm: An audible alarm is sounded
- Renewed activation of Audio Pause 20 min
- The old alarm pause is deleted, the new pause now applies for 20 minutes for overpressure only!

Notes:

- The delay time of 20 seconds applies for each individual alarm condition.
- In the case of alarm conditions "Sensor defective or disconnected" and "Device error" the pump is stopped, irrespective of further conditions. This is marked by the display of a red pump symbol.
- If an alarm is created and if alarm paused is not pressed for 1 hour, the pump is stopped (this does not apply for exceeding P-max). This is also displayed by a red pump symbol. If alarm pause is pressed, the pump restarts immediately if the alarm condition permits this.
- Aside from the alarm condition (displayed in red), possible reasons for the alarm condition may also occur (e.g. "frequent causes: Catheter occluded/disconnected, ventricles collapsed, …). These should provide an indication for the possible reason for this alarm condition, although it is the responsibility of the medical personnel/the physician to determine the actual reason for this alarm condition.
- Should "Audio pause" or "Audio off" be activated, this setting can be cancelled by activating the "Audio on" button (through "Audio on" an audible (acoustic) alarm signal will be reactivated). The "Audio on" field can be reached by pressing the alt key twice.

Figure 27: *LiquoGuard® CSF* – „Audio On"-key

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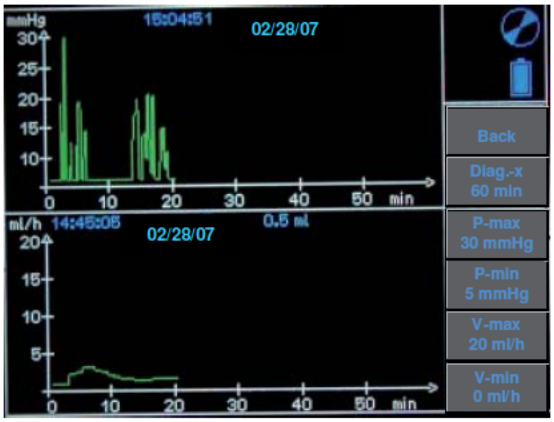
8.7 History

You can move to the "History" function via the display control field key "**History".** You can leave the "History" function via the Standby key, as well as via the Back button or the Alt key.
In the "History" function 2 diagram fields are displayed:

The upper diagram displays the pressure value [mmHg] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].



Display operating keys

Figure 28: History frame

The lower diagram displays the pumped-off CSF volume [ml/h] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].

Display control keys:

- **Diag.-x**
  This key is used to set the time spread of the axis (x-axis) from:
  - 10 seconds to 120 seconds in increments of 10 seconds,
  - 3 minutes to 120 minutes in increments of 1 minute,
  - 3 hours to 72 hours in increments of 1 hour,

  The setting is the same for both diagrams.
- **P-max** / **P-min**:
  You can use these two keys to set the spread of the pressure values (y-axis) in the upper diagram (adjustable from -50 mmHg to 99 mmHg).
- **V-max/V-min** :
  You can use these two keys to set the spread of the volume values (y-axis) in the lower diagram (adjustable from 0 ml/h to 130 ml/h).

You can view the long-term process of the two diagrams in time frames using the turn-switch.
The two blue digital displays in the lower diagram will show you the time frame for time and date of the y-axis position. The volume value on the right indicates how much CSF (ml) was conveyed in that precise time period (whereby the balance is determined from the displayed measurement values).

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8.8 Output of memory data

The internal memory of ***LiquoGuard®*** provides space for 150.000 data sets.
In the following table you can see the relation between sampling interval and memory storage time:

Sampling interval	Memory storage time
6.0 s	10d 09h 39m
5.0 s	8d 16h 03m
4.0 s	6d 22h 26m
3.0 s	5d 04h 49m
2.5 s	4d 08h 01m
2.0 s	3d 11h 13m
1.5 s	2d 14h 24m
1.0 s	1d 17h 36m
0.5 s	20h 48m
0.2 s	8h 19m
0.1 s	4h 09m

Please remember: The smaller the sampling interval, the more frequently the data will have to be stored on a card, since the data will otherwise be overwritten.

The following data is stored in the internal memory of ***LiquoGuard® CSF.***

- Date
- Time
- Pressure
- Flow
- Compliance
- P-Set
- Flow-Set
- Pause: 1 if pause, otherwise 0
- Pumping: 1, is pump is activated, otherwise 0
- Marker: at the moment always 0
- Statuscode

Table headlines:

Date	Time	Pressure	Flow	Compliance	P-Set	Flow-Set	Pause	Pumping	Marker	Statuscode

An MMC or SD memory card (format: FAT 16) can be used to read out data created by ***LiquoGuard® CSF***. Insert the memory card into the slot next to the pump, whereby the contacts must point towards the pump head. ***LiquoGuard® CSF*** will ask whether the data must be written to the card. Confirmation with "Yes" will immediately start the copying process. The card symbol will change its color to orange; the inside of the symbol will display the percentage of the already copied data. After copying is completed, the symbol changes back to blue and the card can be removed.

Figure 29: Symbol for memory card

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During writing the software checks whether a memory card is full. The writing procedure becomes irregular towards the end and if there is insufficient space, the error message "Error while writing to card!“ will be displayed. The started file is subsequently deleted and the card symbol will display “Err“, until the card has been removed.
In this case ensure that there is sufficient memory on your card and then resave. (A full internal memory requires approx. 4 - 5 MB memory capacity).

ATTENTION: The card must not be removed during the copying process!
All data on the memory card may be irretrievably lost!

8.9 Replacement of tube set

After 5 days, ***LiquoGuard® CSF*** displays two round flashing red arrows in the info field of the keys lock (see page 26) together with the red text "Please change tube set!". This indication is not an alarm. If keys lock is active, the tube set symbol alternates with the key symbol. After 7 days, ***LiquoGuard® CSF*** emits the same message as an alarm. The alarm pauses can be used here, but the alarm does not disappear during this application.
In order to perform a proper change of the tube set, the application has to be interrupted with "Set change" (see 8.10).

Figure 30: Symbol for tube set replacement

8.10 Interruption of an application

There are 2 ways to interrupt an application:

1) Press and hold the **"ON/OFF – Standby – key"** for at least 2 seconds
2) Open the front cover of the pump of the ***LiquoGuard® CSF***

Both of these ways cause a new selection menu to appear on the right side of the display showing 4 different points to be selected (Interrupt, END, Change set, Esc)

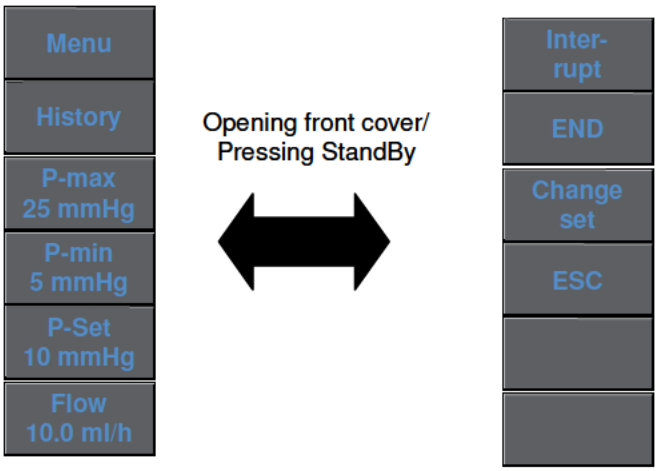

Figure 31: Interrupt, END, Change set

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Should you wish to change the tube set, select "Change set". If you want to interrupt the application (e.g. to perform a CT), select "Interrupt". In both cases, the next question to appear will be, "Interrupt application?". By selecting "Yes", the question, "valve to catheter closed?", will appear.
Be sure to see that the shut-off valve to the catheter is closed, then verify this with "Okay". The tube can now be removed (and reconnected later) or the tube set can be renewed.
When the tube set is reattached, one should not forget to open the shut-off valve to the catheter once again.

Notes:

- If the sensor cable is disconnected, the notice "Interruption, connect tube set" will appear and the symbol for a circulating pump will be displayed in red. The measuring value will be displayed as -- . In the data record you can recognize this condition as measuring values < - 90 mmHg
- Pulling the plug from the tube set without following the instructions described above will always lead to the alarm condition of "Sensor defective or disconnected". Should this occur, reattach the plug. Should you wish to end or interrupt the application, or to change the tube set, please follow the instructions described above.
- When the alarm condition "Sensor defective or disconnected" appears, it is impossible to activate "Audio pause" or "Audio off". An intentional removal of the tube set must be performed using the 4 keys on the right edge of the display (Interrupt, End, Change set, Esc; see Figure 31) (as described above, these 4 keys can be activated using the Standby key or by opening the cover). The device will recognize any other procedure as being faulty.
- With "Esc" you will always be able to return to the normal control display.

8.11 Exiting the application

Press and hold the ON/OFF - Standby key for at least two seconds. As described under 8.10, a selection menu with 4 points will appear. Select "End". The question "Sure to turn off the device?" will appear and the total volume of the application will be displayed. If confirmed with "Yes", ***LiquoGuard® CSF*** will exit the application and switch off.

Please observe that you cannot start a new application with the used tube set.

Should you have forgotten to read out the data via the memory card, you can restart ***LiquoGuard® CSF*** and read out the data one last time. The connection of a new tube set deletes all existing data.

In Standby mode (***LiquoGuard® CSF*** - is connected to AC power) the blue LED flashes and the battery is charged.

If the AC power chord is disconnected, ***LiquoGuard® CSF*** is switched off.

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8.12 Demonstration mode

The device has a demonstration mode ("Demo mode"), which may only be used for the purpose of performing demonstrations and for teaching! The Demo mode can be recognized through the red flashing "Demo" indicator to the upper left of the display (to the right and beside ICP/P_{CSF}).
One automatically comes to the Demo mode when a special, unsterile demonstration tube set is connected.
Note: In the Demo mode, the device will turn off automatically after a certain period of time without previous warning! The Demo mode should NEVER be used on a patient!

8.13 System menu

Use the display control field key “Menu” to access the "System menu". However, access to the system menu is only possible if ***LiquoGuard® CSF*** is in "Pause mode". The selection bar is moved with the turn-switch. The corresponding sub-menu is selected by pressing the turn-switch. The submenus consist of several parameters that are displayed in sequence. A further parameter is always reached by pressing the turn-switch. You can now change the preset value by turning the turn-switch. A value being edited is displayed as orange during this time. If you want to accept the changed value, press the turn-switch. A text will appear in the display as a reminder: "Confirm changes with the wheel".

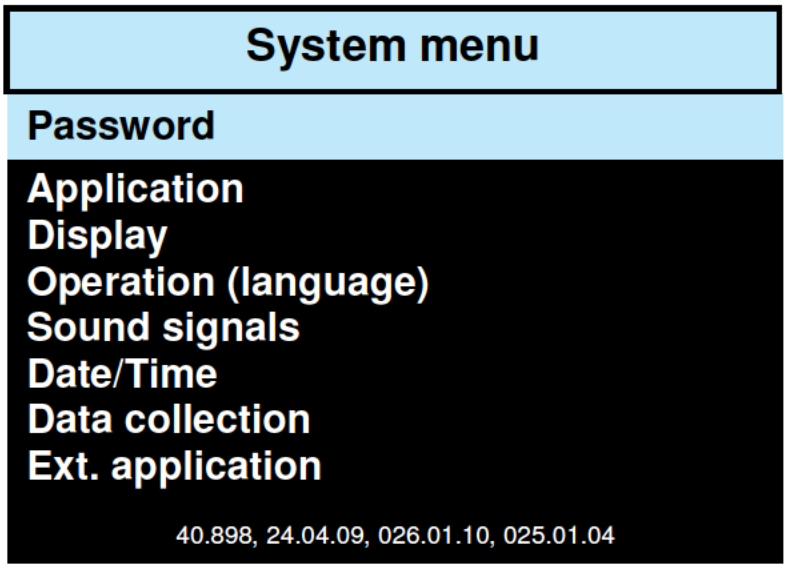

Figure 32: System menu

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Input of figures in the system menu is also possible in numbers. To activate this function during number input in the system menu, press the Alt key. A numeric keyboard appears in which you can enter values using the wheel. Press “END” to accept the values. Values which are too large are automatically limited by the maximum value. The Alt key therefore no longer serves as Esc at this point.

Figure 33: Numerical input

If the value is not to be adopted, leave the level with the Standby key or wait until the system menu is automatically exited - a negative confirmation tone is then sounded. You can set the time for automatic exiting (Standard 60 seconds).

8.13.1 Sub-menu Password

This point currently has no function for the operator. All menu items remain visible for the operator.

8.13.2 Sub-menu Application

The settings for the application are made in the Application sub-menu.

(1) Sampling rate memory [s]

Meaning: Time step in which a measured value is saved to memory.

Default value: 6.0 seconds
Minimum value: 0.1 seconds
Maximum value: 600 seconds

(2) Duration of volume balance [h]

Meaning: Time step for calculating the volume balance – also see page 23 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h).

Default value: 24 hours
Minimum value: OFF (set values: OFF, 2 h … 24 h, steps of 2)
Maximum value: 24 hours

(3) Flow increment

Meaning: This setting changes the increment for the operating field "Flow" (ml/h).

Default value: 1.0
Minimum value: 0.1
Maximum value: 10.0

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(4) Pressure increment

Meaning: This setting is used to change the time step for the operating fields "P-max / P-min / P-Set" (mmHg).

Default value: 1.0
Minimum value: 1.0
Maximum value: 10

(5) Duration Audio pause

Meaning: This setting sets the time for the shortest possible duration of "Audio paused".

Default value: 20 minutes
Minimum value: 1 Minute
Maximum value: 20 minutes

(6) Define application

Meaning: This can be used to reset the type of application during an application.

Possible parameter settings: lumbar, ventricular
(No default value, setting remains after reset)

8.13.3 Sub-menu Display

The settings for the display are made in the "Display" sub-menu.

(7) Range diagram

Meaning: The pressure axis in measuring mode is automatically scaled according to the alarm limits. In order to display a larger range, 20 % more than the upper alarm limit and 20 % less than the lower alarm limit are shown. The percentage is always related to the upper alarm value.

Default value: 20 %
Minimum value: 0 %
Maximum value: 100 %

Example: P-min = 5 mmHg, P-max = 25 mmHg, the diagram ranges from 0 mmHg (5-5) to 30 mmHg (25+5).

(8) Timeout backlight [s]

Meaning: In order to save power or to have a darker screen during night operation, the background lighting automatically switches into the darkest setting after an adjustable time (seconds). If this function is not wanted, the parameter can be set to OFF. During battery operation, the display is always darkened after 5 seconds.

Default value: OFF
Minimum value: OFF
Maximum value: 600 seconds

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(9) Brightness Display

Meaning: The brightness of the background lighting of the display is preset here. The value directly affects the display as it is changed so that the user can find the correct setting more easily. Setting is made in 4 steps.

Default value: 4
Minimum value: 1
Maximum value: 4

(10) Colour mode

Meaning: You can select a colour mode setting between 1 and 0.

"1" " means "dark" display background colour
"0" " means "light" display background colour
(Default value: “dark” display background colour)

8.13.4 Sub-menu Operation (language)

The "Operation" sub-menu contains functions that relate to the behavior of the unit with respect to the user.

(1) Language (language)

Meaning: The display language can be set here, and further languages can be stored.

Default value: ENGLISH
Value (depending on configuration): DEUTSCH, ENGLISH, Français, Svenska

(2) Operation Timeout [s]

Meaning: Settings or key activations are exited after a set time in seconds, independent of the level or in which parameters the input is carried out. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the input can only be exited by pressing the service screen "Standby" or "Alt". This time does not apply to the system menu.

Default value: 10 seconds
Minimum value: 1 second
Maximum value: 120 seconds

(3) Timeout menu [s]

Meaning: The system menu is closed after the preset time in seconds, independent of the level or the parameter currently being entered. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the system menu can only be exited by pressing the service screen "Standby" or "Alt".

Default value: 60 seconds
Minimum value: OFF
Maximum value: 600 seconds

8.13.5 Sub-menu Sound signals

The operator cannot change the volume of the activation signal.

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8.13.6 Sub-menu Date/Time

The system clock of ***LiquoGuard®*** can be set or changed respectively in this sub-menu.

(1) Date format

Meaning: Setting the date format

Default value: DD.MM.YYYY
Possible parameter settings: DD.MM.YYYY; MM/DD/YYYY; YYYY-MM-DD

(2) Clock: Year

Meaning: Setting of the current year

Minimum value: 2001
Maximum value: 2099

(3) Clock: Month

Meaning: Setting of the current month

Minimum value: 1
Maximum value: 12

(4) Clock: Day

Meaning: Setting of the current day

Minimum value: 1
Maximum value: 31, depending on the set month

(5) Clock: Hour

Meaning: Setting of the current hour

Minimum value: 0
Maximum value: 23

(6) Clock: Minute

Meaning: Setting of the current minute

Minimum value: 0
Maximum value: 59

(7) Clock: Second

Meaning: Setting of the current second

Minimum value: 0
Maximum value: 59

8.13.7 Sub-menu Data collection

(1) Decimal point

Meaning: Decimal markers in figure display on memory card. This setting is required for various countries.

Default value: Comma
Possible parameter settings: Comma, full stop

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(2) Data format MMC

Meaning: Setting the data format output depending on evaluation software

Default value: ASCII
Possible parameter settings: ASCII, LABpilot

8.13.8 Sub-menu Extended application

(1) Hysteresis controller [mmHg]

Meaning: This setting pre-selects a defined hysteresis for the pressure controller (target pressure curve). The hysteresis is symmetric to the target value, i.e. a target value of 12 mmHg and a hysteresis of 0.5 mmHg starts the pump at a pressure higher than 12.5 mmHg and will pump until the pressure is lower than 11.5 mmHg.

Default value: 0.5 mmHg
Minimum value: 0.5 mmHg
Maximum value: 1.5 mmHg

(2) Filter time control [s]

Meaning: The measured value for display of the digital pressure value can be filtered to avoid too high pressure changes of the digital pressure value as well as a continuous on and off of the pump. In order to filter out the pulse beat, the value must be set to at least 1.0 seconds. The set value displays after which time period 63% of the new value was reached after a step.

Note: This value is coupled to the pulsation alarm during ventricular drainage. If the pulsation alarm is ON, it is activated, the value is automatically set to 1.0; if pulsation alarm is OFF, it is set to 0.0 (in order to achieve a more rapid reaction time for the pump). This can be set manually by way of the system menu, but will once again be returned to the standard values when an adjustment is made for the pulsation alarm.

Default value: 1.0 (lumbar drainage, lumbar infusion test and ventricular drainage if pulsation alarm ON); 0.0 (ventricular drainage if pulsation alarm OFF)
Minimum value: 0.0
Maximum value: 60.0

(3) Filter time display or filter time display lumb. [s]

Meaning: The measured value for display in the diagram can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. If a clearly higher value is selected instead of a time resolution of 6 seconds, we recommend setting a longer filter time to enable the display of an averaged value. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 0.0 ventricular drainage; 0.5 lumbar drainage / lumbar infusion test
Minimum value: 0.0
Maximum value: 60.0

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(4) Filter time history [s]

Meaning: The measured value to store the data for the history function and the memory card can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. But then the scan time for the memory must obviously be set to 0.1 seconds. For a storage time of 1 second or more you should also select a filter constant of 1 second or more, so that averaged values can be stored. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 1.0
Minimum value: 0.0
Maximum value: 60.0

(5) Average value volume [min]

Meaning: Period for the calculation of the average volume flow

Default value: 15
Minimum value: 15
Maximum value: 60

(6) System information

Meaning: The setting "Yes" is used to display system information serving Möller Medical service staff for remote diagnosis.

(7) Reset System menu

Meaning: With the setting or changing of Reset System menu to "Yes", all changed setting parameters in the system menu are reset to standard values stipulated by the manufacturer. If confirmed with "No", all settings changed by the operator will be retained.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Troubleshooting

***LiquoGuard®* CSF may not be opened by the operator!**

This chapter describes some problems which may occur in connection with ***LiquoGuard® CSF*** Several possible solutions are listed for each problem. The first proposed solution is generally the most suitable. If the problem is not resolved, work through the proposed solutions in the order listed until the fault is rectified. ***LiquoGuard® CSF*** must always be switched off during connection or disconnection of connectors, with the exception of the tube set. If this does not remove the error, please contact the Möller Medical service division: service@moeller-medical.com.

Problem	Solution
Not functional, the display is switched off. Or ***LiquoGuard® CSF*** cannot be activated.	***LiquoGuard® CSF*** is not correctly connected to the AC power supply. Check power supply, switch on any multiple sockets, and check feed line. If these possibilities can be excluded, the error must be corrected by the service centre.
Pump does not rotate.	Pump is in "PAUSE" mode
Moistness penetrated the connectors	Pull AC power chord. Allow connectors to dry.
The device issues a rhythmic beep	Indicates an alarm. Press the Standby key 3 times in succession. If the device returns to this condition repeatedly, the device should be checked by Service.

If these measures do not eliminate the problem, the device should be inspected by Möller Medical service personnel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10 Service

If the solution to a problem cannot be found, please contact the responsible service centre of Möller Medical.

Each return delivery of ***LiquoGuard® CSF*** must exclude risk of infection by a previously conducted disinfection procedure. The disinfectant may not be sprayed into the memory card slots.

Consumable materials should be disposed of in accordance with hospital guidelines.

Service Information

Never open the device if it is connected to the power supply. Attention - even then internal unit parts can still be voltaged.

Möller Medical service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
D – 36043 Fulda
Phone: +49 (0) 661 / 94 19 5 - 0
Fax. +49 (0) 661 / 94 19 5 - 90
http://www.moeller-medical.com
E-mail:info@moeller-medical.com

Service
Phone: +49 (0) 661 / 94 19 5 - 48
Fax. +49 (0) 661 / 94 19 5 – 92
E-mail:service@moeller-medical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11 Accessories

The products described here represent only a small selection of the equipment available for ***LiquoGuard® CSF***. The currently valid list of equipment (including the prices) can be requested from Möller Medical on a separate Order form (neurochirurgie-vertrieb@moeller-medical.com; +49-(0)661-94195-85).

11.1 Tube set for LiquoGuard®

REF.-No.: 92 007 836 (1500 mm/59.06 inch)
1 cmpl packed Article No.: **00 002 650**

REF.-No.: 92 008 568 (2000 mm/78.74 inch)
1 cmpl packed Article No.: **00 002 911**

11.2 *LiquoGuard®* Software: Lumbar Infusion Test

Additional option for ***LiquoGuard®*** Article No.: **00 003 165**

11.3 Tube Set for the Lumbar Infusion Test *LiquoGuard®*

REF. No.: 92 008 646 (1500 mm)
1 cmpl packed Article No.: **00 002 962**

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12 Option: Lumbar Infusion Test (Not available in the US)

Unlike in CSF drainage, this application consists of infusing artificial cerebrospinal fluid (CSF) into the spinal canal.

ATTENTION: A prerequisite for the lumbar infusion test is that the operator is familiar with the regular use of ***LiquoGuard®,*** that she/he has received extensive training on the device and has read and understood the instruction manual in its entirety.

12.1 General Description

The lumbar infusion test is an established clinical method for indirect measurement of the CSF absorption capability of patients with normal pressure hydrocephalus (NPH). Following the puncture of the intrathecal space, a suitable infusion system with combined pressure measurement is connected, fluid is pumped into the subarachnoid space of the patient at a defined flow rate, and the cerebrospinal pressure is measured simultaneously. The user determines the flow rate and detects the initial and final fluid pressure values.
In the lumbar infusion test with ***LiquoGuard®***, artificial CSF ("infusion solution" - saline solution or CSF substitute) is infused into the patient at a defined flow rate (volume flow rate "Flow"). The pressure value prior to infusion (P-Start) and the stabilized pressure value during infusion (Plateau) are required to compute the ROF (Resistance to OutFlow). The ROF is computed as follows:
(Plateau [mmHg] – P-Start [mmHg]) / Flow [ml/min].
This value is indicated on the ***LiquoGuard®*** display. The ROF dimension is [mmHg / (ml/min)]. The display indicates this in the same manner, although "Flow" is adjusted in [ml/h].
The patient must lie down for the duration of the application to avoid excess pressure.
Qualified personnel must be present for the duration of the application. The measured value depends directly on the initial pressure and the plateau pressure set by the physician. The physician is therefore directly responsible for the measurement results.

Attention:
Reaching a plateau level is dependent on the health of the patient. The physician must monitor the patient constantly and must interrupt or discontinue the test using the Pause key in cases where the patient is observed to demonstrate dangerous pressure levels. The evaluation of these pressure levels is alone the responsibility of the physician; the ***LiquoGuard®*** serves merely as an aid to make this work easier.

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Option: Lumbar Infusion Test (Not available in the US)

12.2 Purpose

The option "lumbar infusion test" of the ***LiquoGuard®*** may only be used in conjunction with the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646**. This tube set also contains the spinal cannula (touhy needle) which is needed for the infusion test.

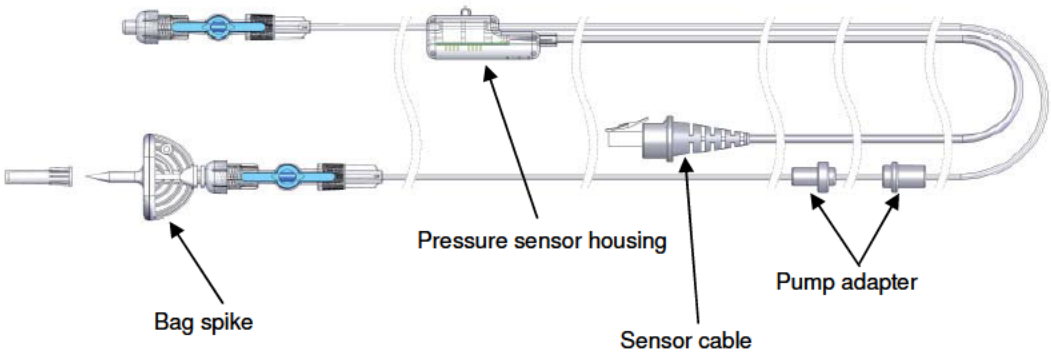

Figure 34: Tube set for lumbar infusion test (spinal cannula and adhesive electrode not displayed)

The purpose of the tube set "tube set for lumbar infusion test ***LiquoGuard®***" is to convey at constant flow rate up to 100 ml infusion solution (physiological saline solution or CSF substitute) through the spinal canal with simultaneous pressure measurement. The purpose of the device in conjunction with the tube set is: "to carry out the lumbar infusion test".
The appropriate location for its application includes monitored medical hospital rooms or neurosurgical practices. Qualified personnel must stay with the device/patient for the entire duration of the application.
The application time is limited to one hour.

The tube set for the lumbar infusion test is intended for use in combination with ***LiquoGuard®*** and must therefore be connected to this system, i.e. the set alone cannot fulfill the intended purpose of the system. It has been designed exclusively for the infusion of CSF-like fluid into the subarachnoid space and must not be used for the infusion of drug solutions or other constituents. The lumbar infusion test only serves for NPH diagnosis by means of the evaluation method referred to as "lumbar infusion test" in the related literature. The withdrawal of CSF or the connection to other body systems (e.g. blood system) are incompatible with its intended use.

For this special application ***LiquoGuard®*** may be used for the infusion of fluid (saline solution or CSF substitute) into the spinal canal.
It is, however, not an infusion pump because the lumbar infusion test serves diagnostic purposes and is continuously monitored by the operator.

ATTENTION: The lumbar infusion test must not be the only means of diagnosis resulting in measures taken on the patient.

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Option: Lumbar Infusion Test (Not available in the US)

12.3 Indications

Diagnostic indications for lumbar infusion test

The nervous system (brain, spinal cord) is surrounded by cerebrospinal fluid (CSF). The production and absorption of CSF are in a stable balance. Normal pressure hydrocephalus (hereinafter abbreviated as NPH) is a disease that involves an imbalance between the production and absorption of CSF. Patients with this clinical picture can show numerous different symptoms such as gait disorders (magnetic gait), memory disturbances and micturition problems (incontinence). These symptoms are typical of NPH, but can also be diagnosed in individuals with other cerebral disorders (such as Alzheimer's disease or other dementia problems). The treatment of NPH involves the continuous drainage of CSF from the ventricles of the brain into another body cavity, usually intraperitoneal (ventriculoperitoneal shunt = VP shunt) or into the blood system (usually into the atrium, i.e. ventriculo-atrial shunt = VA shunt). In order to determine whether and how a shunt system can contribute towards successful therapy, meticulous diagnosis must be performed in order to ascertain whether a patient actually suffers from NPH. Besides the determination of clinical symptoms, imaging diagnosis is required in order to check for typical NPH symptoms (extension / disproportion of ventricles, effacement of the cerebral sulci, etc). Since, however, the combination of clinical and imaging exams is not sufficient for safe diagnosis, further examination methods must be applied. Besides continuous lumbar drainage, the lumbar infusion test represents an additional method for NPH diagnosis verification.

12.4 Execution of the lumbar infusion test

The puncture of the intrathecal space is a prerequisite for the lumbar infusion test. The patient is usually placed in the lateral position, the skin in the centreline of the lumbar spine is disinfected, and under sterile conditions the subarachnoid space is punctured using a suitably dimensioned spinal cannula. As soon as the proper CSF flow is ensured, a tube system is connected to the positioned needle. This tube system is connected to a pressure measuring device. Using an infusion pump, sterile, CSF-like fluid can be infused via the tube system. Prior to starting the infusion, the initial pressure must be measured. Afterwards, the fluid is infused at a defined rate (in most cases 1 to 2 ml/min) while continuously measuring the pressure until a specific plateau pressure has been reached, or until a critical pressure value forces the attending physician to abort the test. To calculate the ROF ratio (resistance to outflow, indicated in mmHg/ml/min), the pressure difference determined (plateau pressure – initial pressure) is divided by the flow rate (ml/min). A ratio higher than the critical value (in most cases 12-18 mmHg/ml/min) is an essential criterion for the diagnosis of an NPH. However, expert literature does not describe the lumbar infusion test as a single method for NPH diagnosis, and this method is not suitable for this purpose.

Puncture of the subarachnoid space

The subarachnoid space is punctured by means of a spinal cannula (usually a Touhy needle).

Intrathecal CSF drainage

The withdrawal of CSF requires the surgical installation of an approved cannula into the intrathecal space. This surgical intervention is indicated in case of suspicion of NPH.

12.5 Contraindications

The contraindications determined for any other puncture of the subarachnoid space also apply in this context:

Absolute contraindications: Blood coagulation disorders, thrombocythemia, superficial or deep infections of the skin, bone, meninges or brain. Especially in case of cerebral,

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meningeal or intraventricular infections (encephalitis, meningitis and ventriculitis), increased intracranial pressure, CSF passage dysfunctions and expansive spinal column or cord processes

12.6 Use in Conjunction with other Products

The option "lumbar infusion test" of the ***LiquoGuard®*** may only be used in conjunction with the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646** by Möller Medical. Accordingly, the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646** may only be used with the option "lumbar infusion test" of the ***LiquoGuard®***.

12.7 Patient Population

This application may only be used on patients with suspected normal pressure hydrocephalus (age group: usually middle-aged to elderly).

12.8 Remaining Risks

The use of ***LiquoGuard®*** with the "lumbar infusion test" option poses the following risks when carrying out the lumbar infusion test: increased CSF pressure, fluid infusion outside the subarachnoid space in the event of malpositioning of spinal cannula, cerebrospinal fluid infection.

12.9 Application and Operation

The lumbar infusion test is incorporated as option and can be selected via the menu prompt at the beginning (see Page 30). If the option is available, "*Infusion test*" is displayed on the screen when the device is switched on (when software version is displayed).

As the lumbar infusion test is a diagnostic procedure during which small pressure differences are decisive, qualified personnel must stay with the patient throughout the entire process and attend the application. This is important as changes in the position of the patient would more significantly affect the measurement than the additional infiltration.

The operator must manually start and finish the procedure as the automatic mode is risky for the same reasons. In this way the operator specifies the initial pressure as well as the changed final pressure.

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Option: Lumbar Infusion Test (Not available in the US)

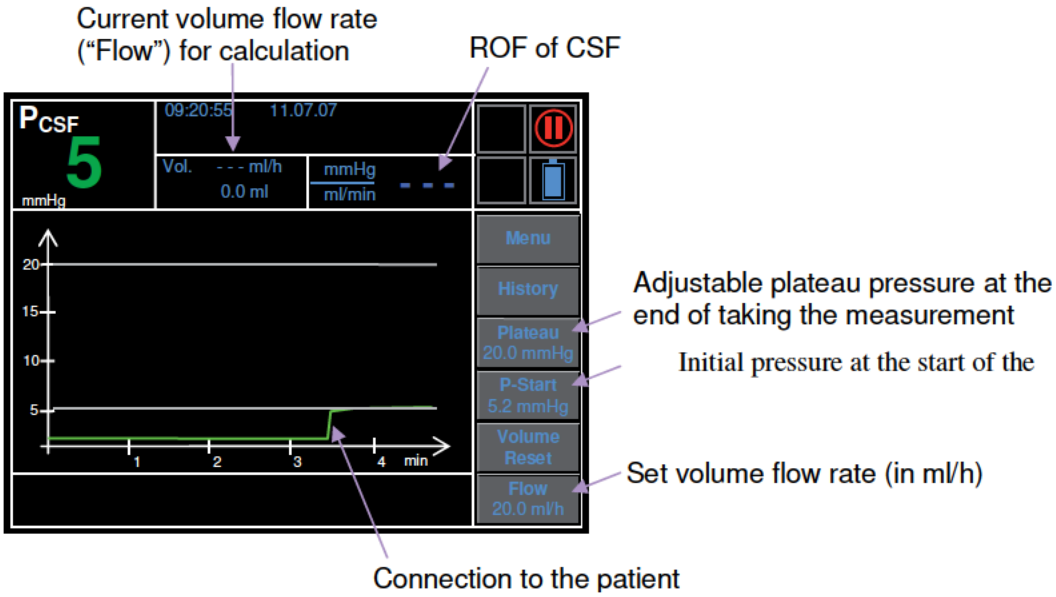

Figure 35: Display setup for option "lumbar infusion test"

Notes:

- The filtered pressure values only are displayed.
- Two horizontal gray curves are displayed rather than the alarm limits. The operator sets one curve to the initial pressure value. The second curve can then be set to the final pressure value.
- The pressure axis scaling is based on these two curves; however, they can be moved directly on the screen prior to accepting the values. The display is rescaled by accepting the values.
- These two cursor values and the set volume flow rate are always used to compute the CSF flow resistance. The physician has to make the moment he accepts this value as the actual measured value dependent on the current pressure signal; meaning the moment when the measured pressure has actually reached the upper plateau.
- The motor no longer stops during pumping when the pressure has dropped below the lower alarm pressure, but rather when the upper alarm limit is exceeded.
- There is no "Pressure too constant" alarm for the infusion test. This parameter is also skipped in the menu.
- The "History" function is also available for the infusion test. A wider pressure range can be viewed here when taking the measurement.
- Data storage and data transfer to a memory card work in the same way as in the Drainage Mode.

12.9.1 Preparation

For the first steps please see at page 30.
→ „Select application": For the lumbar infusion test select "Infus-T".

Afterward, please carry out the following procedures:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.

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Option: Lumbar Infusion Test (Not available in the US)

2. Insert the tube set into the pump (see page 31).

3. "Sensor cable - connect to pump and wait."
→ If you haven't done it yet: Connect the sensor cable to the pump (see page 32). The next step is indicated automatically.

4. "Bag with infusion solution - connect to tube set and confirm."
→ Remove the protective cap from the spike and use it to prick the container with the CSF substitute.
As soon as you have verified with "Okay", the pump will begin running with a maximum velocity.
Note: By pressing ESC, you will be returned to "Connect the sensor cable to the pump and wait". If the sensor cable is still connected, the device will automatically continue to the next step ("… container with the infusion solution…"). Should you wish to interrupt this process, you must first disconnect the sensor cable from the device and then press Esc. Hereby, you will return to "Connect sensor cable to the pump and wait", where you can now press Esc once again in order to return to the site where a particular application can be selected.

5. "Fill tube – Press END once tube is filled."
→ Remove the protective cap from the one way stop cock and fill (aerate) the tube set.
Wait until fluid starts dripping from the tube set, then press "END".
Note: If air still remains in the tube set, the measurement may be inaccurate and air may be pumped into the patient.

6. Remove the additionally wrapped spinal cannula (Touhy needle) from the packaging and puncture the patient. Wait until the cannula is filled with CSF.

7. Connect the cannula with the tube set.

8. "Pressure sensor - Attach to patient."
→ Attach the pressure sensor to the patient to avoid inaccurate measurements. After you have pressed "Okay", the current pressure will be applied as "P-Start" (initial pressure). This is typically the correct pressure for starting the application. The operator, however, can still change this value at a later stage.

Note: Until this point in time, the tube set can still be removed by pressing "Esc" and returning step-by-step in order to start at the beginning. The tube set is not yet marked as being used.
As soon as you have connected the catheter and the pressure sensor to the patient, and have verified this with "Okay", the tube set is marked as used and can no longer be used elsewhere. Once again, the message "Connect sensor cable to the pump and wait" appears briefly, whereby the device controls whether or not a sensor cable has actually been connected.
As of this point in time, the alarm function is also activated and the device is in normal operation.

12.9.2 Taking the Measurement

At the end of the menu prompts the ***LiquoGuard®*** is in Pause mode, i.e. the pump is inactive. Now check whether the current pressure is relatively constant and whether it complies with the automatically set start curve ("P-Start"). If the start curve does not comply with the constant pressure, adjust the start curve using "P-Start".
If the pressure is not constant, please check whether the sensor was attached correctly. The patient must remain still, otherwise fluctuations in pressure may occur.

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Once the pressure is stable (constant) and the start curve is correctly set, press the "Pause" key to start the pump.

Notes:

- If the current pressure and the start curve are identical, only the start curve will be visible.
- The display runs from the right-hand to the left-hand side. The current values are always indicated on the right-hand side (unlike the Drainage Modes).
- No value is displayed as long as the pump is in Pause mode because there is no volume flow rate ("Flow").
- When the pump mode of the device is activated, the pump is always active for 8 seconds, after which pumping is interrupted for 2 seconds in order to measure the pressure until pumping once again resumes, a procedure which continues repeatedly.

12.9.3 Infiltration

The pressure increases after the pump is activated until a new stable pressure plateau has been reached. This constant pressure that corresponds to the set flow of the pump is required to compute the "ROF of CSF". The operator must set the reached plateau pressure via "Plateau", whereby she/he must ensure that this plateau value is actually stable and does not rise further.
"ROF of CSF" is always computed with the currently applicable settings/values, so that the operator has an idea what the probable result may be at the end of taking the measurement.
If "Flow" is changed during the application, the operator will have to wait for a stable plateau pressure again.

Note:

- The start curve (P-Start) can be adjusted throughout the application.
- In practice it is often difficult to reach a stable plateau value. The final value is subject to strong variation. In this case, it must be ensured that the pressure does not increase any further. The attending physician is responsible for setting the correct plateau pressure value.

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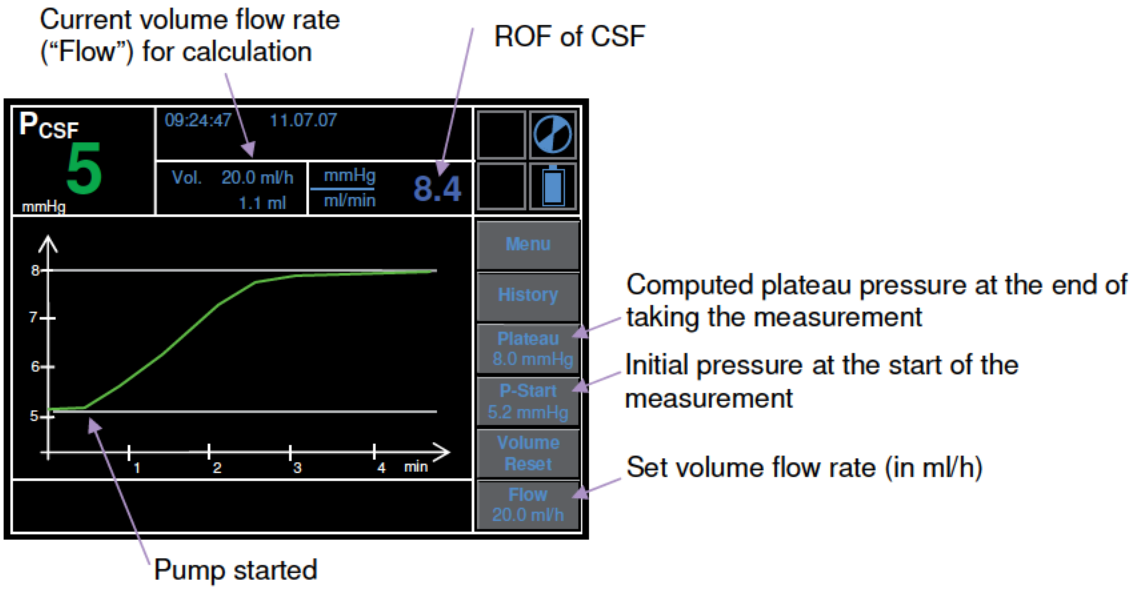

Figure 36: Display setup for option "lumbar infusion test" during the application

Setting options:

- **Plateau**: P-Start to 75 mmHg, default value: 40 mmHg
- **P-Start**: -15 mmHg to Plateau, default value: 0 mmHg
- **Flow**: 1 - 120 ml/h, default value: 20 ml/h

12.9.4 Alarms

Alarms can occur for "Pressure too high" (upper alarm limit exceeded) and "Pressure too low" (dropping below lower alarm limit) throughout the infusion test. These alarms can be set to "Audio paused" or "Audio off" analog to the drainage mode (see also Page 38). Press the "Alt" key (also see Page 25) to call up a second menu selection. Here you can adjust the alarm limits.

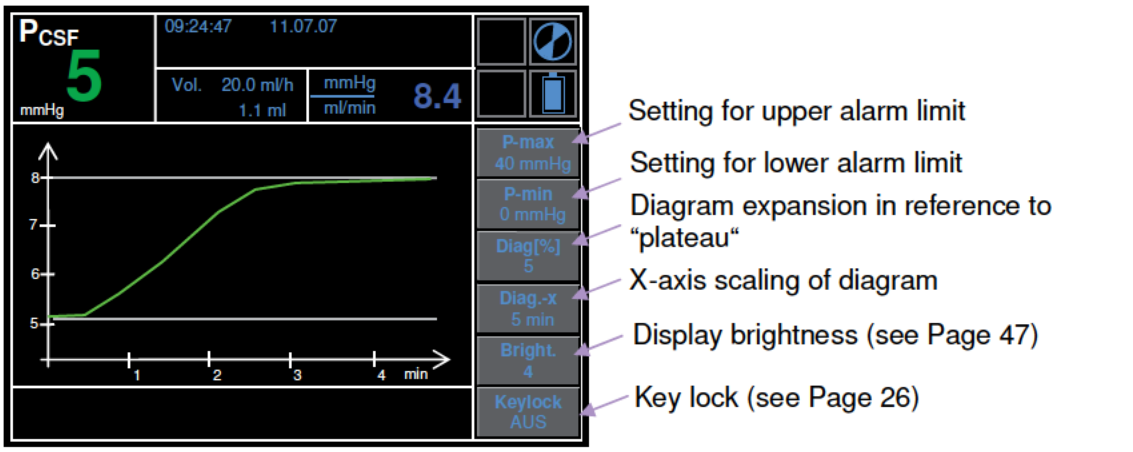

Figure 37: Display setup for option "lumbar infusion test", 2nd selection menu

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Option: Lumbar Infusion Test (Not available in the US)

Setting options:

- **P-max**: P-min to 75 mmHg, default value: 40 mmHg
- **P-min**: -15 mmHg to P-max, default value: 0 mmHg
- **Diag [%]**: 0-50, default value: 0
- **Diag. x**: 60 seconds to 20 minutes, default value: 5 minutes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 8

LABELS FOR THE LIQUOGUARD CSF

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Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF – DEVICE LABELING

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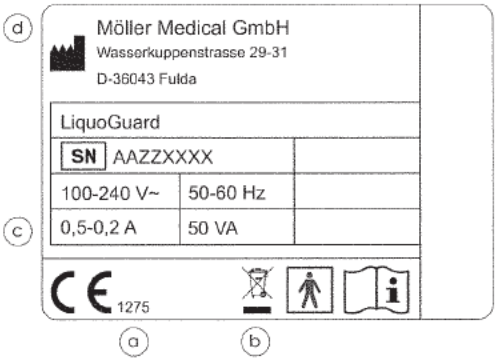

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ZZ = Herstellmonat d.h.: Für Monat November ist ZZ = 11
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Schrift: Schwarz

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d	Hersteller	KO 3014	08.10.08	AH				
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LIQUOGUARD CSF – PACKAGING LABELING

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Möller Medical GmbH
Wasserkuppenstrasse 29-31
D-36043 Fulda

LiquoGuard, REF 00002563

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0,5-0,2 A	50 VA

CE 1275

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Aufschlüsselung der Seriennummer :

AA = Herstelljahr d.h.: Für Herstelljahr 2006 ist AA = 06
ZZ = Herstellmonat d.h.: Für Monat Februar ist ZZ = 02
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APPENDIX 9

LABELS FOR THE LIQUOGUARD CSF TUBING SET, 1500MM

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIQUOGUARD CSF TUBING SET, 1500MM – PACKAGING LABELING

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Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 650

REF.: 92 007 836

1500 mm

+40°C (104°F)
+10°C (+50°F)

STERILE EO

MRI

PHT DEHP

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

20009691 - 2010-03

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LIQUOGUARD CSF TUBING SET, 1500MM – PACKAGING LABELING: VARIABLE DATA

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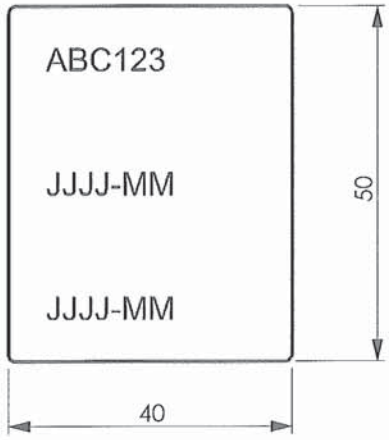
(a) Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

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							Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:
							Halbzeug: Rollen - Haftetiketten 50 x 40 mm	
						Datum / Name	Aufkleber	
					Bearb. 28.03.07 LW			
					Gepr. 15.03.12		für Schlauchset "LiquoGuard"	
					zul. gespeichert von: ahorwart	15.03.2012 11:05:01		
					Vertraulich/Confidential			
b	Haltbarkeit	KO3769	15.03.12	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Es sind alle Rechte vorbehalten insbesondere Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP002-001 00 09-00 b-4	Blatt 1 von 1
a	Chargenbez. geä.	KO 467	07.02.11	MU-De				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-001 00 09-00 0 - 4		Ers. für: LDP002-001 00 09-00 a-4	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF TUBING SET, 1500MM – PATIENTS STICKER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-001 00 12-00 d-4

LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			
LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			
LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			
LiquoGuard® Drainageset	2007-05		
Art.No. 00 002 650			
REF.: 92 007 836	LOT L010489A/1/2		
1500 mm			
Möller Medical GmbH · 36043 Fulda, Germany			

LiquoGuard®
Drainageset

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

30004037 – 2009-03

Achtung! 1. Originalablage des PDF's für Fertigung : Dokumentenablage _Gültig

2. "Chargenbezeichnung" und "Verwendbar bis" werden chargenspezifisch angepasst!!!

MöllerMedical
Wasserkuppenstrasse 29-31 • 36043 Fulda
Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com

Art.-Nr.: 30 004 037

Allgemeintol.

Maßstab 1:1 | Gewicht: | Volumen:

Werkstoff: bez.: Druckerei Mergard | Werkstoff-Nr.: (c) 6,8 cm x 8,5 cm

Halbzeug:

	Datum	Name
Bearb.	29.01.08	LW
Gepr.	16.03.09	
Norm		

Patientenaufkleber

Schlauchset "LiquoGuard" 1500 mm

Zust.	Änderung	KB-Nr.	Datum	Name
d	Größe Ref-Nr., Art.-Nr. Datum geändert	KO 3105	16.03.09	HOR
c	Größe, 4 Aufkleber	KO 3058	07.01.09	HOR
b	Logo + Anschrift	KO 3010	29.09.08	AH
a	neues Logo	KO 2981	03.07.08	AH

Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.

Dateiname: LDP002-001 00 12-000 - 4

Ers. für: LDP002-001 00 12-00 c-4

LDP002-001 00 12-00 d-4

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 10

LABELS FOR THE LIQUOGUARD CSF TUBING SET, 2000MM

Back to **List of Appendices**
Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF TUBING SET, 2000MM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 911

REF.: 92 008 568

2000 mm

+40°C (104°F)
+10°C (+50°F)

STERILE EO

MRI

PHT DEHP

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

20008691 - 2010-03

Achtung! Originalablage des PDF's für Fertigung : Dokumentenablage _Gültig

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 691		Allgemeintol.	Maßstab 1:1 / Gewicht: / Volumen:
								Werkstoff: bez.: Druckerei Mergard / Werkstoff-Nr.: 14,8 cm x 10,5 cm Halbzeug: JAC script weiß, Klebstoff D131 80g/m²
						Datum	Name	Verpackungsaufkleber
					Bearb.	29.03.07	LW	
f	kpl. überarbeitet	KO3262	01.03.10	Mü-De	Gepr.	01.03.10		Schlauchset "LiquoGuard" 2000 mm
e	Logo + Anschrift	KO 3010	29.09.08	AH	Norm			
d	neues Logo	KO 2981	03.07.08	AH	zul. gespeichert von: sdehler		02.03.2010 15:43:18	
c	Text überarbeitet	KO 2835	17.03.08	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwider-			Blatt 1 von 1
b	hinzu	KO 2801	15.01.08	LW				LDP002-003 00 04-00 f-4
a	Art.-Nr. hinzu	KO 2735	04.12.07	LW	muster Eintragung vorbehalten.			
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-003 00 04-00 0-4			Ers. für: LDP 002-003 00 04-00 e-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF TUBING SET, 2000MM – PACKAGING LABELING: VARIABLE DATA

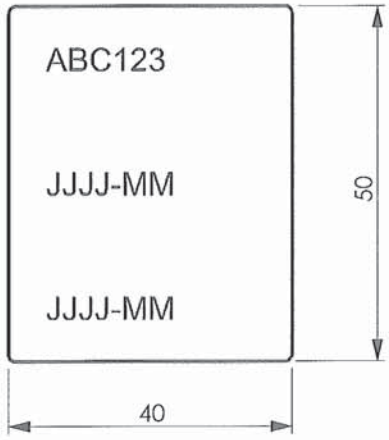
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(a) Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

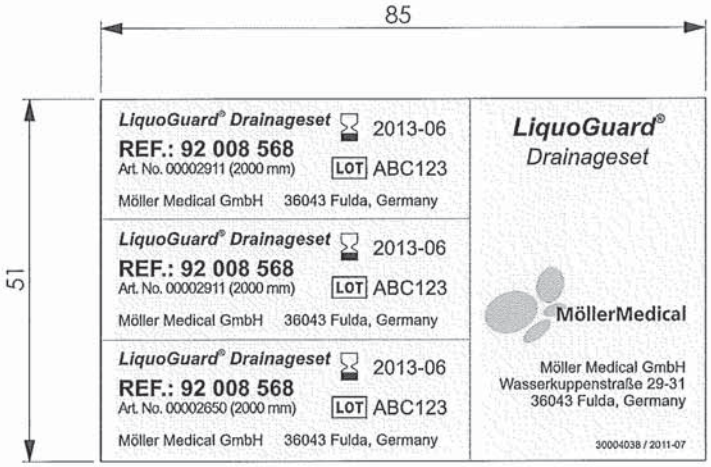
MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 687	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:
							Halbzeug: Rollen - Haftetiketten 50 x 40 mm	
						Datum / Name	Aufkleber	
					Bearb. 28.03.07 LW			
					Gepr. 15.03.12		für Schlauchset "LiquoGuard"	
					zul. gespeichert von: ahorwart	15.03.2012 11:05:01		
					Vertraulich/Confidential			
b	Haltbarkeit	KO3769	15.03.12	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Es sind alle Rechte vorbehalten insbesondere Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP002-001 00 09-00 b-4	Blatt 1 von 1
a	Chargenbez. geä.	KO 467	07.02.11	MU-De				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-001 00 09-00 0 - 4		Ers. für: LDP002-001 00 09-00 a-4	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF TUBING SET, 2000MM – PATIENTS STICKER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016



Haltbarkeit des Produktes = 1 Jahr 11 Monate

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 30 004 038	Allgemeintol.	Maßstab 1:1 / Gewicht: / Volumen:
							Werkstoff: gef. aus: 70 000 889 / Werkstoff-Nr.:
							Halbzeug:
					Datum	Name	Patientenaufkleber
					Bearb. 29.01.08	LW	
					Gepr. 29.07.11		Schlauchset "LiquoGuard" 2000mm
e	4-flg. in 3-flg. Aufkl. geä.	KO 3577	29.07.11	MÜ-De	zul. gespeichert von: sdehler	29.07.2011 10:12:59	
d	Größe Ref.-Nr., Art.-Nr., Datum geändert	KO 3105	16.03.09	HOR	Vertraulich/Confidential		
c	Größe, 4 Aufkleber	KO 3058	07.01.09	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte		LDP002-003 00 05-00 e-4 / Blatt 1 von 1
b	Logo + Anschrift	KO 3010	29.09.08	AH			
a	[illegible]	[illegible]	[illegible]	[illegible]			
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-003 00 05-00 0-4		Ers. für: LDP002-003 00 05-00 d-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 11

STERILITY VALIDATION REPORT

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10057; Released by CDRH on 07/22/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 12

STERILITY VALIDATION REPORT

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[redacted]

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APPENDIX 13

ACCELERATED AGING TEST REPORT

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

APPENDIX 14

BIOCOMPATIBILITY TESTING ACCORDING TO ISO 10993-1 OF THE LIQUOGUARD TUBING SET

(b)(4)
[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

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[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 15

DEVICE HAZARD ANALYSIS

(b)(4)
[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 16

SOFTWARE REQUIREMENT SPECIFICATION

(b)(4)
[redacted]

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(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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[redacted]

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[redacted]

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[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 17

SOFTWARE ARCHITECTURE DESIGN

(b)(4)
[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or 301-796-8116

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 18

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 19

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

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[redacted]

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[redacted]

(b)(4)

APPENDIX 20

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3110

APPENDIX 21

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TRACEABILITY ANALYSIS

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SOFTWARE DEVELOPMENT PLAN

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ELECTROMAGNETIC COMPATIBILITY, DIN EN 60601-1-2

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(b)(4) Test Report

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LIQUOGUARD CSF SYSTEM CLINICAL TRIAL

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APPENDIX 61

LIQUOGUARD CSF SYSTEM PUBLICATIONS

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B.M. HOELPER

CLINICAL STUDY REPORT OF A NEW PRESSURE AND VOLUME CONTROLLED CSF DRAINAGE SYSTEM (LIQUOGUARD)

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Clinical study report of a new pressure and volume controlled CSF drainage system (LiquoGuard®)

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Summary.

Introduction. Lumbar and ventricular CSF drainage is applied in various indications in neurosurgery. Until now, open hydrostatic systems mostly including a dripping chamber were used. This report presents first experimental and clinical experience using a new, closed CSF drainage system capable of simultaneously draining CSF and measuring CSF pressure (LiquoGuard®).

Material and Methods. CSF pressure is measured by a dual external pressure sensor device taped at an anatomical reference point of the patient and CSF is drained by a peristaltic pump. For ventricular application, drainage is pressure controlled, while in lumbar drainage a constant flow rate can be defined. For experimental evaluation, hydrostatic pressure as well as comparison to an independent pressure sensor technique was calculated for static pressures and pressure changes. During clinical application, intraventricular pressure measured by the new system was compared to established ICP devices (internal and external pressure transducers) in 16 patients. Lumbar drainage with constant flow rate was performed in 4 patients.

Results.
Experimental data comparing the LiquoGuard® pressure sensor to hydrostatic pressure levels and pressure measured by an calibrated pressure measurement device revealed in ranges < 100 mmHg a high accuracy with deviation of 0 – 3 mmHg. Ventricular CSF pressure also was comparable to established sensors (Raumedic Neurovent and standard external pressure transducer). Calculated drained volume differed from measured volume within the drainage bag < 5 % if total CSF amount was > 100 ml. Slit ventricle syndrome was detected early by loss of CSF pulsation, oscillating CSF pressure and reduction of CSF outflow. Catheter occlusion was stated if CSF pressure remained low in contrast to slit ventricle syndrome.

Discussion.
Both experimental and clinical data indicates that the new device allows a precise external CSF pressure measurement with low sensor drift along with the possibility to

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drain CSF simultaneously due to a closed drainage system. This results in several clinical advantages: Adjustment of a dripping chamber is not necessary any more leading to enhanced patient safety and mobility. Lumbar drainage is facilitated by a constant flow rate. Critical conditions such as slit ventricle syndrome or catheter occlusion can be detected by the integrated CSF pulsation detection in addition to alterations in CSF pressure and outflow. Therefore, the system can facilitate handling of ventricular and lumbar drainage and might enhance safety for the patient.

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I INTRODUCTION (BACKGROUND AND RATIONALE)

Lumbar and ventricular drainage of CSF is a daily routine method in neurosurgical practice (3, 5, 10, 18) in several indications. Ventricular CSF drainage might be needed in situations caused either by obstruction of CSF outflow (e.g. by subarachnoid haemorrhage, obstruction of CSF flow by tumor or blood as well as infectious diseases) of distrubtion of CSF resorption (1, 4, 5, 9-11, 13-15, 17, 19). Furthermore, lumbar CSF drainage is needed to treat CSF fistulas or establish diagnosis in normal pressure hydrocephalus (6). However, several important disadvantages occur with current ventricular and lumbar systems. For pressure controlled CSF drainage, permanent alignment of the dripping chamber to anatomical reference points is necessary. Furthermore, reliable measurement of ICP is possible only in a closed drainage system: by positioning the dripping chamber for example above the reference point, only the hydrostatic pressure difference between the fluid level inside the tube and the pressure sensor is measured. Other nursing problems such as disconnection and occlusion of the CSF drainage are frequently registered with long time delay. Additional, technical inconsistencies of pressure measurement due to sensor malfunctions (e.g. sensor drift) and incorrect handling (wrong zero leveling, incorrect adaptation to the monitoring system) might cause wrong ICP readings. By this, the patient might be without surveillance of CSF pressure and imprecise determination of drained CSF volume. In lumbar drainage, nowadays it is very difficult to achieve a continuous CSF flow over time, since CSF outflow depends on position of the catheter, pressure difference between catheter and dripping chamber, positioning of the patient and CSF-dynamics (CSF production, resorption and outflow).

The presented new system (LiquoGuard®) is an externally closed system which might allow drainage of CSF parallel to CSF pressure measurement. Technically, in contrast to the dripping chamber the system is externally closed by a peristaltic pump and by this it allows simultaneous CSF drainage and pressure measurement. Therefore, there should be no need for a dripping chamber due to pressure controlled drainage. Additional, continuous CSF flow especially in the use of lumbar drainage might be possible.

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II STUDY OBJECTIVE AND DESIGN

Study Objective

Purpose of this study was to evaluate if dripping chambers can be replaced by the LiquoGuard® system without any clinical changes and if the LiquoGuard® system is reliable concerning the applicability, accuracy of CSF drainage and CSF pressure measurement. The intend of the LiquoGuard® device to minimize most sources of error mentioned above due to the closed fluid system is evaluated. Furthermore, clinical practice in mounting the pressure sensors at the reference point is studied. In addition, LiquoGuard® is observed in the following clinical situations: catheter disconnection, catheter occlusion and collapsed ventricles. The accuracy of both sensors and the frequency of inconsistencies between both sensors (sensor drift) will be analyzed. For lumbar drainage, the ability of the LiquoGuard® system to drain CSF continuously and the accuracy of drained fluid volume are further examined.

Study Design

For 20 Patients requiring external CSF drainage (ventricular or lumbar) instead of the usually applied dripping chamber the external CSF drainage system LiquoGuard® is used with the same intend to treat. Since the presented new system (LiquoGuard®) is a externally closed system which allows drainage of CSF parallel to CSF pressure measurement, the ICP will be compared to an independent alternative ICP and the calculated CSF volume is compared to the collected CSF volume.

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III SAFETY AND EFFECTIVENESS PARAMETERS

A. Key Safety Parameters

CSF pressure. Most important for ventricular CSF drainage is the correct adjustment of intraventricular pressure. This is performed either externally by adjusting the dripping chamber or by mounting (either taping or fixing by suture) of the ICP pressure sensors (LiquoGuard®). By this, LiquoGuard® must allow to drain comparable CSF volumes to maintain intraventricular CSF pressure. To exclude increased ventricular CSF pressure due to inadequate drainage, an additional external pressure sensor was installed parallel to the LiquoGuard® CSF pressure sensors. Furthermore, alarm functions are activated if CSF pressure is out of physiological ranges.

Drained CSF volume. The CSF volume drained by LiquoGuard® was calculated by the device and displayed. Furthermore, the amount of collected CSF was measured afterwards. To exclude a larger deviation of drained CSF volume, it was possible to read the collected volume outside the drainage bag. Therefore, assuming that a withdraw of a larger amount of CSF might lead to a decrease of CSF pressure, additionally the CSF pressure was measured and a lower CSF pressure alarm was predefined. By this, the drainage of larger CSF amounts should be registered.

B. Key Effectiveness Parameters

Aim of each ventricular and lumbar CSF drainage is to allow CSF flow from the CSF space to an external reservoir, either with determination of the CSF pressure (most ventricular drainage systems) or of the CSF volume (most lumbar drainage systems). Therefore, the effectiveness of the LiquoGuard® system has to be determined by its ability to withdraw CSF from the intrathecal space (ventricular or lumbar), either controlled by the CSF pressure or by the volume. Since the withdrawn CSF can be sampled in the drainage bag, the effectiveness of the LiquoGuard®-System can be measured directly and immediately during clinical practice.

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IV PATIENT ENROLEMENT

A. Inclusion Criteria

In the study, neurosurgical patients with the need of a ventricular or lumbar drainage were included. All patients underwent an operative procedure to introduce an external drainage catheter into the CSF space. However, this was done independent of the use of a conventional system or the LiquoGuard® system. Indications with the need of an external drainage are subarachnoid hemorrhage, intraventricular hemorrhage, head trauma, ventriculitis, CSF fistula and normal pressure hydrocephalus.

B. Exclusion Criteria

Since the operative procedure to apply an external drainage device does not differ between the conventional drainage systems and the evaluated system, no additional operative or nursing step must be done. Therefore, there are no exclusion criteria that can be assumed to be exclusion criteria for the use of the LiquoGuard® system which differ from the exclusion criteria for all external CSF drainage systems. For completion, relative exclusion criteria for external lumbar or ventricular drainage (both conventional dripping chamber and LiquoGuard® system) are pathologies in haemeostasis, coagulopathies, and severe infections disease. However, in many cases CSF drainage has to be applied immediately in life threatening situations.

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V STUDY MATERIALS AND METHODS

A. Description of Device

The LiquoGuard® system (Moeller Medical, Fulda, Germany) consists of a device including a peristaltic pump, inputs for pressure sensors, and several external interfaces. The external drainage system consists of a tube with two integrated pressure sensors. The tube can be inserted into the peristaltic pump and the sensors are connected to the pressure sensor interface. After zeroing of the sensors, CSF drainage can be immediately started and current ICP, CSF pulsation (for ventricular drainage) as well as withdrawn CSF volume are displayed. Sensor information provided by the manufacturer is a sensor accuracy ± 0,375 mmHg, long-term drift of < 1 mmHg and a total system deviation of < 2 mmHg, manufacturer states that the volume calculated by the device deviates ± 15% in maximum. Upper and lower ICP alarm threshold can be set. For ventricular drainage, pulsation of the CSF is detected, displayed and loss of pulsation leads to an activation of an alarm function.

B. Patient Entry

For evaluating the possibility of continuous CSF drainage, the LiquoGuard® system was connected the ventricular drainage in 16 patients and lumbar drainage in 4 patients. In ventricular application, the LiquoGuard® pressure sensor was taped to the patient head at the level of the foramen Monroi and ICP was measured by an additional intraventricular applied pressure sensor catheter (Raumedic Neurovent®) or by an external pressure transducer connected to the external tubing system by a three way connector.

C. Surgical Procedure

For application of the LiquoGuard® CSF drainage system no surgical procedure is needed. However, the application of each external CSF device requires an operative procedure independent on the use of the external drainage system. For ventricular drainage, a burr hole was performed according to standard landmarks (about 2 cm lateral of the superior sagittal sinus and 0.5 cm anterior to the coronal suture, mostly right-sided). After incision of the dura, a ventricular catheter was introduced with a

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length of about 5-6 cm into the ventricular system until CSF dropped out of the drainage. Then, the catheter was either tunneled and sutured to the skin or was fixed by a PEEK bolt (Raumedic). For lumbar drainage, a standard lumbar drainage kit (Integra) was used. The intrathecal space was approached in the level of L3/4 or L4/5 by a Touhy-Needle and the lumbar catheter was introduced in cranial direction with a length of 5-15 cm. Externally, the catheter was sutured to the skin and additionally taped.

D. Postoperative Care

After ventriculostomy, ICP was adjusted to 10-20 mmHg depending on the disease of the patient and according to the previous standard of the height of the dripping chamber. Drained CSF volume was set in the range between 5 to 25 ml/h for ventricular drainage. Upper alarm was set at 20 – 40 mmHg, lower alarm at 0-5 mmHg according to the patient's disease. ICP measured by the external independent pressure sensor was either recorded automatically every minute or manually by the nursing staff every half hour along with the ICP displayed by the LiquoGuard®, Drained CSF volume was collected and measured every 24 hours for balance. Furthermore, the complete drained CSF volume was measured and simultaneously the volume calculated and displayed by the LiquoGuard® was recorded.

For lumbar drainage, flow rate was set to 5 – 13 ml/h, upper pressure alarm at 40 – 70 mmHg, lower pressure alarm at 0 - 5 mmHg. Pressure from LiquoGuard® and the additional pressure sensor was time locked collected for the complete monitoring time.

Each alarm of the LiquoGuard® had to be prompted by the nursing staff. In cases of an exceeding ICP either the CSF flow rate was increased or other standard steps (medical treatment of elevated ICP or diagnostic procedures) were performed. In cases of an ICP below the lower alarm the threshold was either further lowered, the position of the patient was altered or the mounting of the ICP sensor was checked. In cases of a pulsation alarm and/or a low ICP without visible CSF pulsation, continuity of the ventricular or lumbar catheter was checked and in case of an obstruction the catheter was flushed.

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E. Patient Follow-up

Each patient was followed up during the time of treatment and several days after treatment routinely for clinical signs of CSF infections. However, since the treatment is finished after withdrawing of the ventricular or lumbar catheter, no further follow-up is required and was performed concerning the external CSF drainage system.

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VI STATISTICAL METHODS

After collection of ICP data, the difference between both values was calculated and statistically evaluated for significant differences (Mann-Whitney-U Test). CSF volume was displayed by the LiquoGuard® with hourly and daily balance and total drained CSF amount. The withdrawn CSF volume colleted in the drainage bag was measured and the difference was calculated. All statistical Analysis was performed by using SPSS (V. 12.0).

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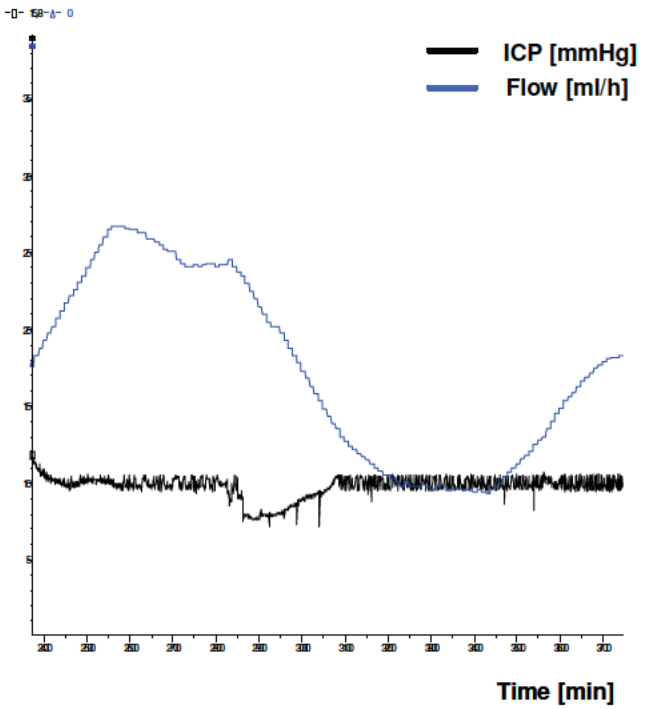
VII RESULTS

Replacement of dripping chamber.

In 20 patients, previous applied dripping chamber was replaced by the LiquoGuard® system (both in ventricular for 16 patients and lumbar application in four applications). After setting of the parameters (desired ICP, maximal CSF drainage in ml/h and alarm limits), in all patients CSF drainage was continued analogous to the dripping chamber. In 16 patients, the self-adhesive pad mounted at the head of the patient had to be replaced, no complications were seen during this procedure. In clinical routine, a standard setting with a maximal flow rate of 20 ml/h is sufficient in most cases. Flow rates of 5 – 20 ml/h are also frequently seen in external dripping chambers.



This graph depicts the flow of CSF (blue line) controlled by the LiquoGuard® system. The ICP was kept at 10 mmHg or below representing the functioning of the system to maintain ICP in predefined range.

For patient transport, mostly the dripping chamber is switched off which might lead to an intermittent increase of ICP. Since the LiquoGuard® system runs on recharchable batteries, there is no need to disconnect the drainage system and thus drainage is also possible during transportation. Furthermore, also during angiography, CT and transport into the OR a continuous CSF drainage is possible which might lead to a better surveillance of the patient and might minimize the risk of ICP peaks during transport without any recognizable negative consequences for the patient.

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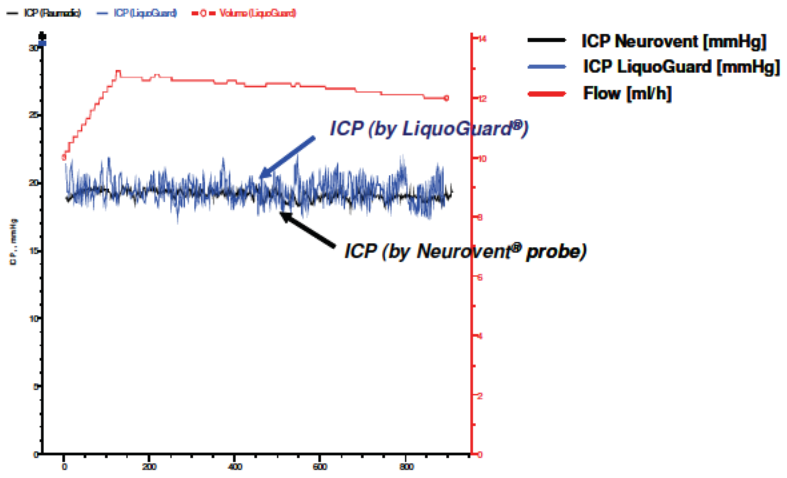
ICP measurement

In ventricular application, ICP measurements between LiquoGuard® and an alternative pressure measuring method differed in a range of 0 – 3 mmHg. The maximal deviation was found between the LiquoGuard® pressure sensor readings and the compared external pressure transducer with 3 mmHg, while differences between the Raumedic Neurovent® and the LiquoGuard were below 3 mmHg. No statistical difference was found during measuring periods between external ICP or intraventricular Raumedic Neurovent® probes and the LiquoGuard® ICP values.



ICP measured by LiquoGuard® (blue line) and an comparable intraventricular system (Raumedic Neurovent® probe, black line) showed absolutely comparable ICP values with deviation < 1 mmHg. The red line indicates the CSF flow controlled by the LiquoGuard® system.

No sensor malfunction was observed in these measurements, however in 4 patient a second disposable drainage system had to be connected due to an operating time of the tube of more than 5 days (as recommended by the manufacturer).

CSF volume

The differences between the drained CSF compared to the calculated volume calculated by the LiquoGuard® was < 10% and no statistical significant difference was found if total drainage volume was > 100 ml. Therefore, both accurate pressure measurement and calculated volume by LiquoGuard® can be used for clinical purpose. Critical situations such as slit ventricle syndrome were detected at a very early point in a typical pattern with loss or CSF pulsation and increasing variability or CSF pressure. Additional, catheter occlusions for both lumbar and ventricular applications were immediately detected by sudden decrease of CSF pressure and

loss of CSF pulsation. For lumbar application, continuous CSF drainage is possible even during mobilization of the patient, while catheter occlusion, malpositioning and disconnection of the catheter were prompted by an alarm.

Collapsed ventricles.

In two patients collapsed ventricles were detected in cranial CT. Prior to CT, in both patients the ICP measured by the LiquoGuard® system altered in an oscillating fashion below the desired ICP, CSF pulsation was lost and the CSF flow rate was reduced (Figure 3). Pausing of CSF drainage led to an equilibration of ICP at pathological levels (> 35 mmHg) with CSF pulsation.

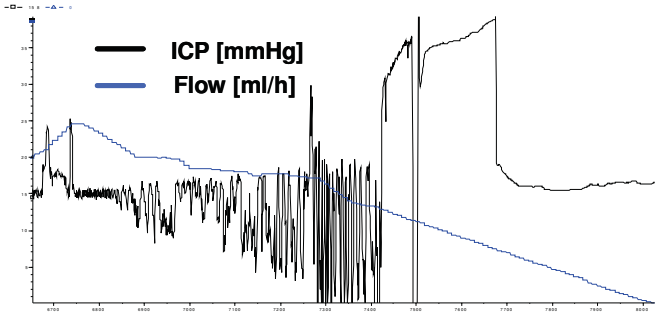


Figure 3. Decrease of CSF outflow or production from the ventricles leads to decrease in CSF flow displayed by the LiquoGuard® (as seen in the blue line) indicating a clinical situation which might be due to collapsed ventricles. Since CSF flow is very low, the amount of drained CSF by the LiquoGuard® is also in very low ranges and a withdraw of small amount of CSF leads to sudden and high changes in ICP. This can be seen in an increase of ICP oscillation, here in the range between 0 and 20 mmHg.

Catheter occlusion.

Several intermittent occlusions of the lumbar and ventricular catheters occurred. Mostly, occlusion was caused by obliteration of the internal lumen of the tube, but in two patients CSF drainage was not possible due to partial withdrawal of catheter to an extradural position. In all situations, CSF pressure was very low (0 – 2 mmHg), CSF pulsation and flow was not detectable (figure 4). Flushing the tube by a small amount of sterile isotonic saline solution ended immediately the occlusion in cases not caused by extradural catheter position.

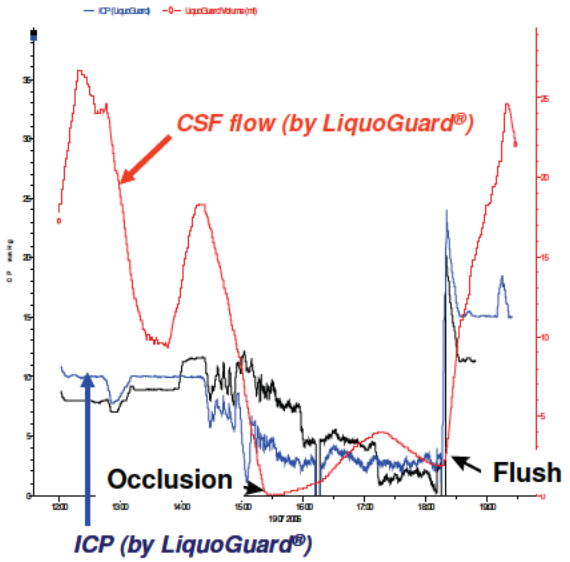


Figure 4. Typical presentation of a catheter occlusion which immediately leads to an reduction of CSF flow (red line) and a decrease of ICP. The ICP decrease is caused by withdrawing of CSF by the LiquoGuard® system without efflux of CSF from the ventricular system.

Clinical.

For evaluating the possibility of continuous CSF drainage, the LiquoGuard® system was connected to ventricular drainage in 16 patients and to lumbar drainage in 4 patients. In ventricular application, the LiquoGuard® pressure sensor was taped to the patient head at the level of the foramen Monroi and ICP was measured by an additional intraventricular applied pressure sensor catheter (Raumedic Neurovent®) or by an external pressure transducer connected to the external tubing system by a three way connector. ICP was adjusted to 10-20 mmHg depending on the history of the patient, drained volume was set in the range between 10 to 25 ml/h. Upper alarm was set at 35 – 40 mmHg, lower alarm at 5 mmHg. For lumbar drainage, flow rate was set to 5 – 13 ml/h, upper pressure alarm at 40 – 60 mmHg, lower pressure alarm at 2 - 5 mmHg. Pressure from LiquoGuard® and the additional pressure sensor was time locked collected for the complete monitoring time. Additional, the drainage volume was colleted and measured in a calibrated cylinder for further comparison to

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the LiquoGuard®. Any occurring alarms, handling problems by the nursing staff were documented.

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VIII DISCUSSION / CONCLUSIONS

Experimental work showed a very stable and reliable pressure measurement by the LiquoGuard® which works in the ranges provided by the manufacturer (complete deviation of the pressure < 2 mmHg). No differences were found in hydrostatic pressure differences and in continuous increase and decrease of pressure. The deviations of the pressure sensor is comparable to other external applied CSF pressure sensors (8, 21) and drift is even lower compared to miniaturized sensors applied into the intradural space (2, 7, 8, 12, 16) Therefore, the applied sensor seems to be suitable for low pressure seen in intracranial and lumbar applications. In clinical setup, ventricular pressure was also measured with high reliability compared to commercially available external and internal pressure sensors. Sensor drift seen in most sensors applied intracranially is negligible and malfunction of one pressure sensor can be detected easily due to the dual architecture of the system. There is only one commercially available system (Raumedic Neurovent duo, 16) offering the possibility to measure two pressures, but in contrast to this the LiquoGuard® compares the two measured pressures continuously. The slight difference between the pressure measured by the LiquoGuard® compared to the external pressure sensor was due to slight differences in positioning the sensor related to the level of the foramen Monroi. The LiquoGuard® pressure system can be taped using an ECG electrode to the patient head, the risk of deviation concerning the measured pressure might be reduced, since usually the external pressure transducer is either fixed at the holding device with is mounted at the bed or directly fixed on the pillow. The fixation of the LiquoGuard® pressure system directly at the patient allows for lumbar and ventricular application a continuous adaptation, the risk of measured pressure which is not corrected to the anatomical reference point of the patient is therefore minimized. In two patients, symptoms of intracranial hypotension relieved after changing the lumbar drainage from discontinuous to continuous manner.

The calculation of drained CSF volume gives further diagnostic information especially for diagnosis of critical situations such as slit ventricle syndrome and catheter occlusions. Furthermore, other therapeutically strategies might be modified using this parameter such as indication for CSF shunting and withdrawing the external ventricular drainage. Detection of CSF pulsation might indicate easily catheter occlusion and slit ventricle syndrome and offers easy and early additional information

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to the neurosurgical staff, since catheter occlusion can not be detected by a pressure sensor mounted at the tip of the catheter. The only limiting factor might be if air comes into the drainage which then might lead to deviations between calculated and measured CSF volume. However, since ICP curve will be dumped by air, ICP pressure pulsation will be reduced.

In conclusion, this new system offers new possibilities for neurosurgical patients for treatment in both, lumbar and ventricular application. The dual pressure sensor technique, independence to a dripping chamber and possibility to drain CSF and measure the CSF pressure simultaneously offers an additional safety and mobility for the patient.

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N. KLEMZ, B. LUTHER, P. KÖSTER, T. NOWAK, E. BERENDES

CONTINUOUS CONTROLLED LUMBAR SPINAL FLUID DRAINAGE FOR PPREVENTION OF SPINAL ISCHEMIA DURING THORACOABDOMINAL SURGERY OF THE AORTA

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"Der interessante Fall"
(Feature article)

Gefässchirurgie 2009 ***(publication: "Vascular surgery 2009")***
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Continuous controlled lumbar spinal fluid drainage for prevention of spinal ischemia during thoracoabdominal surgery of the aorta

Despite various therapeutic applications, attempts to substantially reduce ischemia associated neurological failures following thoracoabdominal aorta surgery have been unsuccessful. The challenge is to find better methods to determine and improve spinal cord perfusion. In addition to the use of shunts, left heart bypasses using pump systems, lowering body temperature, MEP monitoring, as well as clamp-and-repair techniques and inclusion of the spinal arteries in the reconstruction of the aorta, other suitable methods include fluid drainage systems such as the continuous closed variant (LiquoGuard) proposed.

Method

The current practice of lumbar drainage involves manual, irregular fluid withdrawal. The application of LiquoGuard by Möller Medical GmbH, enables for the first time, a continuous, pressure-controlled fluid drainage. Furthermore, in contrast to the established drop-chamber systems, this drainage system is closed and sterile (**Fig. 1**).
The fluid flow is controlled by a pre-programmed spinal pressure and a set maximum flow rate. Excessive drainage is avoided since underpressure never occurs. A pre-operative, time-consuming adjustment of the pressure transducer is not required since the sensor unit can be secured to the nape of the patient quickly and easily.

Case history

A 65-year old patient underwent surgery for a symptomatic thoracoabdominal aortic aneurysm Crawford Type III. A large, penetrating ulcer (PAU) on the right side indicated a high risk of perforation. A tubular prosthesis had previously been implanted as a result of an infrarenal abdominal aortic aneurysm. Due to the specific position of the TAA in the visceral segment of the aorta, an endovascular procedure was excluded.
The operation technique consisted in a left thoracoabdominal, extraperitoneal approach with an internal aorto-aortal shunt implantation. Resection of the aneurysm was performed by using a tubular prosthesis, with the inclusion of the spinal arteries TH 11 and 12, as well as all visceral arteries. Cooled, pharmacological rinsing perfusion was temporarily performed on an intestinal artery and a renal artery respectively. After successful reconstruction of the aorta, the internal shunt was removed and the thoracolaparotomy wound closed.
Prior to anaesthetisation, the patient received a thoracic peridural catheter to ensure analgesia. Another catheter was inserted in the L4/5 spinal region for lumbar drainage and incorporated with the LiquoGuard system. The drainage tube was fitted into the pump. The pressure sensor connector was connected to the pump and a zero balance performed. The interspinal pressure limit was set at 10 mmHg. The continuous flow rate was set at a mean value of 20 ml per hour and the application started. The system operated in a continuous and smooth manner throughout the duration of the surgery. Manual intervention was not required, thus ensuring that the system was permanently sterile, unlike conventional methods of manual fluid withdrawal via drop-chamber systems. Interspinal pressure peaks were particularly evident during aortic cross-clamping (**Fig. 2**). However, the pressure never exceeded 12 mmHg. The flow rate set avoided pressure peaks occurring from the outset.

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During the duration of the surgery, a total of 25 ml of fluid were drained by the LiquoGuard system without the need for intervention by the anaesthetist.

With a total drainage of 174 ml during the post-operative stage, the catheter was smoothly removed after 72 hours.
The patient indicated no post-operative neurological failure following a brief weaning stage. None of the feared side effects of lumbar drainage were noted.

Discussion

Spinal ischemia is a complication arising during thoracoabdominal aortic surgery. Over the past 25 years the incidence rate has ranged between 5 and 20% [7, 14]. Neurological failures such as sensorial deficit, paraparesis and paraplegia have resulted. As with so-called hybrid procedures, even modern techniques such as endoluminal stent-graft implantation in the treatment of thoracoabdominal aneurysmata (TAAA), constitute a risk of neurological failures, albeit to a lesser degree [2]. The paraparesis and paraplegia incidence rates are 4.2% and 8.5% respectively [21].
Often further complications arise during post-operative procedures, thus increasing patient morbidity. In particular, higher incidence in pneumonia and increased reintubation resulting from diaphragmatic respiratory impairment, are reported. Other examples include renal failure, urinary passage infections and major decubitus ulcers. The mortality rate with full paraplegia is recorded at about 20% [18]. Even in cases of anastasis, a complete recovery is the exception rather than the rule.
The protection of the spinal cord, therefore, is important during thoracoabdominal aorta reconstruction. The most common neurological safeguard is measuring the fluid pressure in the lumbar spinal canal and draining spinal fluid [17]. Since cross-clamping of the thoracic aorta causes increased pressure in the spinal canal, continuous lumbar drainage can reduce spinal cord compartment lesions. This increased intrathecal pressure is further strengthened by a secondary reperfusion-related tissue oedema resulting from a disturbance of the blood-spinal cord barrier [13]. The spinal cord oedema also impacts on the microcirculation. Spinal perfusion is influenced by the ratio of the spinal perfusion pressure to the tissue pressure in the osseous compartment.
Clinical data recorded in prospective randomised studies on the protection derived from spinal fluid drainage, indicate the neuroprotective advantages of spinal cord fluid drainage during and after thoracic aorta cross-clamping; these studies, however, have been repeatedly challenged [6, 8, 18]. Intraoperative spinal canal pressure monitoring is, therefore, recommended. In the event that the pressure limit of 15 mmHg is exceeded, fluid can be removed through a lumbar drainage in lying position in order to reduce the spinal pressure and raise the perfusion pressure in the spinal cord [3, 4, 12, 16]. The intraspinal pressure limit should not exceed 10 to 12 mmHg [4, 9]. Post-operative drainage monitoring is continued for another 72 hours in order to prevent a secondary pressure increase [1, 11, 17].
Temporary side effects and permanently manifest complications due to cerebrospinal fluid drainage are seldom reported in conjunction with thoracoabdominal aortic procedures. Catheter-associated meningitis (1.2%) and catheter fracture (1.8%) can be caused by the common intermittent fluid withdrawal in drop-chamber systems. Intraspinal haematoma (3.2%) and intracranial subdural haematoma due to excessive manual drainage (3.5%) are also reported [5, 10, 15, 20, 22]. From an anaesthesiological and legal perspective, therefore, indications in favour of lumbar fluid drainage are to be considered crucial [20]. In 2000, Coselli et at. [7] indicated a reduction in paraplegia and paraparesis of 80% in patients with thoracic aorta aneurysms where lumbar fluid drainage had been performed.

Conclusion

Fluid drainage within a sterile system (LiquoGuard) can minimise the incidence of temporary side effects and permanently manifest complications resulting from the particular surgical method, allowing for a broader application.

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Fig. 1 LiquoGuard

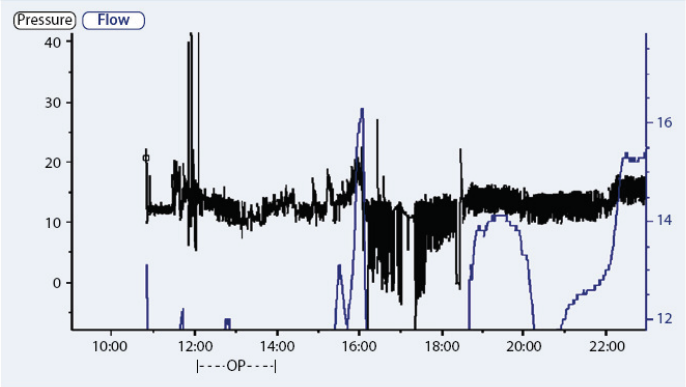

Fig. 2 Fluid pressure and flow during surgery and during the post-operative stage

Abstract

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N. Klemz · B. Luther · P. Köster · T. Nowak · E. Berendes

Continuous controlled lumbar spinal fluid drainage for prevention of spinal ischemia during thoracoabdominal surgery of the aorta

Abstract

Spinal ischemia is an unresolved problem in thoracoabdominal surgery of the aorta. As a result, neurological failures such as sensory deficits occur, as well as paraparesis and paraplegia. Therefore, protection of the spinal cord during thoracoabdominal surgery is a major challenge. The most commonly used method of neurologic surveillance is measurement of spinal fluid drainage and cerebrospinal pressure in the lumbar spinal canal. Complications such as meningitis or spinal catheter fracture can be caused by intermittent fluid withdrawal in the drop-chamber system. Further complications include intraspinal hematoma and intracranial subdural hematoma due to excessive manual drainage. So far, cerebrospinal fluid drainage systems have been manual and unbalanced. Using LiquoGuard (Möller Medical), continuous pressure-controlled cerebrospinal fluid drainage has been enabled for the first time. Furthermore, this drainage system is closed and sterile, in contrast to established drop-chamber systems.

Keywords

Spinal ischemia · Thoracoabdominal surgery · Lumbar drainage · LiquoGuard

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Conflict of interest: The author declares that no conflict of interests exists.

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M. KUDERNATSCH, S. NAUROS, P.A. WINKLER

AUTOMATICAL PRESSURE- AND FLOW-CONTROLLED VENTRICULAR CSF DRAINAGE LIQUOGUARD®: TWO YEARS OF EXPERIENCE WITH OVER 50 CHILDREN IN PEDIATRIC NEUROSURGERY AND EPILEPSY SURGERY

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Behandlungszentrum Vogtareuth
Schön Kliniken

Automatical Pressure- and Flow-Controlled Ventricular CSF Drainage LiquoGuard®: Two Years of Experience with over 50 Children in Pediatric Neurosurgery and Epilepsy Surgery

Manfred Kudernatsch, Suleyman Nauros, Peter A. Winkler

Klinik für Neurochirurgie und Epilepsiechirurgie, Behandlungszentrum Vogtareuth

Introduction:
At the clinical centre Vogtareuth (Fig. 1), a department of neuropediatry as well as departments for neurosurgery and epilepsy surgery is in operation. The fields of pediatric neurosurgery and epilepsy surgery are cooperating very closely. Many of the jointly treated patients are suffering from complex forms of hydrocephalus, or need at least a transient post-surgical external CSF drainage. With the legacy open ventricular CSF drains using drip chambers, the handling was unsafe in many cases, in particular on the normal care station, and complications (e.g. overdrainage) occured in some cases (Fig. 2). To ensure better patient safety, we have been using the LiquoGuard®-System (Möller Medical), since 2006 in some test cases, and since 2007 systematically.

Fig. 1

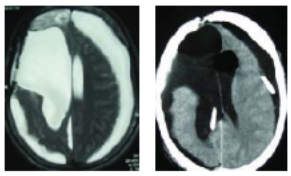

Fig. 2
After functional right hemispherectomy, a CSF overdrainage of about 200ml, caused by uncontrolled mobilization, led to a expanding hygroma on the opposite side. The hygroma left had to be treated by a subdural drainage.

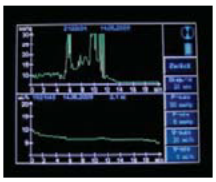

Fig. 3
History presentation (LiquoGuard®-System) of an artificial ICP increase, caused by screaming of the child (above).
The CSF flow remained constant throughout this phase. An overdrainage – as is common with legacy ventricular drains using drip chambers – did not occur.

Material and Method:
Since 2007, the common external CSF drains (drip chambers that have to be level-adjusted in relation to certain anatomical reference points) have been replaced by the LiquoGuard® system (Möller Medical) with almost all neuropediatric-neurosurgical patients. Particularly in epilepsy surgery, in connection with surgeries when a hydrocephalus condition was diagnosed, or resections of several cerebral lobes and extended opening of the ventricular system was required, this system was systematically used. Further application areas were verification of hydrocephalus diagnoses and external drains in connection with shunt infections and shunt-related complications. In total, the LiquoGuard® system was used on more than 50 children. We have analyzed and evaluated the data with regard to drainage-associated complications.

Results:
In none of the over 50 cases, the LiquoGuard® system caused any complications. Neither any overdrainage, nor any overdrainage-related complication that required surgical treatment, occurred. The advantages became even more visible, the more uncooperative, restless or mobile a child was. Neither coughing, crying/screaming (Fig. 3), unintended change of position, epileptic seizures or extreme mobility (Fig. 4) led to uncontrolled CSF losses. In these situations, had the child been treated with a drip chamber, a continuous supervision by nurses or parents would have been mandatory, since only the instantaneous closing of the drain would have prevented unintended loss of CSF.
With transient post-surgical use of the LiquoGuard® system, it was possible to remove the external drains earlier. The daily drained volumes were in some cases significantly lower, since no intended CSF losses came on top of the actually required CSF drainage volume.

Fig. 4
Ten days after vertical, parasagittal hemisperectomy with intrauterine media infarct and hydrocephalus, this girl was able to move about the hospital grounds by bicycle with active external CSF drainage and LiquoGuard® system (visible on the bicycle carrier).

Discussion:
Especially in the neuropediatric normal care station, the significant advantages of the LiquoGuard® system as compared to a drip chamber-based system were most obvious. Patient safety with a running external ventricular drainage was increased, while supervision and nursing effort was reduced. A continuous ICP measurement supplemented supervision, especially with children in the early post-surgical phase. Overdrainage-related complications did not occur. Besides patient safety, patient satisfaction was also increased significantly, since even longer mobile phases were possible with a running system and no complications.

Schön Kliniken. Die Spezialisten

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April 16, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Traditional 510(k) Premarket Notification for LiquoGuard CSF System

To Whom It May Concern:
Möller Medical submits the enclosed Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**.

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis.

The **LiquoGuard CSF System** is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The **LiquoGuard CSF System** controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The **LiquoGuard CSF System** also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

The **LiquoGuard CSF System** consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF and LiquoGuard CSF Tubing Set

Classification and Product Code:
21 CFR § 882.5550, "Shunt, Central Nervous System and Components", Class II, JXG

The Möller Medical **LiquoGuard CSF System** is substantially equivalent to the Central Nervous System devices "Integra NeuroSciences corporation (K030289, K032817)" and "Codman & Shurtleff, Inc. (K061568)" in terms of intended use, design, operating principles, and materials.

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Design and Use of the Device **LiquoGuard CSF System:**

Question	**YES**	**NO**
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

**Only valid for LiquoGuard CSF Tubing Set*

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device. The enclosed Traditional 510(k) is submitted in duplicate (as required) with an electronic CD-ROM copy serving as the second copy of the submission. The electronic copy is an exact duplicate of the paper copy and has been prepared per FDA's instructions (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm).

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
MOELLER MEDICAL GMBH 10472 Mira Vista Drive Santa Ana CA 92705 US	Grant Geckeler 2.1 E-MAIL ADDRESS ggeckeler@geoinc.org 2.2 TELEPHONE NUMBER (include Area code) 714-283-1682
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

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[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted] 04-Apr-2012

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Grant Geckeler

From: paygovadmin@mail.doc.twai.gov
Sent: Thursday, April 12, 2012 7:02 PM
To: ggeckeler@geoinc.org
Subject: Pay.gov Payment Confirmation: FDA User Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: FDA User Fees
Pay.gov Tracking ID: 256BBKBK
Agency Tracking ID: 6061163
Transaction Type: Sale
Transaction Date: Apr 12, 2012 10:02:03 PM

Account Holder Name: Dr. Christoph Traxler Transaction Amount: (b)(4) [redacted] Billing Address: Heinrich-von-Bibra-Platz 1a
City: Fulda
Zip/Postal Code: 36037
Country: GER
Card Type: MasterCard
Card Number: **********5552

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04.04.2012		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Möller Medical GmbH	Establishment Registration Number *(if known)*: 3006611221		
Division Name *(if applicable)*:	Phone Number *(including area code)*: +49 661 941 95 0		
Street Address: Wasserkuppenstraße 29-31	FAX Number *(including area code)*: +49 661 9 41 95 850		
City: Fulda	State / Province:	ZIP/Postal Code: 36043	Country: Germany
Contact Name: Juliane Dragon			
Contact Title: Regulatory Affairs Manager	Contact E-mail Address: jdragon@moeller-medical.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: G.E.O. Inc.			
Division Name *(if applicable)*: ATTN: Grant Geckeler	Phone Number *(including area code)*: +1 714 312 6863		
Street Address: 1612 Jenks Drive	FAX Number *(including area code)*: +1 714 637 2460		
City: Corona	State / Province: CA	ZIP Code: 92880	Country: USA
Contact Name: Grant Geckeler			
Contact Title:	Contact E-mail Address: ggeckeler@geoinc.org		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257, Release Date CDRH

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [x] New Device
- [x] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [x] Software/Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other*(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [x] Process change:
  - [x] Manufacturing
  - [x] Packaging
  - [ ] Sterilization
  - [ ] Other*(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other*(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason*(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent/Applicant
  - [ ] Design/Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason*(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason*(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10957, Release date CDRH

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JXG	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K030289	1	Hermetic Plus External CSF Drainage System	1	Integra Life Sciences Corporation
2	K032817	2	External Drainage Set	2	Integra NeuroSciences Implants S.A.
3	K061568	3	CODMAN EDS 3 CSF External Drainage System	3	Codman & Shurtleff, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

External CSF Drainage System

	Trade or Proprietary or Model Name for This Device		Model Number
1	LiquoGuard CSF	1	00002563
2	LiquoGuard CSF Tubing Set (1500mm)	2	00002650, REF. 92007836
3	LiquoGuard CSF Tubing Set (2000mm)	3	00002911, REF. 92008568
4	Safety Cushion for Tubing Set	4	00002701
5	Attachment Clamp	5	00002672

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K070099	2 K082222	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
JXG	21 CFR 882.5550	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

882 - Shunt, Central Nervous System and Components

Indications *(from labeling)*

Continous measurement of CSF pressure and CSF drainage

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Note:Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number*(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Möller Medical GmbH		Establishment Registration Number: 3006611221
Division Name*(if applicable)*		Phone Number*(including area code)*: +49 661 941 95 0
Street Address: Wasserkuppenstraße 29-31		FAX Number*(including area code)*: +49 661 941 95 850
City: Fulda	State / Province	ZIP Code: 36043 / Country: Germany
Contact Name: Juliane Dragon	Contact Title: Regulatory Affairs Manager	Contact E-mail Address: jdragon@moeller-medical.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name*(if applicable)*		Phone Number*(including area code)*
Street Address		FAX Number*(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name*(if applicable)*		Phone Number*(including area code)*
Street Address		FAX Number*(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11135-1	ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development process for medical devices	2007	04/04/2012
2	10993-7	ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008	04/04/2012
3	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2003	04/04/2012
4	60601-1-2	EN	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2002	04/04/2012
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Pugh, Dominique *

From: Pugh, Dominique *
Sent: Tuesday, December 17, 2013 8:59 AM
To: GGECKELER@GEOINC.ORG
Cc: DCCLetters
Subject: K121248 SE LETTER
Attachments: K121248 SE LETTER.pdf

Tracking:

Recipient	Delivery
GGECKELER@GEOINC.ORG	
DCCLetters	Delivered: 12/17/2013 8:59 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Binoy Mathews, MS, CDRH/ODE/DNPMD/NSDB

Subject: 510(k) Number K121248

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?	X	
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		
Neonate/Newborn (Birth to 28 days)		
Infant (29 days to < 2 years)		
Child (2 years to <12 years)		
Adolescent (12 years to <18 years)		
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Nanotechnology		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	21 CFR § 882.5550
Class:	II
Product Code:	JXG
Additional Product Codes:	

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Quynh T. Hoang -S 2013.12.13 17:38:59 -05'00'
Division Sign-Off	Joyce M. Whang -S 2013.12.13 18:17:21 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K121242/A1

Mathews, Binoy

From: Allen, Samie Niver
Sent: Tuesday, August 27, 2013 4:39 PM
To: Mathews, Binoy
Cc: Garcia, Diane; Pugh, Dominique *; Chin, Yeuly *
Subject: FW: K121248/S2

Binoy,

I just discussed this with Diane. You can take S2 down to DCC to get converted to an amendment, which stops the review clock. However, this is not an eCopy hold issue. As Diane informed you, you need to contact the company and have them submit a new formal response to the DCC and stress to them that the eCopy needs to match the paper copy. They had multiple eCopy hold letters because of this issue this last go-around.

Thanks
Samie

From: Allen, Samie Niver
Sent: Tuesday, August 27, 2013 4:03 PM
To: Mathews, Binoy
Cc: Garcia, Diane (Diane.Garcia@fda.hhs.gov)
Subject: K121248/S2

Binoy,

I heard that you came down to DCC to have them put S2 back on eCopy hold. We are not going to do that. The eCopy matches the paper copy. As I told you before, it is against policy to put submissions that are in the review queue back on eCopy hold. Furthermore, even requesting that action because the response is not what you wanted is not justified to consider not following the eCopy policy.

Now, if you are going to take the position that this is not a response to the TH (and the appropriate people have agreed), then what you are talking about is converting that Supplement to an Amendment, which is not the same as putting it on eCopy hold.

Thanks,
Samie Allen, CAPT, USPHS
Policy Analyst
FDA/CDRH/ODE
samie.allen@fda.hhs.gov
301-796-6055

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Chin, Yeuly *

From: Mathews, Binoy
Sent: Wednesday, August 28, 2013 11:28 AM
To: Chin, Yeuly *; Allen, Samie Niver; Garcia, Diane; Pugh, Dominique *
Cc: Nandkumar, Srinivas
Subject: FW: K121248-S002 Möller Medical
Follow Up Flag: Follow up
Flag Status: Red

Hi Yeuly,

Here is my email to the sponsor. Thanks for your help.

--Binoy

From: Mathews, Binoy
Sent: Wednesday, August 28, 2013 11:25 AM
To: 'Kosak, Maria'
Cc: 'Grant Geckeler'; 'Grant Geckeler'
Subject: RE: K121248-S002 Möller Medical

Hello Maria,

Your official response is incomplete and hence we will be placing your submission K121248/S2 back on hold. Please provide your response to our deficiencies from our November 2012 deficiency letter along with an identical eCopy and send it to the Document Control Center. Before sending us your response, kindly verify that your submission contains the correct version of your document. Thank you.

Regards,

Binoy Mathews

Binoy J. Mathews
Biomedical Engineer/Scientific Reviewer
Neurostimulation Devices Branch
Division of Neurological and Physical Medicine Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
WO66 Room 2455
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-796-6475
e-mail: binoy.mathews@fda.hhs.gov

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notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

From: Mathews, Binoy
Sent: Wednesday, August 28, 2013 10:11 AM
To: 'Kosak, Maria'
Cc: Traxler, Christoph; Lang, Stefan; Gottl, Stefan; Grant Geckeler; Amanda Sandoval; Grant Geckeler
Subject: RE: K121248-S002 Möller Medical

Hi Maria,

I am sorry to hear you are having so much trouble with your S2 submission. Currently the official response we have on file is not the version you intended. I suggest you send in your intended paper and eCopies after careful verification that it is the correct version and both copies are identical. Please send this to the Document Control Center (DCC) so as to make it your official response. I cannot complete my review until I am working with the official response through the DCC. Please note, that I am not aware of your current communication with the DCC. If you have been instructed on how to proceed by them, please let me know and follow their direction. Thank you.

--Binoy

From: Kosak, Maria [mailto:MKosak@moeller-medical.com]
Sent: Tuesday, August 27, 2013 11:33 AM
To: Mathews, Binoy
Cc: Traxler, Christoph; Lang, Stefan; Gottl, Stefan; Grant Geckeler; Amanda Sandoval; Grant Geckeler
Subject: AW: K121248-S002 Möller Medical
Importance: High

Hello Binoy,

I try to call you, but unfortunately you did not were in the office at this moment, so I leaved a voice mail.
Attached you will find the actual version of our "FINAL" submission from May 2013.
Juliane already sent you this document on the 15th of May and I sent this document to you on 15th of August.
We will come back to you as fast as possible when all the problems are solved.

Excuse me very much for all of this confusions.
If you need further information, do not hesitate to contact me.

Best regards,
Maria Kosak
Regulatory Affairs Manager

Möller Medical GmbH
Wasserkuppenstraße 29-31 | 36043 Fulda
fon +49 (0)661 94195 -164 | **fax** -854
mail mkosak@moeller-medical.com
web **www.moeller-medical.com**

HRB 5504 Amtsgericht Fulda
Geschäftsführer:
Peter Schrempp

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Dr. Christoph Traxler

Save a tree. Don't print this document unless it's really necessary!

Von: Grant Geckeler [mailto:grant.geckeler@tpstech.com]
Gesendet: Dienstag, 27. August 2013 17:11
An: Mathews, Binoy
Cc: Kosak, Maria; Traxler, Christoph; Lang, Stefan; Gottl, Stefan; Grant Geckeler; Amanda Sandoval
Betreff: Re: K121248-S002 Möller Medical

Hello Binoy.

Please review the copy with Maria emailed you. It should be dated May 2013.

I suspect the eCopy you were provided by Document Control was somehow an older version (perhaps June 2012?). The correct version is the one Maria emailed (dated on/about May 2013). We are handling this issue still with Document Control, and reply all with updates.

Thanks,

Grant Geckeler
Direct: (714) 312-6863

On Tue, Aug 27, 2013 at 7:27 AM, Mathews, Binoy <Binoy.Mathews@fda.hhs.gov> wrote:
Hello Maria,

Your submission has been assigned to me. Although this is under review, I am troubled because it seems even though the paper and eCopy submission I have are identical, there are no responses to our last set of deficiencies. The current paper copy and eCopy I have are identical to your S1 submission. You had included responses to our deficiencies in the submission which we had two weeks ago and so I am confused as to why you have not included them in this current submission. My contact at the Document Control Center also mentioned that she spoke to someone in your company and verified that the current submission (the one without your response to deficiencies) is the intended submission. Am I missing them somewhere? Have you updated your entire submission to include your responses? To add to my confusion, you emailed me an eCopy which you said was an exact copy of your submission. However, that eCopy contains responses to deficiencies from our S1 Hold Letter. Should I be reviewing the eCopy which was emailed to me or the submission currently in my hand. Kindly reply as soon as possible so that I may begin our review. Thanks.

Regards,

Binoy

From: Kosak, Maria [mailto:MKosak@moeller-medical.com]
Sent: Tuesday, August 20, 2013 2:56 AM
To: Mathews, Binoy

12

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Cc: Traxler, Christoph; Lang, Stefan; Gottl, Stefan; Grant Geckeler; Grant Geckeler; Amanda Sandoval

Subject: K121248-S002 Möller Medical
Importance: High

Hello Binoy!

Do you have news for us relevant to the problems with the Telephone Hold Letter and the eCopy?
We didn´t got any Telephone Hold Letter and our Agent Grant Geckeler got only three eCopy Hold Letter and he reacted immediately.

If you need further information, do not hesitate to contact me.

Best regards,
Maria Kosak
Regulatory Affairs Manager

Möller Medical GmbH
Wasserkuppenstraße 29-31 | 36043 Fulda
fon +49 (0)661 94195 -164 | **fax** -854
mail mkosak@moeller-medical.com
web **www.moeller-medical.com**

HRB 5504 Amtsgericht Fulda
Geschäftsführer:
Peter Schrempp
Dr. Christoph Traxler

Save a tree. Don't print this document unless it's really necessary!

Von: Kosak, Maria
Gesendet: Donnerstag, 15. August 2013 19:33
An: 'Mathews, Binoy'
Cc: Traxler, Christoph; Lang, Stefan; Gottl, Stefan
Betreff: AW: K121248-S002 eCopy Hold Letter
Wichtigkeit: Hoch

Hello Binoy!

Thank you very much for the pleasant call.
Attached you will find the document "Add_Info_LiquoGuard_FINAL_2013-05_000" we transmitted as paper copy and eCopy (DVD) in May 2013 via FedEx.

After a call with FDA representatives the 510(k) #K121248 was revised, the deficiencies were corrected and had some influence in the 510(k) submission.
This response to 510(k) #K121248 includes the additional information requested by FDA in the letter dated November 20, 2012 and the deficiencies from the FDA call 5th of April 2013.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA's questions are presented in *italic* font for ease of review and the deficiencies were responded in the "clinical data" (please refer to Appendix 1).
Please take a look at the attachment.
The structure of the document "ADDITIONAL INFORMATION FOR 510(K) PREMARKET NOTIFICATION #K121248" is that you will find under point 2 the FDA's questions / requests and the Möller Medical response were below and we included a reference / link to the relevant appendix.
The deficiencies from the FDA call were included in the text from the "clinical data".
The double counts were corrected in the hole text.
The detail analyses we had made only for the occlusion, are caught up for all sanguineous issue →
Please refer to point 2.3 "Infections" page 11, to point 2.4 "Hemorrhage" page 14, to 3.3 "Infections" page 18 and to point 3.4 "Hemorrhage" page 19.

If you need further information, do not hesitate to contact me.

Best regards,
Maria Kosak
Regulatory Affairs Manager

Möller Medical GmbH
Wasserkuppenstraße 29-31 | 36043 Fulda
fon +49 (0)661 94195 -164 | **fax** -854
mail mkosak@moeller-medical.com
web **www.moeller-medical.com**

HRB 5504 Amtsgericht Fulda
Geschäftsführer:
Peter Schrempp
Dr. Christoph Traxler

Save a tree. Don't print this document unless it's really necessary!

Von: Mathews, Binoy [mailto:Binoy.Mathews@fda.hhs.gov]
Gesendet: Mittwoch, 14. August 2013 21:07
An: Kosak, Maria
Betreff: RE: K121248-S002 eCopy Hold Letter

Hello Maria,

I was assigned your file yesterday. On looking over the contents very briefly, I noticed that you did not include a section which responded directly to the deficiencies we sent in our last Telephone Hold Letter. Could you either let me know where this is included in your submission or compile one for me so that my review team does not have to take time searching the entire document for responses to their questions. Kindly send me this information at the earliest. Thank you.

--Binoy

From: Kosak, Maria [mailto:MKosak@moeller-medical.com]
Sent: Wednesday, August 07, 2013 12:17 PM
To: Mathews, Binoy
Cc: Traxler, Christoph; Lang, Stefan; Grant Geckeler; Grant Geckeler
Subject: K121248-S002 eCopy Hold Letter

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Importance: High

Hello Binoy,

Thank you very much for your support to find the problems and to remove them.
I try to call you, but unfortunately you did not were in the office at this moment.

I got the message from Grant and Amanda that this submission went out again yesterday via FedEx as a DVD with the Tracking Number 796401181271.

The files originally sent over were renamed to match the required naming convention.

I kindly ask you to give me a confirmation when the post delivery from the submission arrived and please give me a confirmation when you process this submission and , because this is very important for us.
Please contact for this confirmation Mr. Dr. Christoph Traxler ctraxler@medimondi.com and me Maria Kosak mkosak@moeller-medical.com.
Many thanks for your support and understanding.

Is it possible to have a call tomorrow ?
I will try to call you at 9:00 a.m. (3:00 p.m. MEZ) or you can tell me a time of day.

If you need further information, do not hesitate to contact me.

Best regards,
Maria Kosak
Regulatory Affairs Manager

Möller Medical GmbH
Wasserkuppenstraße 29-31 | 36043 Fulda
fon +49 (0)661 94195 -164 | **fax** -854
mail mkosak@moeller-medical.com
web **www.moeller-medical.com**

HRB 5504 Amtsgericht Fulda
Geschäftsführer:
Peter Schrempp
Dr. Christoph Traxler

Save a tree. Don't print this document unless it's really necessary!

Vertraulichkeitshinweis: Diese Nachricht ist ausschließlich für die Personen bestimmt, an die sie adressiert ist. Sie kann vertrauliche und/oder nur für den/die Empfänger bestimmte Informationen enthalten. Sollten Sie nicht der bestimmungsgemäße Empfänger sein, kontaktieren Sie bitte den Absender und löschen Sie die Mitteilung. Jegliche unbefugte Verwendung der Informationen in dieser Nachricht ist untersagt.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Binoy Mathews

Subject: 510(k) Number K121248/S1

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM			

Rev. 2/29/12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Srinivas Nandkumar 2012.11.21 12:20:44 -05'00'

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Mathews, Binoy

From: Mathews, Binoy
t: Wednesday, November 21, 2012 1:21 PM
To: 'ggeckeler@geoinc.org'
Subject: K121248/S1 on HOLD:

Attachments: K121248_S1_Moller_Letter_TH.pdf

Dear Mr. Geckeler,

We have reviewed your submission and have a few concerns that need to be addressed before the review can continue. Therefore, your submission is being placed on hold. You will not be receiving a letter in the mail. This email is issued in place of a formal letter. Attached are the specific issues that need to be addressed before the review can proceed. Also attached is the standard language found in formal Request for Additional Information Letters regarding methods of response.

Please feel free to contact me if you have any questions or concerns.

Regards,

Binoy Mathews

K121248_S1_Moller
etter_TH.pd...

Binoy J. Mathews
Biomedical Engineer/Scientific Reviewer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Division of Neurological and Physical Medicine Devices
Neurostimulation Devices Branch
WO66 Room 2455
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-796-6475
e-mail: binoy.mathews@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Date: November 20, 2012

Contact person: Grant Geckeler
Free lance consultant
4375 Prado Road, Suite 103
Corona, CA 92880
Phone: +1 714 283 1683
Fax: +1 714 637 2460
E-mail: ggeckeler@geoinc.org

To: Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda
GERMANY

Subject: K121248/S1 Liquoguard

Cc: Record

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information provided. Therefore, this 510(k) will be placed on telephone hold. To complete the review of your submission, we require the following information:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Binoy Mathews at (301) 796-6475. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification 510(k) Review
Traditional
K121248/S1

Date: November 19, 2012
To: The Record
From: Binoy Mathews

Office: ODE
Division: DNPMD

510(k) Holder: Möller Medical GmbH
Device Name: Liquoguard CSF System
Contact: Grant Geckeler
Phone: +1 714 283 1683
Fax: +1 714 637 2460
Email: ggeckeler@geoinc.org

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Liquoguard CSF System into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?	X		

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF system consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

(b)(5)

[redacted]

S001
Sponsor has revised their submission to now include a secondary predicate device. Information is as follows:

1. Intergra NeuroSciences Corporation: K030289,K032817
2. Codman & Shurtleff, Inc..: K061568
3. Camino NeuroCare Inc.: K962928

The addition of device #3 in the list above addresses the lack of an Intracranial Pressure Monitor within the list of predicate devices.

BJM COMMENTS: The Camino NeuroCare is an acceptable predicate for the subject device.

IV. Indications for Use

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

(b)(5)

[redacted]

S001
Clinical Review was performed by Dr. Mohammed Bydon. No concerns were raised with regard to the IFU statement.

V. Predicate Device Comparison

Table 1: Substantial Equivalence Devices

Trade Name	510(k) Submitter/Holder	510(k) Number
Hermetic Plus External CSF Drainage System External Drainage Set	Integra LifeSciences Corp	K030289 K032817
CODMAN EDS 3 CSF External Drainage System	Codman & Shrutleff, Inc.	K061568

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Table 2: Device Comparison

	Möller Medical	**Integra LifeSciences Corporation (K030289, K032817)**	**Codman & Shrutleff, Inc. (K061568)**
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure.	Externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients.	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and patient.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber
Height alignment of patient and device	Device can be positioned arbitrarily, only the pressure sensors need to be aligned	Alignment is critical because it controls the target pressure	Alignment is critical because it controls the target pressure
Device Adjusting Fluid Flow	LiquoGuard CSF peristaltic pump controlled by pressure at sensor location	None - fluid flow is not controlled or limited	None - fluid flow is not controlled or limited
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF system	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high * Pressure too low * Physiological pressure pulsation lost * Pressure remains constant for too long * Dual sensors deviate in readings (defective sensor) * Watchdog or main controller does not respond to each others requests (device or software malfunction) * Battery low	No integrated alarm functions	No alarm functions

(b)(5)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

S001
Sponsor has revised their predicate device comparison table to include the addition of an ICP monitor as a secondary predicate. eCopy is unavailable to copy new comparison table into this memo. Please refer to submission.

BJM COMMENTS: The new comparison table is acceptable.

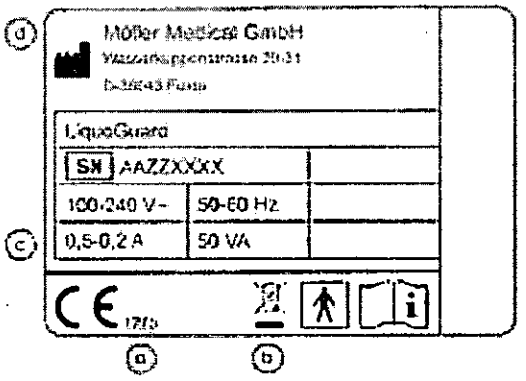
VI. Labeling

[...]

Comment: The sponsor provided packaging illustrations, operating manual, and catalog numbers for their device. These were not reviewed because the predicates are incorrect.

S001

The following are labels provided in the submission



Aufschlüsselung der Seriennummer:

AA = Herstelljahr d.h.: Für Herstelljahr 2004 ist AA = 04
ZZ = Herstellmonat d.h.: Für Monat November ist ZZ = 11
XXXX = fortlaufende Geratenummer mit 0001 beginnend unabhängig von Herstelljahr und Herstellmonat.

Schrift: Schwarz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Möller Medical GmbH
Wasserkuppenstrasse 29-31
D-36043 Fulda

LiquoGuard, REF 00002563

SN AAZZXXXX		
100-240 V~	50-60 Hz	
0,5-0,2 A	50 VA	

CE 1275

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 650

REF.: 92 007 836

1500 mm

STERILE EO

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

LiquoGuard® Drainageset 2007-05
Art.No. 00 002 650
REF.: 92 007 836
1500 mm
Möller Medical GmbH 36043 Fulda, Germany

LiquoGuard® Drainageset 2007-05
Art.No. 00 002 650
REF.: 92 007 836
1500 mm
Möller Medical GmbH 36043 Fulda, Germany

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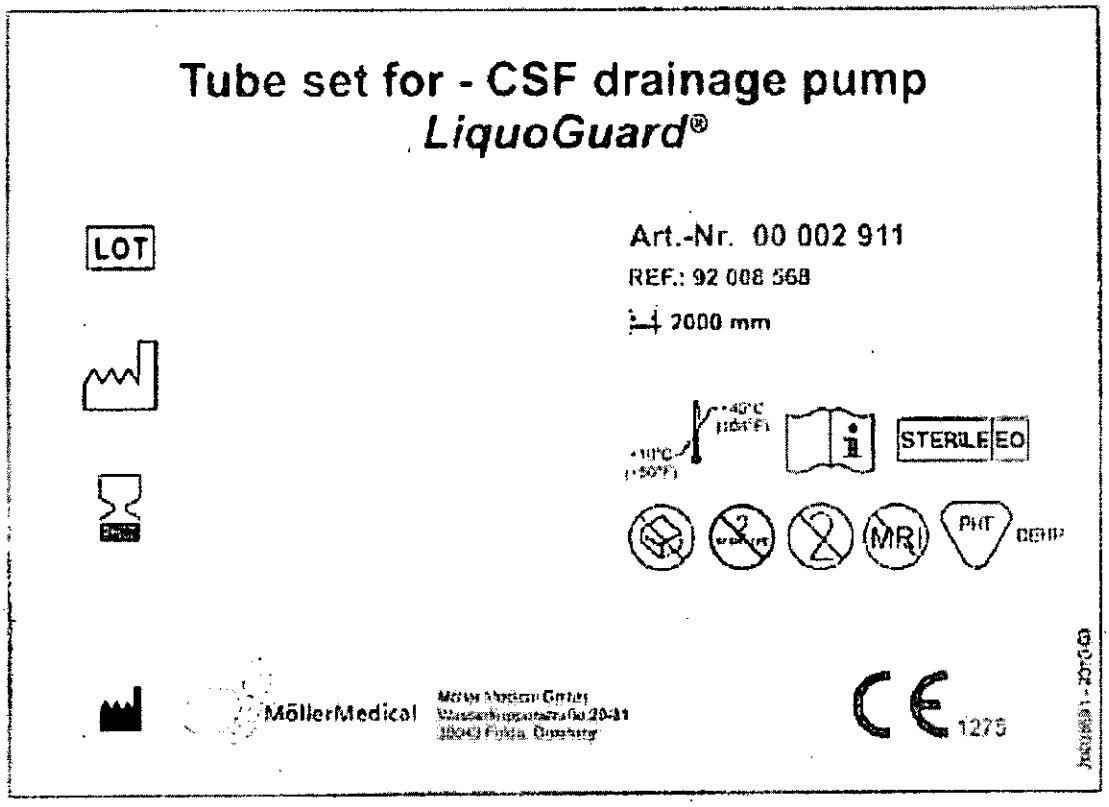
LiquoGuard® Drainageset 2007-05
Art.No. 00 002 650
REF.: 92 007 836
1500 mm
Möller Medical GmbH 36043 Fulda, Germany

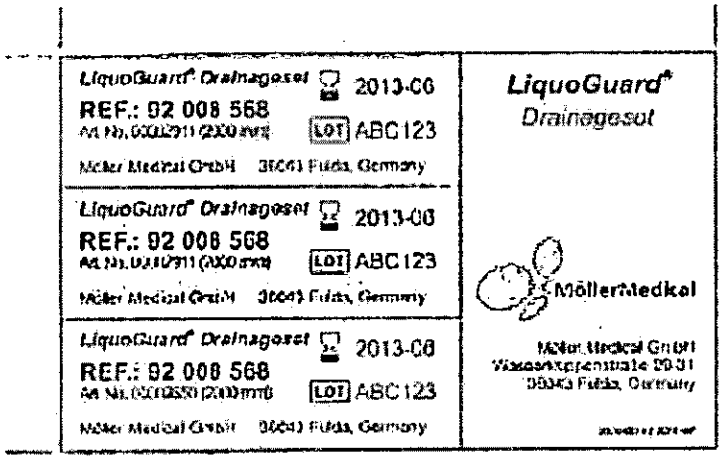
LiquoGuard®
Drainageset

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118





BJM COMMENTS: Packaging Labels should be provided in English. All symbols should be accompanied by appropriate description.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

VII. Sterilization/Shelf Life/Reuse

(b)(4)

[redacted]

The EtO sterilization process has been successfully validated in accordance with ISO 11135-1. In addition, the EtO residual analyze was performed according to ISO 10993-7 and all requirements were met.

The initial sterilization validation was performed in 2006 according to ISO 11135:1994 and ISO 10993-7:1995. To meet all requirements of the revised standards a re-validation of the sterilization was performed in 2010. The validation of 2006 and 2010 together fulfill all requirements of the ISO 11135-1:2007 and the ISO 10993-7:2008.

Please refer to **Appendix 11** and **Appendix 12** for the sterility validation reports of 2006 and 2010 for the LiquoGuard CSF Tubing Set.

The LiquoGuard CSF Tubing Set is packaged in a blister of PETG (700µm, medical grade), sealed with a Tyvek foil which is in accordance with ISO 11607-1. Proposed shelf life is 2 years - please refer to **Appendix 13** for the accelerated aging test report.

Comment: The sponsor provided sterilization method and validation for their device. These were not reviewed because the predicates are incorrect.

S001

(b)(4) Clinical Trailo

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- You provide in Appendix 13 Accelerated Aging Test Report 2 Years Shelf Life. You test microbial barrier properties after accelerated aging (2 years) and mechanical treatment. Please explain what the mechanical treatment means and provide the protocol or method of the mechanical treatment.

- You provide in Appendix 8 and 9 device and package labeling. You include several symbols on your labeling. Please be advised, for products sold in the US, descriptive text must accompany the international symbols on all packaging, except for the "Rx" symbol, or the text can be used without the symbols present. Please modify your labeling to include the missing descriptive text.

VIII. Biocompatibility

Please refer to **Appendix 14** for the biocompatibility testing according to ISO 10993-1 of the LiquoGuard CSF Tubing Set.

Comment: The sponsor provided biocompatibility evaluation. This was not reviewed because the predicates are incorrect.

S001

Dr. Jeffrey Toy was briefed on the biocompatibility information provided in this submission. The materials used by the tube set, namely PVC is widely used within medical devices and combined with the limited direct contact with the patient, does not pose a risk to the patient. Materials information is provided below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

IX. Software

[...]

Comment: The sponsor provided all of the necessary components of software review. These were not reviewed because the predicates are incorrect.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

S001

Version:		
Level of Concern: Major		
	Yes	No
Software description:		X
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	
Verification & Validation Testing:	X	
Revision level history:		X
Unresolved anomalies:		X

BJM COMMENTS: Sponsor has not provided a sufficiently detailed software description, revision level history, and unresolved anomalies. Sponsor will be asked to provide these sections.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

[...]

Comment: The sponsor identified appropriate predicates and provided copies of the reoprts. These were not reviewed because the predicates are incorrect.

S001

Testing has been conducted to meet the following standards:

- 93/42/EEC
- 73/23/EEC
- DIN EN 60601-1-2
- DIN EN 55011

Test reports are provided in appendix 32.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BJM COMMENTS: Sponsor provides testing reports and compliance to EMC standards 60601-1-2 and CISPR 11 (DIN EN 55011).

XI. Performance Testing – Bench

[...]

Comment: The sponsor provided a comprehensive testing of the individual functions of the device. These were not reviewed because the predicates are incorrect.

S001

Sponsor has performed the following bench tests to ensure safety and effectiveness of their device:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

BJM COMMENTS: **Performed bench tests and results are acceptable.**

XII. Performance Testing – Animal

n/a

XIII. Performance Testing – Clinical

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

50

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

50

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

S3

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

54

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

XV. Deficiencies

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

XVI. Advisory

n/a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XVII. Recommendation

Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG

TH – Telephone Hold

Binoy J. Mathews
2012.11.21 10:05:47 -05'00'

Reviewer | Date

Srinivas Nandkumar
2012.11.21 12:23:24 -05'00'

Branch Chief | Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mathews, Binoy

From: Park, Sunny
t: Monday, November 19, 2012 10:21 AM
To: Mathews, Binoy
Subject: K121248 Moeller LiquoGuard CSF System

Hi Biony,

Below is the sterility deficiencies I've come up with so far. As there was no formal consult and not enough time to review the whole submission or write a memo, I am sending you only the deficiencies.
They need to provide reprocessing instructions for the pump and provide sterilization and packaging information about the drainage bag. I also have one clarification deficiency and package labeling deficiency.
Please let me know if you have questions.
Thanks,

-Sunny

You provide in Appendix 7 Operating Manual for the LiquoGuard CSF Drainage System. Your device consists of a reusable component, LiquoGuard CSF pump, but you do not provide reprocessing instructions for the end user. Please revise your labeling to include the missing reprocessing instructions. For guidance you may wish to consult our guidance, FDA/ODE (April 1996) Labeling Reusable Medical Device for Reprocessing in Health Care Facilities: FDA Reviewer Guidance available from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf.

provide in Appendix 4 Packaging Contents of the LiquoGuard CSF Tubing Set and indicate that a disposable CSF drainage bag is included in the packaging. However, your Sterility Validation Reports WI13-06R, 2006 and WI11-10R, 2010 do not mention the CSF drainage bag being sterilized with the tube set. Please explain if your sterilization validation studies included the CSF drainage bag. In addition, please provide information on the packaging system of the CSF drainage bag.

You provide in Appendix 13 Accelerated Aging Test Report 2 Years Shelf Life. You test microbial barrier properties after accelerated aging (2 years) and mechanical treatment. Please explain what the mechanical treatment means and provide the protocol or method of the mechanical treatment.

You provide in Appendix 8 and 9 device and package labeling. You include several symbols on your labeling. Please be advised, for products sold in the US, descriptive text must accompany the international symbols on all packaging, except for the "Rx" symbol, or the text can be used without the symbols present. Please modify your labeling to include the missing descriptive text.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mathews, Binoy

From: Nandkumar, Srinivas
Sent: Tuesday, November 20, 2012 5:21 PM
To: Bydon, Mohamad
Cc: Mathews, Binoy
Subject: RE: Deficiencies for LiquoGuard CSF system

(b)(4)

[redacted]

From: Bydon, Mohamad
Sent: Thursday, November 15, 2012 10:25 PM
To: Nandkumar, Srinivas
Cc: Mathews, Binoy
Subject: Deficiencies for LiquoGuard CSF system

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Dear Nandu and Binoy,

I have revised the deficiencies for the LiquoGuard CSF system. Please see attached.

Thanks kindly.

Best,

Mo

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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave.
Silver Spring, MD 20993

510(k) MEMORANDUM
Medical Officer Review
K121248

Date: November 14, 2012
To: Binoy Mathews, Lead Reviewer
From: Mohamad Bydon, M.D., Medical Officer **Office: ODE/DNPMD/NSDB**
CC: Srinivas Nandkumar, Ph.D., Branch Chief, ENT

Device: LiquoGuard CSF System
Sponsor: Moller Medical GmbH

Recommendation
The LiquoGuard CSF System is Not Substantially Equivalent to the Predicate Devices. The Sponsor presents clinical data that is not sufficiently powered to detect differences in safety endpoints between the devices.

Background from the Sponsor's Application
Substantial Equivalence:
The Möller Medical LiquoGuard CSF System is substantially equivalent to the CSF drainage systems listed below with regard to intended use, design, operating principles, and materials.
Integra NeuroSciences Corporation K030289, K032817
Codman & Shurtleff, Inc. K061568
The Möller Medical LiquoGuard CSF System shares features with, and is substantially equivalent with regard to these features, to the intracranial pressure monitor listed below (the shared features include CSF pressure monitoring, semiconductor sensor principle, display, alarm functions and data recording).
Camino NeuroCare.TM Inc. K962928

Device Description:
Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

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The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Intended Use:
The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The device also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides alarm functions similar to those of intracranial pressure monitors.

10.2 Indications for use
The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (primary predicate devices).

The LiquoGuard CSF System also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions similar to those offered by intracranial pressure monitors (secondary predicate device).

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

10.6 Summary of substantial equivalence discussion
The LiquoGuard CSF System is a tube system with integrated redundantly designed

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pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CSF drainage. The intrathecal CSF drain is used independent of the LiquoGuard CSF System, and the products approved for intrathecal CSF drainage can be connected to the LiquoGuard CSF System (but are not part of the system). The indication for insertion of intrathecal drainage will not be affected by using the LiquoGuard CSF System.
The control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing dripping chamber systems and the LiquoGuard CSF System. The effective mechanism and the function of the CSF extraction by means of a target valuecontrolled rotor pump in the LiquoGuard CSF System is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard CSF System offers comparable effectiveness to existing CSF drainage systems.
The measuring sensors are comparable to the ones used in ICP monitors (Multi Parameter Monitor), as well as many functions (ICP value display, trend analysis, etc.), alarm

11.2 Product idea of the LiquoGuard CSF System
The key disadvantages of the conventional drainage systems are that they have no integrated alarm functions, that they are error-prone and they cannot measure ICP and drain at the same time with only one access to the patent. A wrong cock position or a clogged/disconnected catheter can lead to under- or overdrainage. This problem is solved by the LiquoGuard CSF System that replaces the drainage systems above. It consists of (a) a tube set that is connected to the catheter just like the conventional dripping chamber. The tube set contains a dual pressure sensor measuring the pressure inside the tube at the end of the catheter. The other component (b) is an electronically controlled pump removing CSF as long as the measured pressure is excessive. The LiquoGuard CSF System detects many typically occurring and dangerous situations not caught by dripping chambers and / or ICP monitors, e.g. a sudden pressure drop by an accidentally extracted catheter; or a pressure staying constant for an extended period of time (which is unphysiological and may indicate a clogged/disconnected catheter or an accidentally opened 4-way stop cock).

11.3 Components of the LiquoGuard CSF System
The LiquoGuard CSF System consists of the LiquoGuard CSF System pump and the LiquoGuard CSF System tube set.

11.3.1 LiquoGuard CSF System pump
The LiquoGuard CSF System main (see **Figure 1**) unit contains a peristaltic pump in which the tube set is inserted and connected for operation. It has a blue turning knob and three touch keys for user operation, a card slot to insert a memory card and a display to show pressure and flow values as well as a pressure and flow history. There are 5 light emitting

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diodes and a speaker for the audible alarms.
The main unit is software operated by a micro controller and energy supplied by mains or battery.

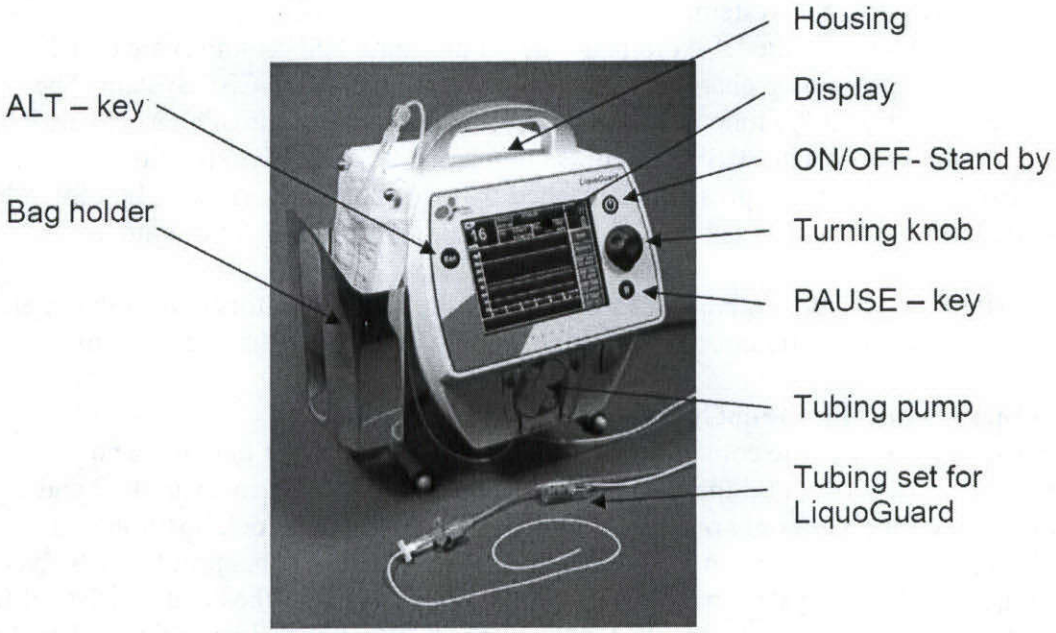

Figure 1: Front view of LiquoGuard CSF System

11.3.2 LiquoGuard CSF System tube set (disposable)

The LiquoGuard CSF System tube set consists of a polyvinyl chloride (PVC) tubing, luer locks, stop cocks, a drainage bag with a reflux valve, specially shaped plastic pieces to ensure correct insertion into the pump, and a pressure sensor housing with two piezoresistant pressure transducers, a cable for connection to the pump and a sticker to attach the sensor housing to the patient's skin. The tube set is only for use with the LiquoGuard CSF System. Please refer to **Appendix 3** for the product materials and **Appendix 4** the packing contents.

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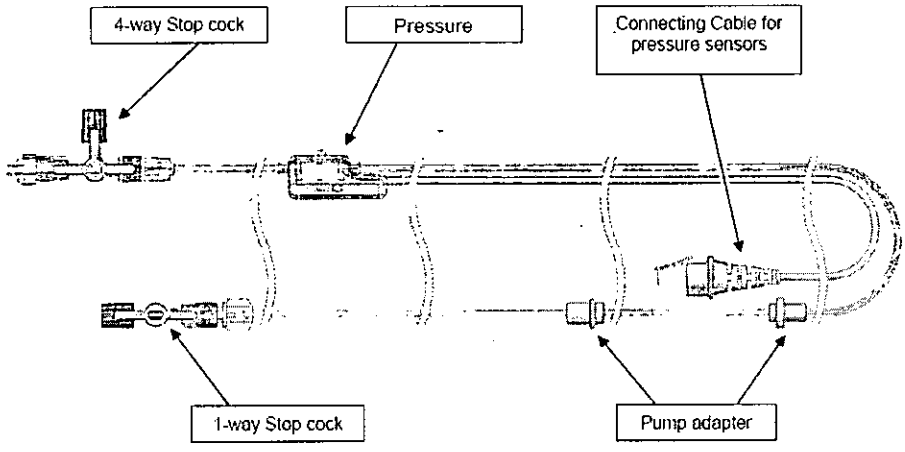

Figure 2: LiquoGuard CSF System tube set as schematic picture with its individual parts

o Every 0.1s, read the measurements of two pressure transducers inside the tubing.
o Compare the two pressure values using the two microcontrollers of the LiquoGuard CSF System. If the resulting values differ by more than the combined tolerance of both sensors, assume that at least one of the sensors is malfunctioning: in this case, ignore all settings and all measured values, stop the pump, and sound an alarm.
o Otherwise, average the measured pressure value over the two pressure transducers and over a short time frame (configurable, standard setting 1s). The result is the CSF pressure shown on the device display – we call it simply ICP (intracranial pressure) in the following. The goal of this averaging is to remove the physiological pressure pulsations caused indirectly by the heart beat from the measurement.
o If ICP is higher than P-set (desired pressure, ordered by physician) by some small margin, operate the pump.
o If ICP is lower than P-set by some small margin, stop the pump.
o Independently from P-set: if the measured pressure value (before averaging) is lower than the lower alarm limit, stop the pump.
o Independently from all settings: If measured pressure value (inside the tubing) is lower than 2 mmHg, stop the pump.

11.5.1 Two microcontrollers

There are two microcontrollers. Each one has an analogue to digital converter and calculates the actual pressure inside the tube system. These values are communicated between the two controllers.
The system always displays the arithmetic average of the two measured values (the

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diagram shows the master controller's pressure signal). If both values differ by more than 4 mmHg, an alarm is generated, as the system can't determine which value is the correct one. If the two values are within the valid range the average of the two sensors is used to control the pump.
A comment on the "small margin" mentioned above: this is needed to prevent the pump from starting/stopping too frequently. This small margin is called the "hysteresis"; it is a standard tool in all regulating devices that use only "on" and "off"-states, like switching a pump on or off. In the case of LiquoGuard CSF System, the hysteresis value is configurable and defaults to 0.5 mmHg.
A comment on the "lower alarm limit" mentioned above: The default value of the lower alarm setting is 0 mmHg. This setting can be changed by an order of a physician, however the allowed values are restricted to be above or equal to a minimum of -15 mmHg, which is a small negative value, far too small to tear off and aspirate brain tissue. To put this into perspective, note that negative ICPs of -50 mmHg and more occur physiologically in a healthy human being.

Sensor cross-checking:
o LiquoGuard CSF System dual pressure sensor technology measures the pressure inside the tube with two completely independent transducers.
o Even the cables are duplicate.
o If there is any discrepancy between the two sensor readings, LiquoGuard CSF System will sound an alarm and shut the pump off as security measure.

12. Substantial Equivalence Discussion
Primary predicate device: Dripping chamber
The LiquoGuard CSF System shares indications and essential design principles with the following predicate devices, which have been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created.

Table 1: Substantial Equivalence Devices – Dripping Chamber

Trade Name	510(k) Submitter/Holder	510(k) Number
Hermetic Plus External CSF Drainage System External Drainage Set	Integra LifeSciences Corp	K030289 , K032817
CODMAN EDS 3 CSF External Drainage System	Codman & Shrutleff, Inc.	K061568

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Secondary predicate device: Intracranial pressure monitor
The LiquoGuard CSF System shares some technological and functional aspects with the following predicate device, which has been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created and the LiquoGuard CSF System is substantially equivalent to the predicate device.

Table 2: Substantial Equivalence Devices – Intracranial pressure monitor

Trade Name	510(k) Submitter/Holder	510(k) Number
Multi-Parameter Monitor (MPM) Intracranial Pressure Monitoring System	Camino NeuroCara, TM Inc.	K962928

12.3 Summarizing
Many if not all risks leading to accidental, cerebral herniation in both systems (traditional drainage and ICP monitors) can be reduced or even eliminated by the LiquoGuard CSF System. There is no new risk introduced by the LiquoGuard CSF System.
The LiquoGuard CSF System is working equivalently to a drip chamber, with the additional safety that, using LiquoGuard CSF System, a partial or intermittent catheter occlusion may be detected in many cases: In difference to the dripping chamber which must be an open system during drainage the LiquoGuard CSF System can measure the hydrostatic pressure inside the tube (drainage system) during drainage because the drainage system is closed, combined with a CSF pressure monitor and its features like displaying pressure values, curves and trends and enabling alarm functionality. The principles of measurement are comparable to the ICP monitor and its pressure transducer as both systems measure the pressure of the surrounding liquid. The only difference is the position of the transducers, and the fact that LiquoGuard uses dual transducers for redundancy.
The LiquoGuard CSF System behaves comparable to a traditional drainage system even in the case of a clotted catheter or collapsed ventricles. It is able to sound and display alarms to operators, is portable, can be used while not connected to the mains, records and stores data and can be connected to bedside monitor systems, same as the Multi Parameter Monitor.
By combining the functionality of dripping chambers with the features of a computer operated device (ICP monitor) and adding a peristaltic pump the LiquoGuard CSF System benefit is potentiated as some major problems are solved (elimination of sensor drift problematic, protection of accidental over and / or under drainage, pressure measurement simultaneously with CSF drainage, etc.).

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Table 3: System Comparison

Product / Component	Dipping chamber systems		ICP Monitor	Combination
	Hermetic Plus External CSF	CODMAN EDS 3 CSF	Multi-Parameter Monitor	LiquoGuard CSF System
Tube set disposable	•	•		•
CSF drainage bag	•	•		•
Pressure transducer			•	•
Micro controller			•	•
Software operated			•	•
Data storage			•	•
Button / Foil keypad			•	•
Screen			•	•
Ports			•	•
Casing			•	•
Power supply			•	•

20. Performance Testing – Clinical

The LiquoGuard CSF System has the same indication for use as the primary predicate devices (external cerebral spinal fluid (CSF) drainage) and the same technological characteristics as the secondary predicate device (intracranial pressure measurement), and because all functions can be verified and tested in bench tests, formal clinical performance testing was not deemed necessary based on the products risk assessment.

To present the safety of the LiquoGuard CSF System a clinical trial was started in 2009, 75 cases have been collected and are included in the study report. The LiquoGuard CSF System is CE marked in Europe since 2006 where the study was performed. Please refer to **Appendix 60** for the study protocols, the results and the discussion.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

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10903 New Hampshire Ave.
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Reviewer Comments

The Sponsor states that in a meeting on April 8, 2009 between the Sponsor and the FDA, they were told that their clinical trial would not need a control group if historical data can be used. With this product, a major safety concern is failure of the pump. It is difficult to test that without a control group and it is highly doubtful that historical data is available on this matter.

The Sponsor states: "The system always displays the arithmetic average of the two measured values (the diagram shows the master controller's pressure signal). If both values differ by more than 4 mmHg, an alarm is generated, as the system can't determine which value is the correct one. If the two values are within the valid range the average of the two sensors is used to control the pump." 4 mmHg is significant and may represent 100% difference between the measured values of the two sensors.

The Sponsor states: "If there is any discrepancy between the two sensor readings, LiquoGuard CSF System will sound an alarm and shut the pump off as security measure." What are the steps that then need to be taken to remove the LiquoGuard system and continue draining CSF? A physician would have to switch out the system. This could take time and result in increased infection. Can you remove the tubing from the pump and set the drain to a pop-off to mitigate?

3 Main issues:

1. Sensor malfunction, 4mmHg b/w 2 sensors
2. Catheter clogging due to stop / go nature of device in diffuse IVH
3. If more catheter changes required, do we have a higher infection rate?

Clinical trial
50 patients LG, 25 drip chamber, but patients distributed over 5 main diagnoses.

Comments to the Sponsor

1. You present clinical data from a trial of 75 patients (50 with the LiquoGuard device and 25 with the standard drip chamber). However, this trial is not adequately powered to detect a statistical difference in safety outcomes between the two devices. There may be differences between catheter change rates, catheter flush rates, and subsequent catheter infection rates between your device and the predicate device. We are concerned that the data you have presented do not accurately represent possible differences between your device and the predicate.

2. In the trial of 75 patients that you present, the patients undergo external ventricular drain placement for 5 different medical conditions: traumatic brain injury (TBI), subarachnoid

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hemorrhage (SAH), intracerebral hemorrhage (ICH), normal pressure hydrocephalus (NPH), and "others". However, the patients are not distributed in a matched fashion across these categories. The random assortment of patients in the various categories does not allow for a direct comparison between your device and the predicate device. For example, while your device may function well in comparison to the predicate in cases of NPH, it may not function well in cases of SAH. We recommend that you match the patients in the various categories to ensure equal distribution and accurate comparisons between the devices.

3. As stated above, you present 5 categories of medical conditions that were included in the study. However, there is no category of diffuse intraventricular hemorrhage (IVH). Diffuse IVH is an important test category for your device since excess blood in the CSF may cause your device sensors and pump to fail at a higher rate in comparison to the predicate. Additionally, if the sensors lead to increased stoppage of flow in cases of IVH, then that may result in increased clotting of the catheter and increased catheter changes, flushes, or infections. We recommend that you collect data on patients with diffuse IVH in order to assess the safety and efficacy of your device when compared to the predicate.

4. You present data in which the LiquoGuard device was in place for an average of 8 days, while the predicate drip chamber was in place for an average of 11 days. Data such as catheter changes, catheter flushes, and catheter infections must be controlled for drainage time. The extra 3 days of drainage with the predicate drip chamber may account for several infections or other complications. We recommend that you control all data for drainage time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name LCDR Andrew Yang

Subject: 510(k) Number K121248

To: The Record

Please list CTS decision code ____

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			X

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21		X	
Neonate/Newborn (Birth to 28 days)		X	
Infant (29 days -< 2 years old)		X	
Child (2 years -< 12 years old)		X	
Adolescent (12 years -< 18 years old)		X	
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		X	
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	Class*	Product Code
882.5550	II	JXG

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: EVB 5/8/12
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

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Yang, Andrew

From: Yang, Andrew
Sent: Tuesday, May 08, 2012 4:52 PM
To: 'ggeckeler@geoinc.org'
Subject: K121248 LiquoGuard CSF System
Attachments: attachment K121248.pdf

Dear Mr. Geckeler

We cannot determine whether the device is substantially equivalent to your chosen legally marketed predicate device. Please see the attached file.

This email is sent in lieu of a formal written letter.

Please feel free to contact me if you have any questions.

LCDR Andrew Yang, BE, ME, EIT
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health
301-796-6860

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copy or other action based on the content of this communication is not authorized. If you have received this document in error please immediately notify us by e-mail or telephone.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Moller Medical GmbH
% Grant Geckeler
Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda
GERMANY

Re: K121248
Trade Name: LiquoGuard CSF System
Dated: April 16, 2012
Received: April 25, 2012

Dear Mr. Geckeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to your chosen legally marketed predicate device. Based on our review of your submission, it appears that your device has different technological characteristics (continuously monitors intracranial pressure via an electronic pressure sensor, displays pressure trends, and generates audible alarms), that could affect safety and effectiveness, and raises a different type of safety and effectiveness question (e.g., whether the device will appropriately start or cease to drain cerebrospinal fluid in the event of software or electronic component failure).

Because we have completed our first review of your 510(k) submission, we are providing you with an opportunity to respond to this letter so you may attempt to address the regulatory issue identified above. Please be advised that an inadequate resolution of this issue in your next response will likely result in a not substantially equivalent determination. Please also be advised that a substantive review of your 510(k) submission, including performance data, has not been conducted at this time.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your 510(k) number (above) and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact LCDR Andrew Yang at (301) 796-6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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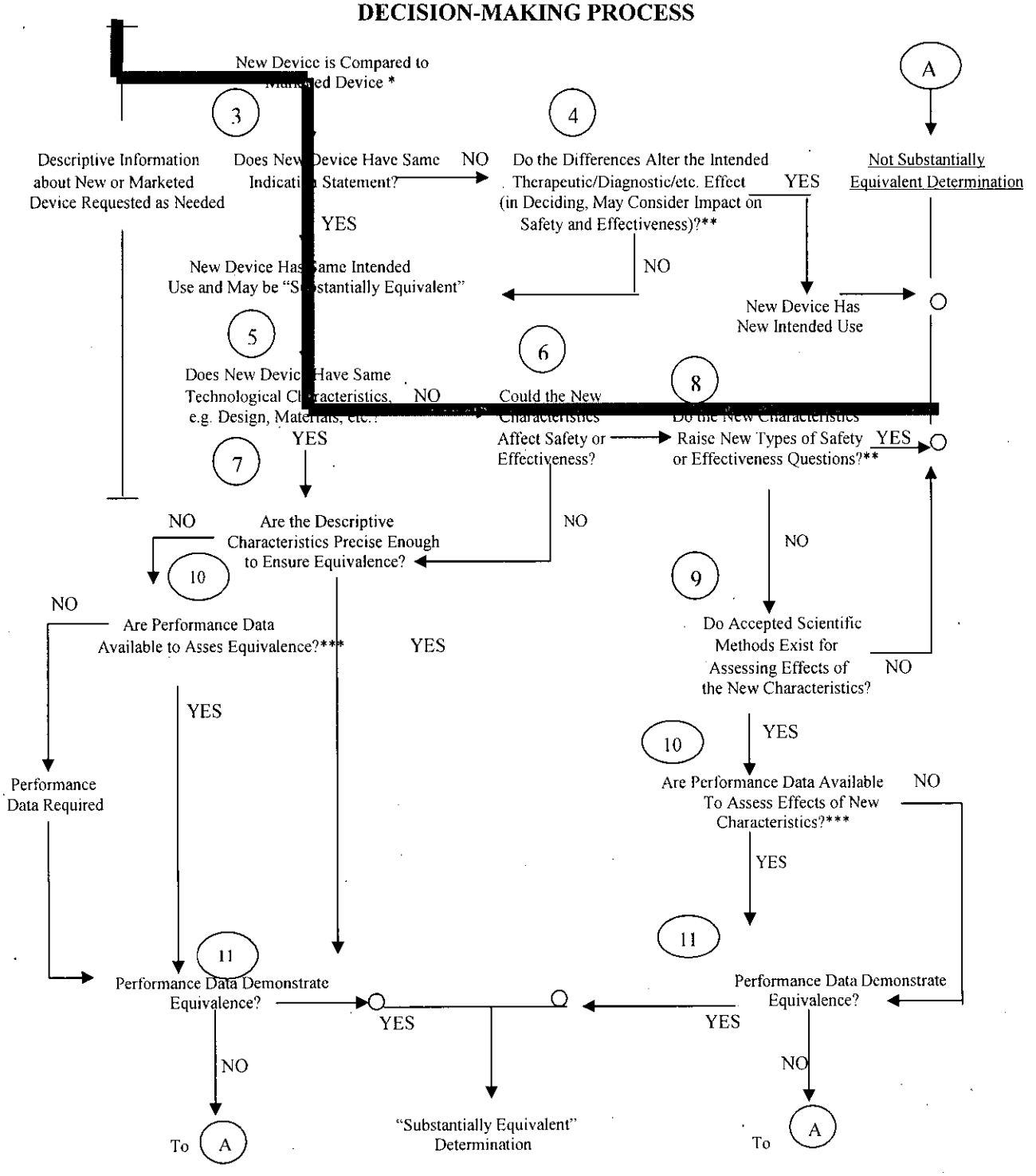
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)			X
5. a. Did the firm request expedited review? (See management.)☐			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

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Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s
http://www.fda.gov/cdrh/ode/guidance/1567.html

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	X		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	X		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	X		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	X		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.			X
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html. FDA Standards program www.fda.gov/cdrh/stdsprog.html. Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html			X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	X		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	X		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	X		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	X		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			X

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Title	Related Information	Present	Inadequate	N/A
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**			X
Kit Certification	Device Advice http://www.fda.gov/cdrh/ode/odecl874.html			X

Last Updated: 9/3/08 – Brandi Stuart

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification 510(k) Review
Traditional
K121248

Date: May 8, 2012
To: The Record
From: Andrew Yang

Office: ODE
Division: DONED

510(k) Holder: Möller Medical GmbH
Device Name: Liquoguard CSF System
Contact: Grant Geckeler
Phone: +1 714 283 1683
Fax: +1 714 637 2460
Email: ggeckeler@geoinc.org

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Liquoguard CSF System into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?	X		

Cerebrospinal fluid (CSF) drainage in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF system consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump and connected to the intrathecal drainage catheter (not part of the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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product). The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF system combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Comment: Though the sponsor would like us to believe this is a drainage catheter with a pressure monitoring feature, no such predicate exists. Rather, it is apparent that this is an intracranial pressure (ICP) monitor with a drainage feature. Deficiency

IV. Indications for Use

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Comment: The wording is similar, but the ability to measure the ICP is unique. Because of this, the device more closely resembles an ICP monitor with drainage capability. Deficiency

V. Predicate Device Comparison

Table 1: Substantial Equivalence Devices

Trade Name	510(k) Submitter/Holder	510(k) Number
Hermetic Plus External CSF Drainage System External Drainage Set	Integra LifeSciences Corp	K030289 K032817
CODMAN EDS 3 CSF External Drainage System	Codman & Shrutleff, Inc.	K061568

Table 2: Device Comparison

	Möller Medical	Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure.	Externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients.	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and patient.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber
Height alignment	Device can be positioned	Alignment is critical because it	Alignment is critical because it

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Möller Medical	Integra LifeSciences Corporation. (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)
of patient and device	arbitrarily, only the pressure sensors need to be aligned	controls the target pressure	controls the target pressure
Device Adjusting Fluid Flow	LiquoGuard CSF peristaltic pump controlled by pressure at sensor location	None - fluid flow is not controlled or limited	None - fluid flow is not controlled or limited
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF system	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high * Pressure too low * Physiological pressure pulsation lost * Pressure remains constant for too long * Dual sensors deviate in readings (defective sensor) * Watchdog or main controller does not respond to each others requests (device or software malfunction) * Battery low	No integrated alarm functions	No alarm functions

Comment: This illustrates both the technical superiority and differences from the predicates. The predicates are all passive mechanical devices that use a siphon to drain fluid rather than an electric motor to drive a pump. The predicates are poorly selected and this section will need to be completely redone. Deficiency

VI. Labeling

[...]

Comment: The sponsor provided packaging illustrations, operating manual, and catalog numbers for their device. These were not reviewed because the predicates are incorrect.

VII. Sterilization/Shelf Life/Reuse

The LiquoGuard CSF Tubing Sets are sterilized using the EtO sterilization method at the following facility:

(b)(4) [redacted]

The EtO sterilization process has been successfully validated in accordance with ISO 11135-1. In addition, the EtO residual analyze was performed according to ISO 10993-7 and all requirements were met.

The initial sterilization validation was performed in 2006 according to ISO 11135:1994 and ISO 10993-7:1995. To meet all requirements of the revised standards a re-validation of the sterilization was

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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performed in 2010. The validation of 2006 and 2010 together fulfill all requirements of the ISO 11135-1:2007 and the ISO 10993-7:2008.

Please refer to **Appendix 11** and **Appendix 12** for the sterility validation reports of 2006 and 2010 for the LiquoGuard CSF Tubing Set.

The LiquoGuard CSF Tubing Set is packaged in a blister of PETG (700µm, medical grade), sealed with a Tyvek foil which is in accordance with ISO 11607-1. Proposed shelf life is 2 years - please refer to **Appendix 13** for the accelerated aging test report.

Comment: The sponsor provided sterilization method and validation for their device. These were not reviewed because the predicates are incorrect.

VIII. Biocompatibility

Please refer to **Appendix 14** for the biocompatibility testing according to ISO 10993-1 of the LiquoGuard CSF Tubing Set.

Comment: The sponsor provided biocompatibility evaluation. This was not reviewed because the predicates are incorrect.

IX. Software

[...]

Comment: The sponsor provided all of the necessary components of software review. These were not reviewed because the predicates are incorrect.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

[...]

Comment: The sponsor identified appropriate predicates and provided copies of the reoprts. These were not reviewed because the predicates are incorrect.

XI. Performance Testing – Bench

[...]

Comment: The sponsor provided a comprehensive testing of the individual functions of the device. These were not reviewed because the predicates are incorrect.

XII. Performance Testing – Animal

n/a

XIII. Performance Testing – Clinical

n/a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?	X		If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
The language is carefully written to emulate a drainage catheter like its predicates. However, it also identifies features not possible in those predicates such as monitoring and tracking pressure.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
n/a

3. Describe the new technological characteristics:
The subject device is an electronic device that uses a sensor to measure intracranial pressure (ICP) and drain fluid via an electric pump when pressures exceed target values. The screen also outputs the pressure trend. These features make this device more similar to an ICP monitor than a simple drainage catheter.

4. Explain how new characteristics could or could not affect safety or effectiveness:
In the event of a software or electrical failure, the device may fail to start or cease drainage. Both conditions can lead to permanent brain damage or death.

5. Explain how descriptive characteristics are not precise enough:
n/a

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
Software and electrical failure is a new type of safety risk for this category of devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. Explain why existing scientific methods can not be used:
n/a

8. Explain what performance data is needed:
n/a

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
n/a

XV. Deficiencies

Comment: No deficiencies, other than the incorrect predicate, were found in this initial review. A comprehensive review will commence if/when the sponsor responds with a more acceptable predicate.

XVI. Advisory

n/a

XVII. Recommendation

~~Regulation Number: 882.1480~~
~~Regulation Name: Neurological endoscope~~
~~Regulatory Class: Class II~~
~~Product Code: GWG~~

S.N.

TH – Telephone Hold

5/8/12

Reviewer — Date

Branch Chief — Date 5/8/12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MöllerMedical

K121248/S002

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

September 12, 2013

FDA CDRH DMC
SEP 16 2013
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Additional Information for Traditional 510(k) Premarket Notification K121248/S002
LiquoGuard CSF System – eCopy Hold Letter 6th of September 2013

To Whom It May Concern:

Möller Medical submits the enclosed Additional Information for Traditional 510(k) Premarket Notification K121248 regarding the LiquoGuard CSF System in response to FDA correspondence dated November 20, 2012 on the eCopy. The original 510(k) Premarket Notification for the LiquoGuard CSF System was submitted as Traditional 510(k) on April 25, 2012.

With this amendment, Möller Medical is providing additional information in order for FDA to complete their review of the LiquoGuard CSF System. Möller Medical believes that the enclosed information provides sufficient information to allow FDA to review and provide clearance for the LiquoGuard CSF System.

The eCopy is an exact duplicate of the paper copy. The paper copy was submitted on Mai 15, 2013 and September 3, 2013.

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

Based on the materials submitted herewith, Möller Medical requests FDA to determine the **LiquoGuard CSF System** to be substantially equivalent to the referenced predicate US legally marketed device. In the event FDA needs to contact Möller Medical during the review of this information, please contact the US Agent of Möller Medical GmbH Grant Geckeler at +1 714 283 1683, by fax +1 714 637 2460, or by email: ggeckeler@geoinc.org or the undersigned at +49 661 941 95 0, by fax +49 661 941 95 850, or by email: info@moeller-medical.com.

Sincerely,

Dr. Christoph Traxler
General Manager

Maria Kosak
Regulatory Affairs Manager

Enclosure: Cover Letter and one eCopy (CD-ROM)

40

FB_002_004
Cover_Letter_2013-09_002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K121248/S2

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MöllerMedical

FDA CDRH DMC
SEP 03 2013
Received

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

August 29, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Additional Information for Traditional 510(k) Premarket Notification K121248/S002
LiquoGuard CSF System

To Whom It May Concern:

Möller Medical submits again the enclosed **Additional Information for Traditional 510(k) Premarket Notification K121248** regarding the **LiquoGuard CSF System** in response to FDA correspondence dated November 20, 2012. The original 510(k) Premarket Notification for the **LiquoGuard CSF System** was submitted as Traditional 510(k) on April 25, 2012.

With this amendment, Möller Medical is providing additional information in order for FDA to complete their review of the **LiquoGuard CSF System**. Möller Medical believes that the enclosed information provides sufficient information to allow FDA to review and provide clearance for the **LiquoGuard CSF System**.

The enclosed additional information for K121248/S002 is submitted in duplicate with an electronic (CD-ROM) copy serving as the second copy of the documentation. Additionally, the additional information for K121248/S002 is submitted per Email.

The 510(k) applicant and submitter is Möller Medical GmbH, Wasserkuppenstraße 29-31, 36043 Fulda, Germany. In accordance with 21 CFR § 882.5550, Möller Medical requests that the FDA hold as confidential commercial information, the intent of Möller Medical to market the device.

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Sincerely,

Dr. Christoph Traxler
General Manager

Maria Kosak
Regulatory Affairs Manager

Enclosure: One paper copy and one electronic copy (CD-ROM)

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Cover_Letter_2013-08_001

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K121248/S2

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May 13, 2013

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10903 New Hampshire Avenue
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FDA CDRH DMC
AUG 28 2013
Received

Additional Information for Traditional 510(k) Premarket Notification K121248 LiquoGuard CSF System

To Whom It May Concern:

Möller Medical submits the enclosed **Additional Information for Traditional 510(k) Premarket Notification K121248** regarding the **LiquoGuard CSF System** in response to FDA correspondence dated November 20, 2012. The original 510(k) Premarket Notification for the **LiquoGuard CSF System** was submitted as Traditional 510(k) on April 25, 2012.

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Sincerely,

Dr. Christoph Traxler
General Manager

Juliane Dragon
Regulatory Affairs Manager

Enclosure: One paper copy and one electronic copy (CD-ROM)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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September 12, 2013

Food and Drug Administration
Center for Devices and Radiological Health
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Additional Information for Traditional 510(k) Premarket Notification K121248/S002
LiquoGuard CSF System – eCopy Hold Letter 6th of September 2013

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Sincerely,

Dr. Christoph Traxler
General Manager

Maria Kosak
Regulatory Affairs Manager

Enclosure: Cover Letter and one eCopy (CD-ROM)

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Cover_Letter_2013-09_002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ADDITIONAL INFORMATION FOR 510(K) PREMARKET NOTIFICATION #K121248/S002

LIQUOGUARD CSF SYSTEM

Legal Manufacturer:
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GERMANY

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

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(b)(4)

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

APPENDIX 1

CLINICAL DATA:

(b)(4)

[redacted]

(b)(4)

(b)(4)

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APPENDIX 2

OPERATING MANUAL

Back to **List of Appendices**

Back to **Chapter 2.2 – Question 2 – LiquoGuard CSF pump: Reusable component**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Edition: 2013-05 C
Software versions: 025.01.04 and 026.01.16
Art.-No.: 20008814

US

LiquoGuard® CSF

Operating Manual

Möller Medical GmbH, Wasserkuppenstr. 29-31, DE - 36043 Fulda
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 Manufacturer

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Service
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The manufacturer reserves the right to make technical improvements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 General Safety Instructions

3.1 Explanation of the safety symbols

Important information is marked in these operating instructions. This information is vital to exclude danger to patient and operating personnel, and to avoid damage or malfunction.

Achtung	Warning, important information
Gefahr	Caution! Hazard to patient or operating personnel
Hinweis	Information or help
	Application part BF
~	Identification symbol for electrical and electronic devices
	Alarm signal deactivation switch AUDIO PAUSE
	Consult instruction for use
SN	Serial number
	Manufacturer
REF	Catalogue number
LOT	Lot number
	Date of expiration
	Date of manufacture
	Application range
STERILE EO	Sterilized using ethylene oxide
	Do not use if packaging is damaged

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

General Safety Instructions

Do not reuse

Do not resterilize

Not for use in an MRI field

Contains or presence of phthalates

Overall length

Each application of the unit is subject to precise knowledge of and compliance with these operating instructions. This operating manual does not replace the inservice of the user by the sales representative. The device must only be operated by qualified personnel or those with an equivalent level of knowledge and experience.

If components are used that do not correspond to the original parts of the manufacturer, the performance, safety and EMC behaviour may be impaired.

3.2 Manufacturer

The manufacturer can be regarded as being responsible for the safety, reliability and serviceability of the unit if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out only by those persons who have been authorized by him to do so.
- the electrical installation of the relevant room the applicable requirements and regulations (eg VDE 0100, VDE 0107 or IEC-) and corresponds
- the equipment is used in accordance with the instructions and local regulations and national variations are observed.
- specified in the technical data conditions are met

The instrument may not permit the manufacturer can't be changed and the use is permitted only by qualified personnel. The manufacturer commits to take back old devices according to the Electronic Equipment Act.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

General Safety Instructions

3.3 Precautionary duties of the operator

The operator is responsible for proper operation of this medical product.
Regular training courses are recommended by the manufacturer and on demand. Furthermore, the relevant provisions on the training and development apply to medical devices.
The instruction manual does not replace the first instruction of the user by the manufacturer or a person authorized by the manufacturer. The initial instruction takes about 2 hours (depending on eg number of persons and functions of the unit, which is trained on). As training material is used in each case the current operating instructions that comes with the device.

Only qualified personnel may operate this unit. Operating instructions do not replace a proper inservice. Clinical application may only be performed by people who have been properly inserviced by qualified personnel.

The unit may not be operated if connected to power supplies whose soundness is doubtful. The supply voltage must match the details specified on the nameplate. Liquids must not penetrate parts of the device, which carry electrical voltage. Do not spray cleansing fluid into the memory card slot. Unplug the AC power cord prior to cleaning.[1]

---

[1] See cleaning and disinfection, page 13

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General Safety Instructions

3.4 Supplementary devices

Supplementary devices are not part of the unit's delivery scope:
Any additional equipment that is connected to the analogue and digital interfaces of the device must be proven to meet the requirements of the relevant EN specifications, (e.g. EN60601 for electrical medical devices). All device configurations must also satisfy the applicable version of the electrical system safety standard EN60601-1-1. Any operator connecting the additional devices is the system configurer and is therefore responsible for ensuring that the system safety standard EN60601-1-1 is upheld. In case of questions, please contact the manufacturer.

3.5 Single-use

Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.
Dispose of used disposable items according to your health requirements. To prevent leakage of the tubing set, you should need to dispose of the drainage sets that all valves are closed.

3.6 Electro-magnetic emission

The ***LiquoGuard® CSF*** is suitable for operation in the stipulated electro-magnetic environment. The customer and/or operator of the ***LiquoGuard® CSF*** should ensure that it is used in one of the electro-magnetic environments described below.

Measurement of emitted interference	**Conformance**	**Guidelines for the electro-magnetic environment**
Emitted high-frequency interference acc. to CISPR 11	Group 1	
Emitted high-frequency interference acc. to CISPR 11	Class B	The ***LiquoGuard®*** uses HF energy exclusively for its own function. Its HF emittance is therefore very low and interference with neighbouring electronic devices is improbable.
Harmonic emittance acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emittance acc. to IEC 61000-3-3	Not applicable	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.7 Recommended safety distances

Recommended safety distances between portable and mobile HF telecommunication devices and *LiquoGuard* ®			
LiquoGuard® is intended for operation in an electro-magnetic environment, in which HF disturbances are controlled. The client or operator of ***LiquoGuard®*** can assist in avoiding electro-magnetic disturbances by keeping to the minimum distances between portable and mobile HF telecommunication devices (transmitters) and ***LiquoGuard®*** - depending on the output power of the communication device, as stipulated below.			
Capacity transmitter power [W]	**Safety distance dependent on transmission frequency [m]**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

3.8 Electro-magnetic resistance

Resistance test	**IEC 60601 - testing level**	**Conformance level**	**Electro-magnetic. Environment / Guidelines**
Discharge of electro-static electricity (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should consist of wood or concrete or tiles. If the floor is covered with synthetic material, relative humidity should be at least 30 %.
Rapid transient electrical disturbances/ bursts IEC 61000-4-4	±2 kV for power lines ±1 kV for input and outtput lines	±2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Surge voltages Surges IEC 61000-4-5	±1 kV Normal mode voltage ±2 kV Common mode voltage	±1 kV Normal mode voltage ±2 kV Common mode voltage	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage IEC 61000-4-11	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	The quality of the supply voltage should correspond with that of a typical business or hospital environment. If the operator of the product demands continued functions even during the occurrence of power supply interruptions, we recommend the use of an uninterrupted power supply or battery.
Magnetic field for supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields for the net frequency should correspond with typical values as found in business and hospital environments.
Note: U_T is the AC supply voltage prior to application of the testing level.			

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3.9 Electro-magnetic resistance for non-life-supporting devices

Resistance tests/ Standard	IEC 60601-testing level	Conformance level	Electromagnetic environment / Guidelines
Conducted HF-resistance variable according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	Portable and mobile radio devices should not be used at a distance to the product, including lines, of less than the recommended safety distance, which is calculated according to the equation corresponding to the transmission frequency. **Recommended safety distance:** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{V_1}]\sqrt{P}$ for 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ for 800 MHz to 2.5 MHz with P as nominal transmitter power in Watt (W) acc. to transmitter manufacturer stipulations and d as recommended safety distance in meters (m). According to an on-site[a)] examination, the field intensity of stationary radio transmitters ought to be lower than the correlation level[b)]. Disturbances may occur in the environment of devices carrying the following symbol.
Radiated HF-resistance acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Notes:
NOTE 1 The higher frequency range applies to 80 MHz and 800 MHz.

NOTE 2 These guidelines may not be applicable in all cases. The diffusion of nominal electro-magnetic factors is influenced by absorption and reflection of buildings, objects and people.

a) The field intensity of stationary transmitters, such as radio base stations and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and TV transmitters theoretically cannot be predetermined accurately. An examination of the site should be considered in order to determine the electro-magnetic environment of the stationary transmitter. If the measured field intensity at the site, at which the product is used, exceed the above mentioned conformance levels, the product should be observed to prove the intended function. Unusual performance characteristics may require additional measures, such as changes to the alignment or position of the product.

b) The field intensity should be less than 3 V/m at 150 MHz to 80 MHz.

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4 Purpose

Möller Medical's ***LiquoGuard® CSF*** is a

- pressure controlled
- and / or volume controlled

tube pump for use in: monitored medical rooms in hospitals only.

The purpose of *LiquoGuard® CSF* with the tube set for *LiquoGuard®* REF.-No.: 00003639 (1500 mm/59.06 inch) or REF.-No.: 00003640 (2000 mm/78.74 inch) is the targeted pumping of CSF fluid.

LiquoGuard® may not be used as an infiltration pump or infusion pump.

LiquoGuard® does not serve diagnostic purposes.

4.1 Indications for Use

The ***LiquoGuard® CSF*** system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The ***LiquoGuard® CSF*** system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The ***LiquoGuard® CSF*** system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

4.2 Contraindications

The contraindications do not apply to the use of a CSF draining system such as the ***LiquoGuard® CSF*** system, but to the application of intrathecal CSF drainage itself. As, however, CSF discharge is only applied in connection with CSF drainage, contraindications described below are in connection with the application of external CSF drainage only.

Absolute operative contraindications: Coagulopathy, thrombocythemia.

Relative operative contraindications: In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does simultaneous intake of intrathecal antibiotics in the case of ventriculitis.

Indication for permanent CSF drainage: If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculoperitoneal shunt or a ventriculo-atrial shunt.

4.3 Combination with other products

LiquoGuard® CSF may only be used in connection with Möller Medical's tube set for ***LiquoGuard®*** **REF.-No.: 00003639 (1500 mm/59.06 inch)** or **REF.-Nr.: 00003640 (2000 mm/78.74 inch)** , the tube set may only be used in connection with the ***LiquoGuard®***.

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Purpose

The tube set for ***LiquoGuard®*** REF.-No.: 00003639 or. REF-No.: 00003640 is connected to a surgically implanted CSF draining catheter and does not come into contact with the body.
The tube set for ***LiquoGuard®*** REF.-No.: 00003639 or. REF-No.: 00003640 may only be connected to ventricular drainage catheters with an internal diameter of >= 1 mm (0.039 inch) and with lengths of <= 350 mm (13.78 inch) or lumbar drainage catheters with an internal diameter of >= 0.7 mm (0.028 inch) and a length of <= 800 mm (31.5 inch).

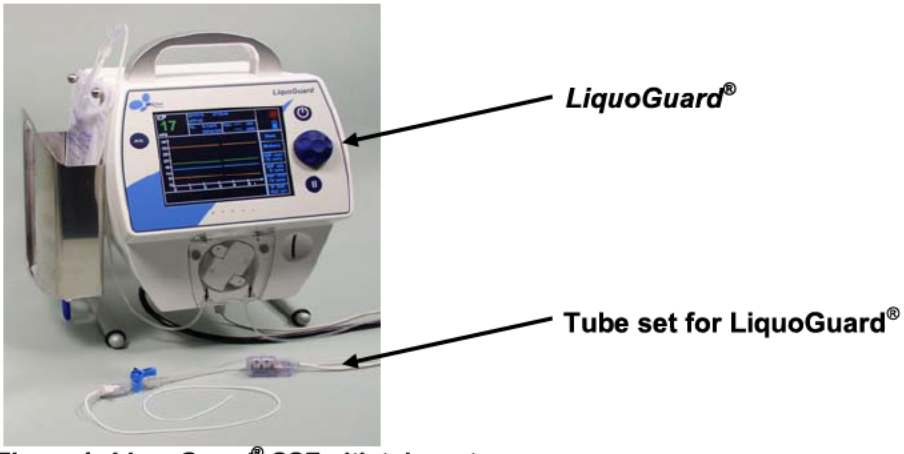

Figure 1: *LiquoGuard® CSF* with tube set

4.4 Patient population

The application may be considered for neonatal to geriatric patients.

4.5 Remaining risk

LiquoGuard® CSF is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error. The remaining risk for the patient exists mainly in the selection of parameters unsuitable for the patient or other application errors. The operator must be aware of this risk.
LiquoGuard® CSF does not serve diagnostic purposes.
For application during computer tomography (CT), the tube set may remain attached to the patient. ***LiquoGuard® CSF*** must be disconnected.

Application during Magnetic Resonance Tomography (MRT) or near an MRT device is prohibited.

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5 Set-Up and Installation

Ensure that the package has been delivered to you without damage. Please inform your sales representative immediately of any transport damage.

5.1 Unpacking the Device and Checking for Contents

Delivery of ***LiquoGuard®*** always consists of one carton. When unpacking ***LiquoGuard®***, ensure that no parts remain in the package and that all parts are present.

The delivery scope consists of (1 item each):

- ***LiquoGuard® CSF***
- AC power cord
- Operating manual

Every manipulation of ***LiquoGuard®*** requires exact knowledge and observance of these operating instructions. These instructions do not replace proper user training. Only qualified personnel may operate this unit.

We suggest that packaging is retained for further use.
LiquoGuard® may only be shipped in the original packaging.

5.2 Cleaning and disinfection

LiquoGuard® must be prepared according to cleaning guidelines prior to first application.

No humidity must be allowed to enter into the device.
Before cleaning and disinfecting the device surfaces, disconnect the mains plug. Use a lint free, soft cloth for cleaning and disinfecting. Clean using a cloth dampened with mild detergent or disinfectant (e.g.: 70% alcohol). Disinfect the device surfaces with a e.g.: 70% alcohol solution. Ensure that the cleaning and disinfecting agents have evaporated before using the device in an application. Visual check: The sockets of all connections and cable plugs must be free of all dirt.

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5.3 Installation

Remove ***LiquoGuard® CSF*** from its packaging and place it on a suitable, steady surface. Be careful when installing the product, ensure that the plug is easily accessible on the bottom of the device in order to separate the device completely on demand from the grid.

LiquoGuard® CSF can be:

- safely positioned in a suitable, stable location.
- suspended on a 25 mm (0.98 inch) x 10 mm (0.39 inch) wall rail.
- or attached to an IV pole with a diameter of 25 mm (0.98 inch).
- be universally or with the attachment lug (optional) mounted on different infusion uprights or bedside

Observe the maximum tube length of 1.5 m/59.06 inch (REF.-No.: 00003639) or 2 m/78.74 inch (REF.-No.: 00003640) between catheter and ***LiquoGuard®***.

Figure 2: *LiquoGuard®* standing on base feet

Figure 3: *LiquoGuard®* - view from behind
Pole clamp

Insert the AC power chord into ***LiquoGuard® CSF*** at the lower side of the casing side and into a plug with connected protective earth conductors. Please observe the stipulated voltage values on the type plate.

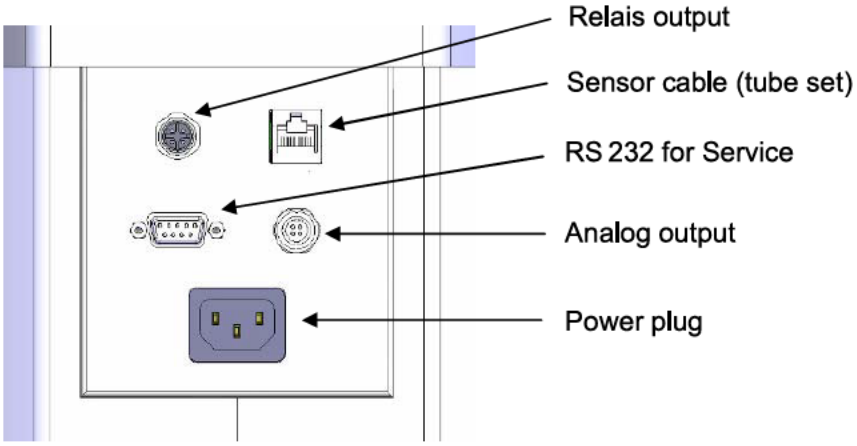

Figure 4: *LiquoGuard®* - View from below - Connections

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Set-Up and Installation

The relay output can be used for an alarm connection to the device call system (frequently also known as the diagnostics call or nurse call). The function of this connection must be checked and validated in individual cases (Please Observe the prerequisites for Supplementary devices in Chapter 3.4 on Page 8).
This further alarm routing does not eliminate the need to control the patients. The alert notices from the ***LiquoGuard® CSF*** must be controlled in every case.

Connecting the AC power cord to ***LiquoGuard®*** puts the device into standby mode.

Further startup requires a tube set for ***LiquoGuard®*** by Möller Medical,

REF.-No.: 00003639 or **REF-No.: 00003640.**

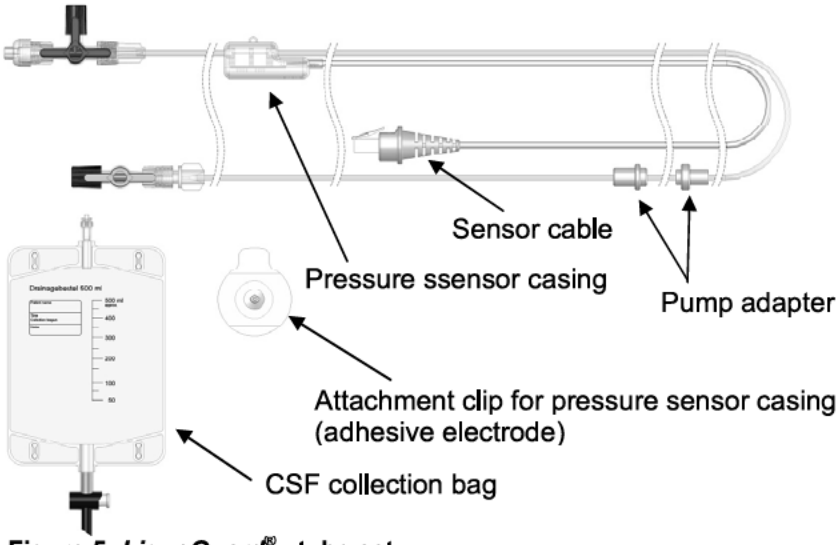

Figure 5: *LiquoGuard®* - tube set

To avoid false alarms, you should familiarise yourself with the alarm concept of ***LiquoGuard® CSF*** (see Page 16).

Please continue reading starting at page 32 for information on Application and operation.

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6 Alarm concept

The ***LiquoGuard® CSF*** alarm concept is designed in such a way that during correct operation the operator is always notified of alarm conditions by visible and audible alarms (i.e. an operator must always be within earshot and visibility range). ***LiquoGuard® CSF*** is equipped with a physiological and technical alarm condition. Alarm condition priority is stipulated with "HIGH Priority" for all alarm conditions. ***LiquoGuard® CSF*** creates visible and audible alarm signals. The alarm system is designed without self-regulating alarm signals.

6.1 Alarm system description

Terms and definitions

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm condition	Condition of the alarm system once it has determined a possible or real threat.	Excess of upper or lower alarm limit	
Alarm condition delay	Time between occurrence of an alarm condition either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), up to system determination of an existing threat.	See chapter 6.2	
Alarm limit	Limit value used by an alarm system to determine an alarm condition.	See chapter 6.2	Control panel
Alarm OFF	Condition of indefinite duration, in which an alarm system or a part thereof does not issue alarm signals	The user can set certain alarm conditions to OFF If these are not useful due to the condition of the patient. It is the responsibility of the user to set these consciously to OFF.	
Alarm paused	Condition of limited duration, in which an alarm system or a part thereof does not issue alarm signals	No possible setting	
Alarm presetting	Set of saved configuration parameters, including the selection of algorithms and initial values for the use of algorithms, which influence or change the effect of the alarm system.	N/A	
Alarm reset	Action performed by operator to cancel an alarm signal, for which there is no currently associated alarm condition.	N/A	

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Alarm concept

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm settings	Alarm system configuration including but not limited to: - Alarm limits - Properties of all conditions of alarm activation and - The values of parameter variables, which determine the function of the alarm system.	In some cases adjustable by user (see chapter 6.2)	
Alarm signal	Signal type created by the alarm system to display the existence (or the occurrence) of an alarm condition.	- Visible alarm signal - Audible alarm signal The audible alarm signal has an audio pressure level of 55dBA at a 1-metre distance	Visible impulse signal via red LED light in service screen. On-board sound emitter
Delay in alarm signal emittance	Time from start of alarm condition to emittance of alarm signal.	Depending on alarm condition, see chapter 6.2	
Audio OFF	Condition of unlimited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	settable	refers to all alarm conditions active at the time of key activation
Audio paused	Condition of limited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	Settable to a maximum of 180 minutes.	refers to all alarm conditions active at the time of key activation
De-escalation	Process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	No application	
Escalation	Process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	No application	
False negative alarm conditions	Missing alarm condition, if a valid triggering occurrence in the patient, in the device or in the alarm system has occurred.	Dual safety-Probability very low	
False positive alarm conditions	Existing alarm condition, if no valid triggering occurrence in the patient, in the device or in the alarm system has occurred.		
Information signal	Every signal, which is not an alarm or reminder signal.	Applies.	
Self-retaining alarm signal	Alarm signal which continues to emit after its triggering occurrence has been eliminated, until it is stopped with a deliberate operator action.	Does not apply.	
Non-self-retaining alarm signal	Alarm signal, which automatically stops if the associated triggering occurrence has been eliminated.	Applies.	
Physiological alarm condition	Alarm condition originating from a monitored, patient-related variable.	Applies.	
Technical alarm condition	Alarm condition originating from a monitored, device or alarm system-related variable.	Applies.	

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6.2 Alarm system overview

Alarm conditions	Pulsation frequency too small (limit value)/ too large (limit value)	n.a.	Pulsations frequency (<=30) or (>= 180)	Averaged value in 12 sec.	Not adjustable by operator Specified to 20 sec	Audible / Visible	Pulsation alarm!	YES
Lower pressure limit value undercut	Measured pressure too low	n.a.	Lower pressure limit value (P-min) Adjustable by operator	Filtered measurement value	Not adjustable by operator Specified to 20 sec	Audible / Visible	Measured pressure too low	YES
Upper pressure limit value exceeded	Measured pressure too high	n.a.	Upper pressure limit value (P-max) Adjustable by operator	Filtered measurement value	Not adjustable by operator Specified to 20 sec	Audible / Visible	Measured pressure too high	YES
Alarm conditions	Physiological alarm condition	Technical alarm condition	Alarm limit	Alarm condition delay	Delay in alarm signal emittance	Alarm signal	Alarm signal description in display	Audio paused or Audio off

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Alarm concept

Alarm condition	Pressure constant	Sensor defective or disconnected
Physiological alarm condition	Measured pressure too constant	n.a.
Technical alarm condition	n.a.	a) „Sensor defective“: Difference between the two sensors is too high b) „Disconnection“: cable can't be detected anymore
Alarm limit	standard 0.2 mmHg; adjustable by operator OFF or 0.1-2 mmHg	a) „Sensor defective“: Difference between the two sensors is > 4 mmHg b) „Disconnection“: Internal device specification
Alarm condition delay	12 seconds	a) „Sensor defective“: n.a. b) „Disconnection“: 3 Seconds
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	a) „Sensor defective“: specified to 20 Seconds b) „Disconnection“: n.a.
Alarm signal	Audible / Visible	Audible / Visible
Alarm signal description in display	Pressure too constant	Sensor defective or disconnected!
Audio pausedor Audio off	yes	no

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Alarm concept

Alarm condition	**Physiological alarm condition**	**Technical alarm condition**	**Alarm limit**	**Alarm condition delay**	**Delay in alarm signal emittance**	**Alarm signal**	**Alarm signal description in display**	**Audio paused or Audio off**
Battery empty	**n.a.**	**Voltage of battery too low**	**Internal device specification**	**n.a.**	**Not adjustable by operator Specified to 20 sec**	**Audible / Visible**	**Battery empty, connect to AC**	**YES**
Internal safety measures from hardware and software tests -dual safety- **These alarm condition or alarm signal descriptions are not displayed. In the case of such alarm conditions, *LiquoGuard*® must be checked by Service.**	**n.a.**	**Internal device assessments**	**Internal device specification**	**n.a.**	**Not adjustable by operator Specified to 20 sec**	**Audible / Visible**	**Device error x**	**YES**

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Alarm concept

6.3 Inspection of alarm functions

Connecting the AC power chord to ***LiquoGuard® CSF*** results in a short peep tone and the two inner red diodes light up. This is a test for the emergency alarm (audible and visible).
A function test is also performed when ***LiquoGuard® CSF*** is activated. An audible information signal is created and the two external red diodes, as well as the central blue diode light up. The motor also starts up and the current software versions as well as the bus address are displayed for a short while.

6.4 Alarm system, dual safety

The path from pressure measurement by ***LiquoGuard® CSF*** to the alarm was designed according to dual safety aspects. This entails 2 sensors in the tube set, dual measurement value recording and processing, as well as various means of alarm emittance.
The two outer red LEDs are activated by ***LiquoGuard®***'s main controls. Alarm signals here (rapid flashing) are supported by displayed information. The audible signal in the main control is a trumpet call.
The two adjacent red LEDs are controlled by the monitoring system. They usually flash slightly delayed from the other LEDs at a slower rhythm.
If the monitoring system determines an error at the main controls, which does not issue an audible alarm, the monitoring system will issue an audible alarm in the form of a rhythmic beep with a fixed frequency. This condition is termed an emergency alarm. It can be cancelled by pressing the standby button three times. If the device returns to this condition repeatedly, the device should be checked by Service.
If a technical fault occurs during battery operation, the device may issue a continuous high-pitched tone. This is also an alarm signal. It can only be cancelled by reconnecting the device to the AC power. There is no other way to cancel this supply alarm.

Important:
The alarm system only refers to ***LiquoGuard® CSF*** itself. Possible signals from an external connected system do not release the operator from his duty to promptly and appropriately react to alarm situations signaled by ***LiquoGuard® CSF*** even if an external system should not display this alarm condition.

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7 Product description

7.1 *LiquoGuard® CSF* design

Figure 6: *LiquoGuard® CSF* - design

LiquoGuard® CSF is switched on and off with the **ON/OFF - Standby key.** All functions of the display control panel are set with the **turn-switch.**
You can change between pause mode and active mode of ***LiquoGuard®*** using the **pause switch.** The pump is switched off in pause mode. The **Standby-key** returns you to the next higher menu level from all sublevels. Pressing the **Alt-key** changes the menu items on the right display edge (see „Second selection menu“, page 26).

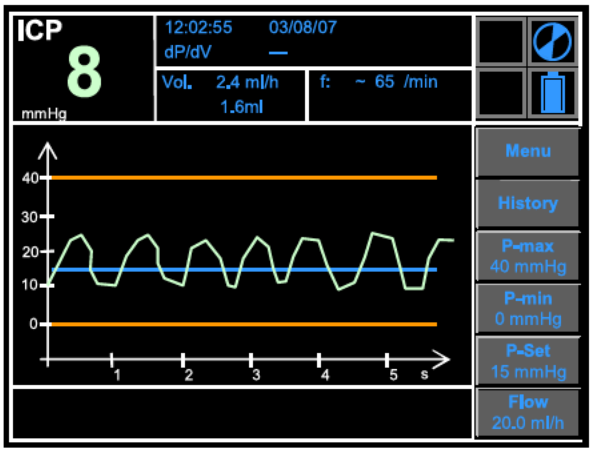

Figure 7: Display of the *LiquoGuard® CSF*

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7.2 Display fields

The monitor design of ***LiquoGuard® CSF*** is divided into display fields and display operating fields.
The **display fields** provide you with the following information:

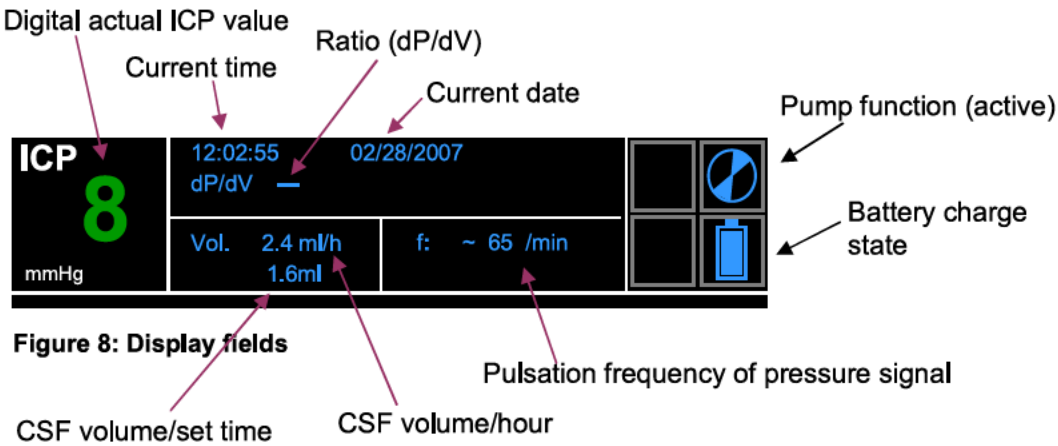

Figure 8: Display fields

7.2.1 Digital actual ICP value or actual P_{CSF} value [mmHg]

The digital actual ICP value/actual P_{CSF} value [mmHg] is the filtered pressure value [mmHg], measured by the pressure sensors. ICP: IntraCranial Pressure [mmHg]; P_{CSF}: Pressure of **C**erebro**S**pinal **F**luid [mmHg]

7.2.2 Ratio dP/dV [mmHg/ml]

Ratio of pressure to volume (Volume elasticity co-efficient, Compliance). This can only be displayed when at least 0.5 ml were pumped between pump start and pump stop and if this created a pressure difference of at least 2 mmHg.
Permanent compliance measurement requires hysteresis set to 1.5 mmHg (under: Sub-menu Extended application; (1) Hysteresis controller [mmHg]).
Note: Accuracy is not better than 20-30%.

7.2.3 Date/Time

These two fields automatically display the current date and current time. The current settings can be changed in the menu.
The date can be displayed in three formats:
DD.MM.YYYY, MM/DD/YYYY, YYYY-MM-DD, e.g.: 28.02.2007; 02/28/2007; 2007-02-28
Note: If the date/time was changed during an application, data (Date/Time) may appear twice or display gaps.

7.2.4 Pulsation frequency of pressure signal (f: ~ ---/min)

This displays the pulsation of the CSF recognised by the device. This recorded pulsation and the alarm conditions are integrated into the alarm concept of the ***LiquoGuard®***. The alarm limits are:

- Upper alarm limit → f >= 180/min
- Lower alarm limit → f <= 30/min

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With sufficiently large fluid pulsation the pulsation frequency complies approximately with the pulse of the patient. In the ventricular mode, pulsation alarm is on by default and is an additional monitoring function to increase patient safety.
It can however be de-activated if required, e.g.: in case of craniectomy/operative decompression: First press the alt key and the right display will appear with a menu containing 5 to 6 sub items (see page 26: “Second selection menu”), Then select "pulse" and set to "NO". The pulsation alarm remains de-activated until this is explicitly changed or a new application is started.
Pulsation recognition is not reliable for permanent lumbar drainage and is therefore not displayed. In this case alarms due to pulsation are not triggered.

7.2.5 CSF volume/hour (Vol. 0.0 ml/h)

This field displays the CSF volume per hour that has been pumped off. The value is always averaged to 15 minutes (adjustable in the system menu) and is updated every minute.

7.2.6 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h)

This field displays the CSF volume per "x" hours that has been pumped off. Variable „x“ can take values between 2 and 24 (steps of 2; see page 47 Duration of volume balance [h]) The value always displays the actual volume in this period. It is updated on an hourly basis. As long as the set balance time (e.g. 24 hours) has not been reached, the actually conveyed volume is displayed in ml. If this function is set to "OFF" in the system menu, the volume measuring function is active, i.e. balancing no longer takes place, and only the conveyed volume is displayed. This counter can always be reset to zero using the alt key and "Reset volume" (see page 26: “Second selection menu”).
Note: In the event that the tubing is changed more frequently for one individual patient without turning off the device, the entire balance will be continued until the end of its use so that the total quantity drained can be read at the end.

7.2.7 Battery charge state

LiquoGuard® CSF was designed for battery supplied operation for a maximum of 3 hours. A progressive decrease of battery capacity is an indication for a damaged battery (contact service). The display field Battery SOC indicates the current battery charge state during battery operation. During mains operation, a filling symbol indicates charging. A full symbol indicates a full battery. During battery operation the battery symbol is red and the blue LED flashes to show the operator that it is not connected to AC power.

Figure 9: Battery charge state

Before the battery is entirely depleted it will sound an alarm and display: "Battery empty, connect to AC!“ The device must then be connected to AC power immediately. If this does

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not occur, the display will turn black after approx. 5-10 minutes and the alarm continues to sound for a few more minutes. The device will then deactivate until it is reconnected to AC power. Discharging the battery completely can cause permanent damage and thus should be avoided. Complete charging of an empty battery requires approximately 8 hours.

7.2.8 Pump function

If pump mode is set to "Pause", the pump will not work. To access the pump function you have to press the "Pause"-key.

Figure 10: Pump function - Pause

7.2.9 Graphic display of patient parameters

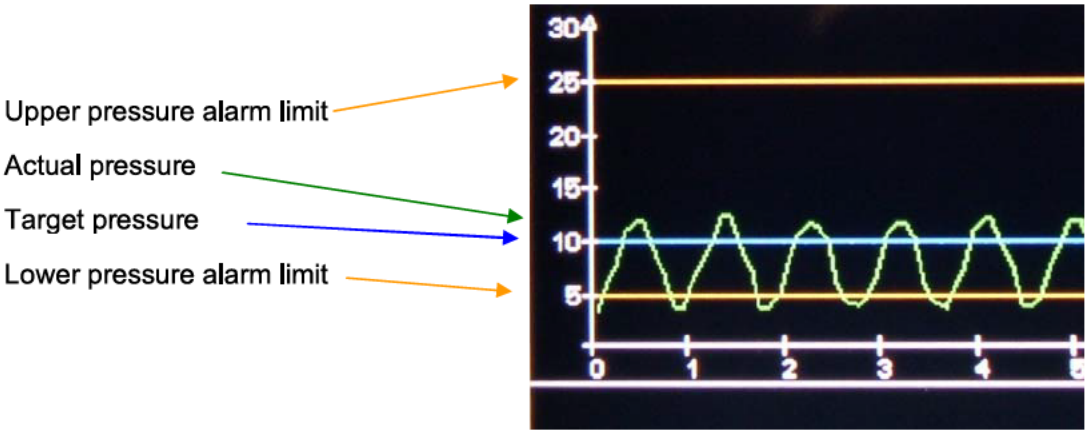

Figure 11: Display of pressure values

The upper pressure alarm limit (P-max) is the upper adjusted alarm limit for the alarm condition. The lower pressure alarm limit (P-min) is the lower adjusted alarm limit for the alarm condition.

7.3 Display operating fields

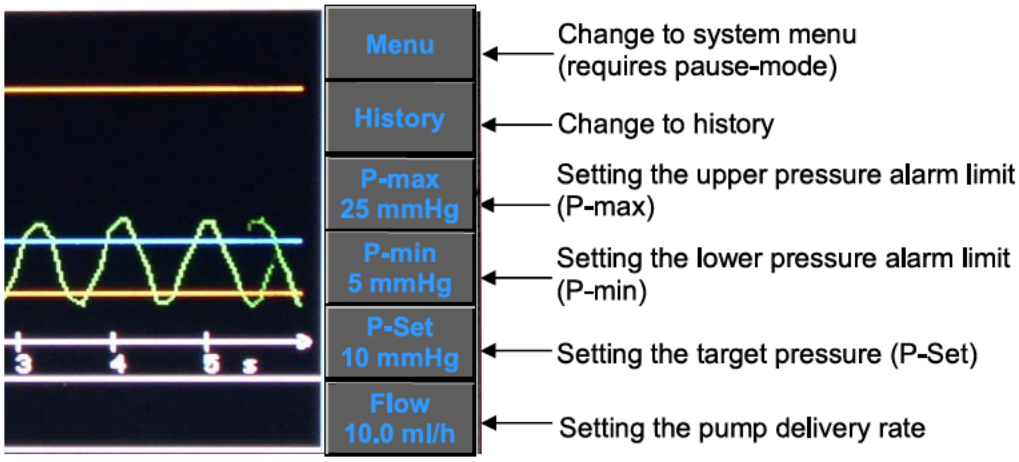

Figure 12: Display operating fields

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product description

The display control fields are selected via the turn-switch of ***LiquoGuard® CSF*** whereby the display control fields change their background color. The respective activated field is highlighted in light blue. Pressing the turn switch activates the selected display operating field and highlights it dark blue. By turning the turn switch changes can now be made in this field. Further depression of the push button activates the changes. (A text will appear in the display as a reminder: "Confirm changes with the wheel".) If the desired function is not confirmed within a preset time by pressing the turn switch, a timeout will occur. A negative confirmation tone is created (400 msec deep tone). In this case the originally set value is kept.

7.3.1 Quick reference guide - Setting/Changing of values:

1. Press the blue turn-switch. The “menu” field will now be highlighted.
2. By turning the switch you can move the illumination to the desired field.
3. By pressing the switch again, the highlighted field turns dark.
4. Now you can set the desired value. Important: You have to confirm this value by pressing the turn-switch again. If you forget to confirm, the new value will not be maintained and after a short interval the device will go back to the old value (operation timeout).
5. After confirmation of the new set value the field is highlighted again.
6. By turning the switch you can move the illumination again to another field.

Notes:

- If the switch is not touched for a short interval, there will be an operation timeout (no field is highlighted anymore) and you have to start at the beginning.
- By each short pressing of the Standby key you can go one step back.

To adjust the patient parameters please also read starting at Page 35.

7.3.2 Second selection menu

Pressing the Alt-key changes the menu items on the right display edge:

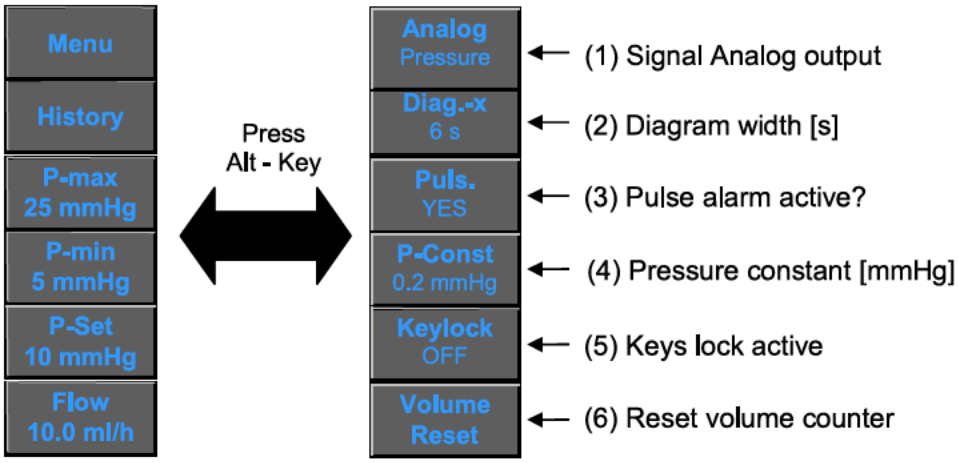

Figure 13: Second selection menu

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Product description

After the timeout period, which also applies for the system menu, you are returned to the standard key allocation as this contains the most information for the application.
Note:
If an audible alarm is active, pressing the Alt key will take you to the alarm pause selection (see page 40 Audio paused or Audio off). Therefore the Alt key has 3 levels, whereby only 2 are used without an alarm.

(1) Signal analog output

Meaning: Selection of the value to be issued via the analog output.

Possible parameter settings: Zero, Pressure, Flow

Note: The "Zero" setting serves offset correction purposes. The Pressure setting issues a value for pressure analog to the CSF-pressure measured by ***LiquoGuard® CSF.***
The same scale (20 ml/h correspond with 20 mmHg) can also be used to issue the pump flow corresponding to the history view.
This may be expedient as pressure regulation is active and if the pressure is consistent. Subsequently the quantitative size is the volume flow.

(2) Diagram width [s]

Meaning: The spread of the X-axis in the display diagram (Display) is stipulated by the Diagram Width (s).

Default value: 6 seconds (ventricular), 60 seconds (lumbar)
Minimum value: 6 seconds
Maximum value: 10 minutes

(3) Pulsation alarm active?

Meaning: Pulse recognition can be de-activated in the system menu, if patient conditions do not permit accurate measurement.

Possible settings: YES, NO (Default value: YES)

Notes:
- This parameter can only be set for ventricular application. The pulsation alarm is always de-activated for lumbar applications.

Attention: There is no reliable alarm function for catheter occlusions, catheter disconnections, or collapsed ventricles if the pulsation alarm is deactivated.

(4) Pressure constant [mmHg]

Meaning: A value of 0.2 [mmHg] means that the minimum pressure and the maximum pressure during the past 12 seconds (120 measured values) must differ by more or equal to 0.2 mmHg, so that no alarm is issued for "Pressure too constant". The alarm delay time of 20 seconds applies here, too.
The purpose of this function is to recognize a torn off/occluded catheter. The function is available for ventricular and lumbar drainage but not for the infusion test.

Default value: 0.2 mmHg
Minimum value: 0.1 mmHg (resp. OFF)
Maximum value: 2.0

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Product description

(5) Keys lock active [min]

Meaning: To prevent unintentional chages to the operating field parameters, "Keylock" can be set, so that ***LiquoGuard® CSF*** creates a keys lock after a certain inactive period. By default this function is set to OFF.

Default value: OFF
Minimum value: OFF (keys lock inactivated)
Maximum value: 60 minutes

Figure 14: Keys lock active

Symbol for active keys lock

If the keys lock is active, a key will appear in the display and no further settings can be performed via the operating field. The key lock is deactivated by pressing and holding the "**Alt key**" for 2 seconds. The lock is automatically re-activated if the preset time has lapsed without key activation.
Note: the keys lock is automatically de-activated every time an audible alarm signal is sounded. This also applies for the opening of the lid, if the question appears: "Interrupt application?".

(6) Reset volume counter
The volume counter is reset to zero when confirming "Volume reset".

Note: The key "Volume reset" is only active if "Duration volume balance" is set to "OFF" in the system menu.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.4 Technical Data

Order number:	**00 002 563**
LiquoGuard® dimensions:	Length x Width x Height: 280 mm x 210 mm x 315 mm (11.02 inch x 8.27 inch x 12.4 inch)
Weight:	approx. 4.8 kg (10.58 lb)
SPL main alarm:	54 dBA
Sound pressure level emergency alert:	49 dBA
Electrical supply:	
Voltage	100 – 240 VAC (alternating voltage)
Frequency	50 – 60 Hz
Current consumption	0.5 – 0.2 A
Protection class:	I
Battery fuse:	Littelfuse Serie 318 10A / 250V
BF applied parts:	Tube set for ***LiquoGuard®*** REF.-No.: 00003639 (1500 mm) REF.-No.: 00003640 (2000 mm)
General characteristics:	
Operating conditions:	
Application temperature range	+10°C to +40°C (+50°F to +91°F)
Humidity	30 to 75 % rel. humidity
Transport - storage conditions	
Temperature	-10°C to +50°C (+14°F to +122°F)
Humidity	less than 90 % rel. humidity
Protection category	IP 20 - ***LiquoGuard® CSF*** IP 20 - Tube set for ***LiquoGuard®***
Pump rate	1 ml/h to 120 ml/h (variably adjustable)
Flow rate accuracy	± 15 %
Pressure range	-15 mmHg to +75 mmHg
Accuracy of pressure sensors (according to data sheet)	± 0.5 mmHg
Display accuracy of system	± 2 mmHg
Relay output:	pure switch output for extra-low voltages of 25V AC / 60V DC, Current limitations: 3 A
Output signal of analog interface:	
Direct connection	5.9 mV/mmHg (Tolerance: ± 12 mV or ± 10 % *)
With TruWave adapter cable	33 µV/mmHg (Tolerance: ± 66 µV or ± 10 % *) *The highest value is valid respectively.

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Product description

<u>Attention</u>: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.5 Recurring inspections

LiquoGuard® CSF must be subjected to safety inspections at least every 12 months. Documents on safety inspections can be requested from the manufacturer.

In addition to the safety inspections, further maintenance of the *LiquoGuard® CSF* is required in order to verify measures for the dual safety of the device.

Maintenance must be conducted by a maintenance center approved by the manufacturer. Information on maintenance can be requested from the manufacturer`s service division (see page 54). Enter safety inspections into the equipment log book and document inspection results. If the device is not fully functional or safe to operate, it must be repaired immediately by device service personnel. The safety inspections and technical measurement checks can be performed by the Service department of Möller Medical service@moeller-medical.com.

7.6 Dimensions, weight and transport information

LiquoGuard® CSF dimensions with packaging:	Length x Width x Height: 580 mm x 430 mm x 415 mm (22.83 inch x 16.93 inch x 16.34 inch)
Weight:	approx. 8 kg (17.64 lb)
Transport and storage conditions	
Temperature:	-10°C to +50°C (+14°F to +122°F)
Humidity:	less than 90 % rel. humidity

When transporting, do not stack more than 3 cartons above one another.

The external packaging is a folding corrugated cardboard box. The internal packaging is made from polyethylene foam rubber.

The packaging material is highly flammable and represents a fire hazard. Keep away from naked flames and do not smoke!

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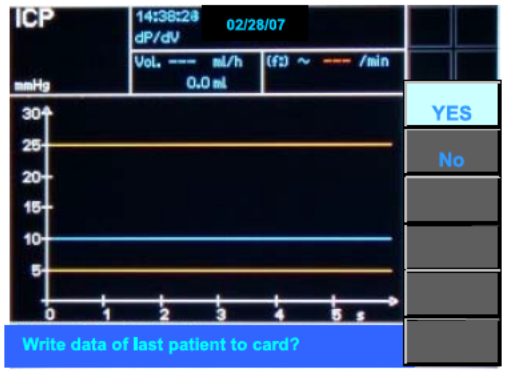
8 Application and operation

LiquoGuard® CSF may only be switched on if power supply is conveyed via power input. The ***LiquoGuard®*** is ready for operation once the **ON/OFF – Standby – button** is activated. ***LiquoGuard®*** starts with a recognition signal and the current software versions as well as the Bus address are displayed for a short while.
Note: The emergency alarm is tested when ***LiquoGuard®*** is plugged in. This means you will have to hear a short beep. A function test is also performed when ***LiquoGuard®*** is activated (see page 21 "Inspection of alarm functions").

As a first step the subsequent display screen will appear.



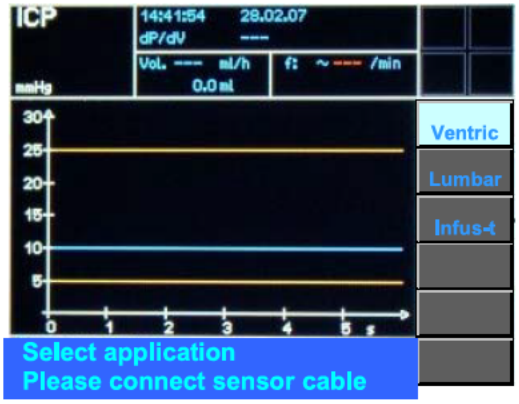
Should you not have written the data from the last patient to the memory card, this procedure can be carried out now (confirmation with the turn switch). All existing data is fully deleted once a new tube set is connected.
(This step can be skipped by activating the alt key or the standby key.)

Figure 15: Write data to memory card?

Select the desired application in the next step:

- **Ventricular drainage (Ventric)**
- **Lumbar drainage (Lumbar)**

Please read page 38 (Ventricular drainage) or page 39 (Lumbar drainage).



Turn the turn-switch to move the highlight to the desired field. Press the turn-switch to confirm the desired application.
(By pressing the "Alt" key or the "Standby" key the device is switched off.)

Figure 16: Select application

The following steps apply only to the following applications: Ventricular drainage or lumbar drainage.

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Application and operation

8.1 Connection of the tube set

Please be sure to see that the following procedures are carried out:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.
2. Connect the tube set to the drainage bag and fasten the drainage bag to the holder provided

Note: Insert the drainage bag into the top of the bag holder at the ***LiquoGuard®*** (see Page 22, Figure 6).The drainage bag is freely suspended by the upper attachment buttons at the bag holder.

3. Insert the tube set into the pump: Ensure that the connecting pieces are correctly seated in the guides. Turn the pump rotor counter-clockwise by three rotations. Check whether the pump tube was correctly threaded.

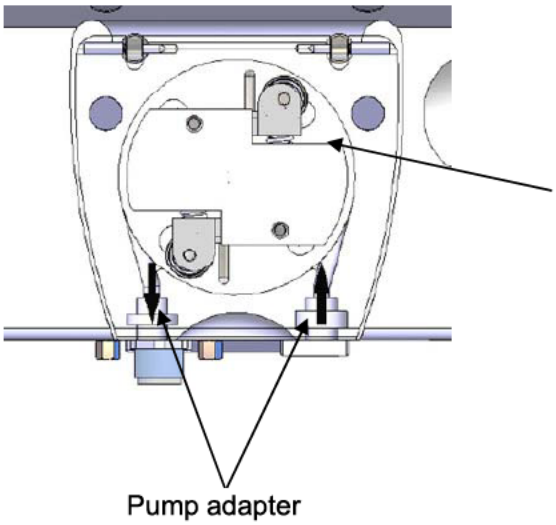

Figure 17: Pump rotor

As a first step you open the front cover of the pump and insert the tube set with the pump adapters into the pump receptacles.

Then thread in the pump tube by manually rotating the pump rotor to the left, threading via this rotor edge.

Manually turning the pump rotor counterclockwise for at least three rotations ensures that the tube is not jammed anywhere.

Then close the front cover.

4. Turn the stop cock of the 4-way manifold by 180° flow direction from the pump to the catheter… and remove the protective cap on the catheter side.

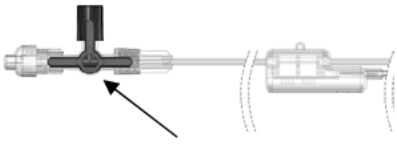

Figure 18: Stop cock setting before the application

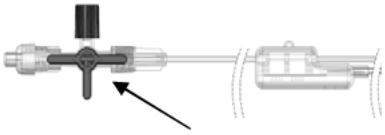

Figure 19: Stop cock setting during the application

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Application and operation

5. If you haven't done it yet: Connect the sensor cable to the ***LiquoGuard®*** (connection under the device).

Figure 20: Connect sensor cable to pump

Notes:

- In the event that a tube set had previously been attached, the point concerning "connect the sensor cable to the pump and wait" will be skipped, since the device will automatically recognize the tube set.
- Should you select a tube set that is unsuitable or which has already been used, the following message will appear: "wrong tube set for this application" and/or "please change the tube set". In this case, disconnect the tube set from the device. The following message will then reappear: "Sensor cable - connect to the pump and wait". Either connect a tube set which is suitable for the selected application or go back a step using the ESC key, in order to select an application for which the tube set is suitable.

6. Connect the catheter to the tube set (Please observe page 11 "Combination with other products").

7. Use the adhesive electrode (attachment area depends on application, see Pages 38/39) to attach the pressure sensor housing to the patient. Follow the display to do so:

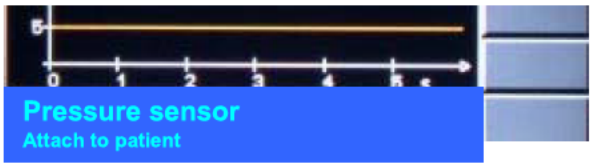

Figure 21: Attach pressure sensor

Until this point in time, the tube set can still be disconnected, use the "Esc" key to return to the beginning step-by-step. The tube set is not yet marked as being used.
As soon as the catheter and the pressure sensor are connected to the patient and this is verified by activating "Okay", the tube set is marked as used and can no longer be employed for a new application. A brief notice appears stating, "Connect sensor cable to the pump and wait", whereby the device checks to see whether the sensor cable is actually connected. At this point the alarm function will activate and the device is put into normal operating mode.

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Notes:

- During all steps observe also the instructions displayed on the ***LiquoGuard®*** and always adhere to the prescribed sequence of steps.
- After you have connected the tube set to the catheter, attached the pressure sensor housing to the patient and confirmed with "OK", ***LiquoGuard®*** electronically marks the tube set as used and it cannot be used again.

ATTENTION:

To avoid possible CSF reflux, always close the 4-way stop cock between the tube set and the catheter before removing or replacing the tube set.

The tube set must be replaced after a maximum of 120 continuous operating hours.

Attention: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

8.2 Setting of patient parameters

Setting of patient parameter target values is carried out via the display control fields, as described as of page 25. For LiquoGuard there are 2 target value settings for application as well as 2 safety settings for the alarm limits:

Setting the patient parameters may only be carried out by qualified personnel.

8.2.1 P-max:

P-max (mmHg) is used to set the upper alarm limit for **LiquoGuard®** alarm conditions. If the filtered actual ICP value is higher than the upper pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 25 mmHg

Minimum value: limited by P-Set
Maximum value: 75 mmHg

8.2.2 P-min:

P-min (mmHg) is used to set the lower alarm limit for ***LiquoGuard®*** alarm conditions. If the filtered actual ICP value is smaller than the lower pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 0 mmHg
Minimum value: -15 mmHg
Maximum value: limited by P-Set

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8.2.3 P-Set or P-Stop

During ventricular application **P-Set** (mmHg) is used to set the target value for pressure regulation. If the filtered actual ICP value (mmHg) reaches a pressure higher than **P-Set**, the ***LiquoGuard®*** pump is activated and pumps off the CSF. Pumping continues until the filtered actual ICP value reaches a pressure value lower than **P-Set.** The symmetrical hysteresis value (standard 0.5 mmHg) of this regulation is adjustable in the menu.
During lumbar application **P-Stop** (mmHg) is used to specify the value under which the pump no longer conveys.

Default value:	15 mmHg
Minimum value:	2 mmHg or limited by P-min
Maximum value:	limited by P-max

8.2.4 Flow

Flow sets the pre-selected flow rate of the ***LiquoGuard®*** pump (ml/h). Therefore pumping of the CSF can be influenced by time.

Default value:	20 ml/h
Minimum value:	1 ml/h
Maximum value:	50 ml/h (ventricular application)
	20 ml/h (lumbar application)

Notes:

- When starting a new application (by switching on the device), the parameters are always automatically reset to the standard values.
- In the event that an application is interrupted or when a tube set is renewed (without turning off the device), the parameter values last used will remain set.

Default values:

- **P-max: 25 mmHg**
- **P-min: 0 mmHg**
- **P-Set: 15 mmHg**
- **Flow: 20 ml/h**
- **Pulse alarm: "ON"; coupled to: Filter time Control 1.0**
- **Pressure constant : 0.2 mmHg**

ATTENTION:

An adjustment of the standard values may only be carried out by specialists.
Before every use, the user should check to see whether the momentary settings are suitable for the patient!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Application and operation

8.3 Short checklist

After attaching the tube set and setting all patient parameters, ***LiquoGuard® CSF*** works independently. Before letting the system work independently you should review the following short checklist:

- **Is the tube set correctly inserted in *LiquoGuard®*?**
- **Are the catheter and drainage bag connected correctly?**
- **Are the stop cocks of the tube set in the correct position for the application?**
- **Are the set patient parameters correct?:**
  - **P-Set or P-Stop - *Pressure setting parameters***
  - **Flow - *Pump delivery rate settings***
- **Are the set alarm limit values correct for the following alarm conditions:**
  - **P-max - *upper alarm limit value for the alarm condition***
  - **P-min - *lower alarm limit value for the alarm condition***
- **Is the pulsation alarm activated?**
- **Is the "Pressure constant" alarm activated and properly set?**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.4 Ventricular drainage

During ventricular drainage, ***LiquoGuard® CSF*** functions as a pressure controlled tube pump. Adjustment specification here is **P-Set.** The pressure housing must be attached at the height of the Foramen Monro. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore the position of the sensor at the head must be considered when evaluating pressure values.

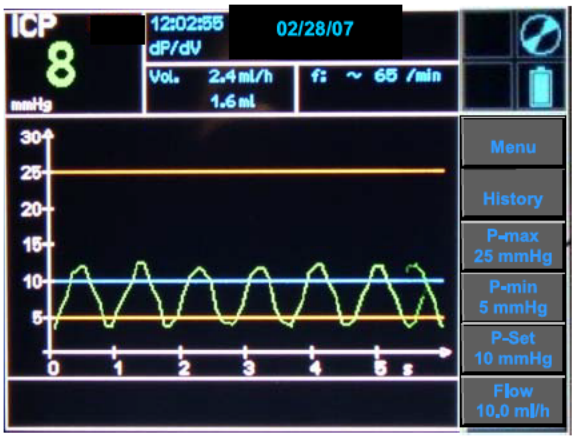

Figure 22: Display setup during ventricular drainage

There are 4 physiological alarm limits during ventricular drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)
- **Measured pulse frequency invalid** (f <= 30/min - fixed limit value)
- **Measured pulse frequency invalid** (f 180/min- fixed limit value)

ATTENTION:
In both important cases of catheter blockage and collapsed ventricles it is usually the case that the pulse can no longer be measured, which triggers an alarm - if activated!

By default, pulsation alarm is set to on. It is an additional monitoring function to increase patient safety (see page 23: Pulsation frequency of pressure signal (f: ~ --/min)).

It would be expedient to deactivate pulse recognition in the system menu, if patient conditions do not permit accurate measurement. As an indication to the operator that pulse recognition is deactivated, the system displays “(f:)" instead of “f:“.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.5 Lumbar drainage

During lumbar drainage, ***LiquoGuard® CSF*** functions as a volume controlled tube pump. The specified setting here is the pump flow rate (**Flow**). During lumbar drainage, pulse recognition is deactivated, the time axis is set to 60 seconds by default and P-Set becomes P-Stop (see page 36, P-Set or P-Stop).
The pressure sensor housing should always be on or slightly below the level of the catheter end in the spine. Ask the patient about his sleeping behaviour. Patients sleeping on their sides should have the pressure sensor housing attached to their backs. Patients sleeping on their backs should have the pressure sensor housing attached to their sides. A safety cushion (available as an accessory) can be applied to avoid pressure pains. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore avoid that the patient lies on the side, at which the sensor is attached.

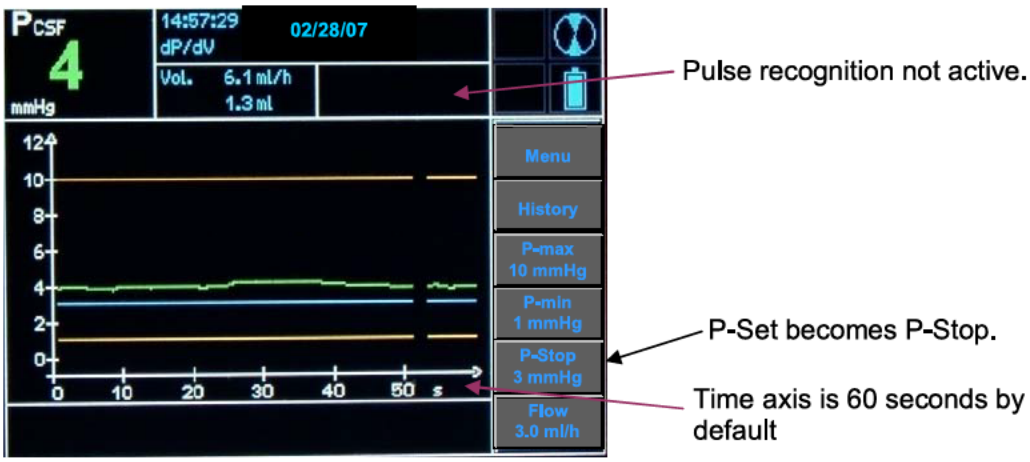

Figure 23: Display setup during lumbar drainage

There are 2 physiological alarm limits during lumbar drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.6 Audio paused or Audio off

In case of an alarm condition, the alarm signals are created with a 20 second delay. The alarm condition is also displayed. In case of multiple alarm condition these are displayed alternatively. (In the example contained in Figure 24 "Measured pulse frequency invalid!" alternates with "Measured pressure too low!".)
Additionally a key menu with 4 options appears on the right hand side of the display: Audio Pause 20 min (duration settable in system menu), Audio Pause 60 min, Audio Pause 180 min and Audio off.

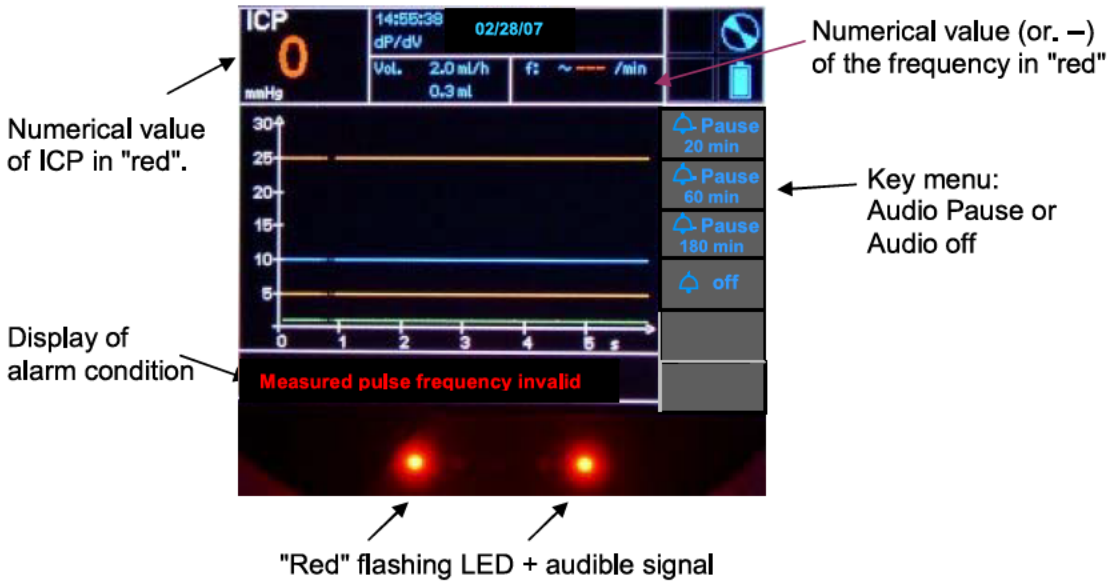

Figure 24: *LiquoGuard® CSF* in alarm mode

The *LiquoGuard® CSF* alarm system cannot be deactivated. The function "Audio paused" or "Audio off" can create a condition in which no audible alarm signal is emitted.

Use the turn switch to select the desired bell (Audio Pause 20 min, Audio Pause 60 min, Audio Pause 180 min or Audio off) and press the turn switch to confirm the function "Audio paused" or "Audio off". This condition is displayed by a crossed out red bell. The remaining duration in minutes is displayed on the left hand side (see Figure 25). In the case of "Audio off" it displays "OFF".

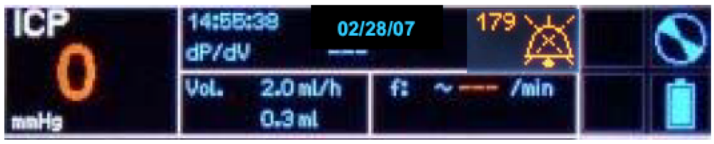

Figure 25: *LiquoGuard® CSF* – Paused audio

"Audio paused" and "Audio off" refer to all alarm conditions active at the time of key activation.

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Application and operation

In the case of the 3 audio pause time, the cancellation of the alarm condition does **not** lead to the cancellation of "Audio paused". In the case of "Audio off" the cancellation of the alarm condition does lead to the cancellation of the condition "Audio off".

Example:
- Alarm due to low pressure and pulse
- Audio Pause 20 min was pressed
- Both alarm conditions are cancelled and return (within 20 minutes) → Audio Pause remains constant
- Pressure rises to overpressure alarm: An audible alarm is sounded
- Renewed activation of Audio Pause 20 min
- The old alarm pause is deleted, the new pause now applies for 20 minutes for overpressure only!

Notes:

- The delay time of 20 seconds applies for each individual alarm condition.
- In the case of alarm conditions "Sensor defective or disconnected" and "Device error" the pump is stopped, irrespective of further conditions. This is marked by the display of a red pump symbol.
- If an alarm is created and if alarm paused is not pressed for 1 hour, the pump is stopped (this does not apply for exceeding P-max). This is also displayed by a red pump symbol. If alarm pause is pressed, the pump restarts immediately if the alarm condition permits this.
- Aside from the alarm condition (displayed in red), possible reasons for the alarm condition may also occur (e.g. "frequent causes: Catheter occluded/disconnected, ventricles collapsed, …). These should provide an indication for the possible reason for this alarm condition, although it is the responsibility of the medical personnel/the physician to determine the actual reason for this alarm condition.
- Should "Audio pause" or "Audio off" be activated, this setting can be cancelled by activating the "Audio on" button (through "Audio on" an audible (acoustic) alarm signal will be reactivated). The "Audio on" field can be reached by pressing the alt key twice.

Figure 26: *LiquoGuard® CSF* – „Audio On"-key

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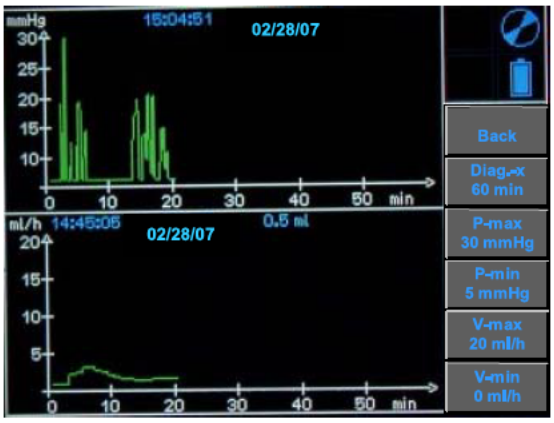
8.7 History

You can move to the "History" function via the display control field key **"History".** You can leave the "History" function via the Standby key, as well as via the Back button or the Alt key.
In the "History" function 2 diagram fields are displayed:

The upper diagram displays the pressure value [mmHg] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].



Display operating keys

Figure 27: History frame

The lower diagram displays the pumped-off CSF volume [ml/h] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].

Display control keys:

- **Diag.-x**
  This key is used to set the time spread of the axis (x-axis) from:
  - 10 seconds to 120 seconds in increments of 10 seconds,
  - 3 minutes to 120 minutes in increments of 1 minute,
  - 3 hours to 72 hours in increments of 1 hour,

  The setting is the same for both diagrams.
- **P-max / P-min**:
  You can use these two keys to set the spread of the pressure values (y-axis) in the upper diagram (adjustable from -50 mmHg to 99 mmHg).
- **V-max/V-min** :
  You can use these two keys to set the spread of the volume values (y-axis) in the lower diagram (adjustable from 0 ml/h to 130 ml/h).

You can view the long-term process of the two diagrams in time frames using the turn-switch.
The two blue digital displays in the lower diagram will show you the time frame for time and date of the y-axis position. The volume value on the right indicates how much CSF (ml) was conveyed in that precise time period (whereby the balance is determined from the displayed measurement values).

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8.8 Output of memory data

The internal memory of ***LiquoGuard®*** provides space for 150.000 data sets.
In the following table you can see the relation between sampling interval and memory storage time:

Sampling interval	Memory storage time
6.0 s	10d 09h 39m
5.0 s	8d 16h 03m
4.0 s	6d 22h 26m
3.0 s	5d 04h 49m
2.5 s	4d 08h 01m
2.0 s	3d 11h 13m
1.5 s	2d 14h 24m
1.0 s	1d 17h 36m
0.5 s	20h 48m
0.2 s	8h 19m
0.1 s	4h 09m

Please remember: The smaller the sampling interval, the more frequently the data will have to be stored on a card, since the data will otherwise be overwritten.

The following data is stored in the internal memory of ***LiquoGuard® CSF.***

- Date
- Time
- Pressure
- Flow
- Compliance
- P-Set
- Flow-Set
- Pause: 1 if pause, otherwise 0
- Pumping: 1, is pump is activated, otherwise 0
- Marker: at the moment always 0
- Statuscode

Table headlines:

Date	Time	Pressure	Flow	Compliance	P-Set	Flow-Set	Pause	Pumping	Marker	Statuscode

An MMC or SD memory card (format: FAT 16) can be used to read out data created by ***LiquoGuard® CSF***. Insert the memory card into the slot next to the pump, whereby the contacts must point towards the pump head. ***LiquoGuard® CSF*** will ask whether the data must be written to the card. Confirmation with "Yes" will immediately start the copying process. The card symbol will change its color to orange; the inside of the symbol will display the percentage of the already copied data. After copying is completed, the symbol changes back to blue and the card can be removed.

Display for memory card

Figure 28: Symbol for memory card

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During writing the software checks whether a memory card is full. The writing procedure becomes irregular towards the end and if there is insufficient space, the error message "Error while writing to card!" will be displayed. The started file is subsequently deleted and the card symbol will display "Err", until the card has been removed.
In this case ensure that there is sufficient memory on your card and then resave. (A full internal memory requires approx. 4 - 5 MB memory capacity).

ATTENTION: The card must not be removed during the copying process!
All data on the memory card may be irretrievably lost!

8.9 Replacement of tube set

After 5 days, ***LiquoGuard® CSF*** displays two round flashing red arrows in the info field of the keys lock (see page 27) together with the red text "Please change tube set!". This indication is not an alarm. If keys lock is active, the tube set symbol alternates with the key symbol. After 7 days, ***LiquoGuard® CSF*** emits the same message as an alarm. The alarm pauses can be used here, but the alarm does not disappear during this application.
In order to perform a proper change of the tube set, the application has to be interrupted with "Set change" (see 8.10).

Figure 29: Symbol for tube set replacement

8.10 Interruption of an application

There are 2 ways to interrupt an application:

1) Press and hold the **"ON/OFF – Standby – key"** for at least 2 seconds
2) Open the front cover of the pump of the ***LiquoGuard® CSF***

Both of these ways cause a new selection menu to appear on the right side of the display showing 4 different points to be selected (Interrupt, END, Change set, Esc)

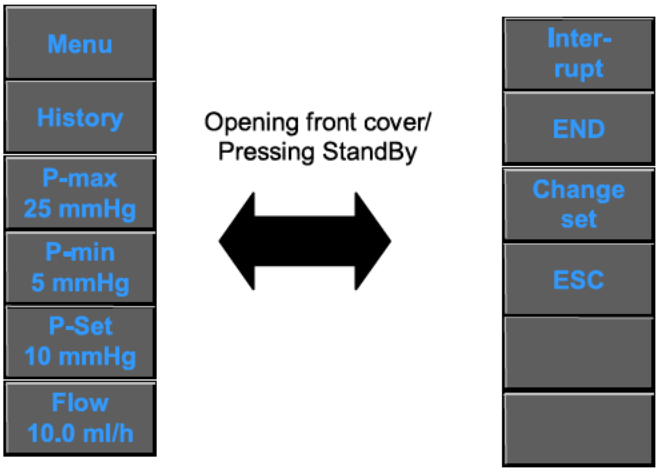

Figure 30: Interrupt, END, Change set

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Application and operation

Should you wish to change the tube set, select "Change set". If you want to interrupt the application (e.g. to perform a CT), select "Interrupt". In both cases, the next question to appear will be, "Interrupt application?". By selecting "Yes", the question, "valve to catheter closed?", will appear.
Be sure to see that the shut-off valve to the catheter is closed, then verify this with "Okay". The tube can now be removed (and reconnected later) or the tube set can be renewed.
When the tube set is reattached, one should not forget to open the shut-off valve to the catheter once again.

Notes:

- If the sensor cable is disconnected, the notice "Interruption, connect tube set" will appear and the symbol for a circulating pump will be displayed in red. The measuring value will be displayed as – . In the data record you can recognize this condition as measuring values < - 90 mmHg
- Pulling the plug from the tube set without following the instructions described above will always lead to the alarm condition of "Sensor defective or disconnected". Should this occur, reattach the plug. Should you wish to end or interrupt the application, or to change the tube set, please follow the instructions described above.
- When the alarm condition "Sensor defective or disconnected" appears, it is impossible to activate "Audio pause" or "Audio off". An intentional removal of the tube set must be performed using the 4 keys on the right edge of the display (Interrupt, End, Change set, Esc; see Figure 30) (as described above, these 4 keys can be activated using the Standby key or by opening the cover). The device will recognize any other procedure as being faulty.
- With "Esc" you will always be able to return to the normal control display.

8.11 Exiting the application

Press and hold the ON/OFF - Standby key for at least two seconds. As described under 8.10, a selection menu with 4 points will appear. Select "End". The question "Sure to turn off the device?" will appear and the total volume of the application will be displayed. If confirmed with "Yes", ***LiquoGuard® CSF*** will exit the application and switch off.

Please observe that you cannot start a new application with the used tube set.

Should you have forgotten to read out the data via the memory card, you can restart ***LiquoGuard® CSF*** and read out the data one last time. The connection of a new tube set deletes all existing data.

In Standby mode (***LiquoGuard® CSF*** - is connected to AC power) the blue LED flashes and the battery is charged.

If the AC power chord is disconnected, ***LiquoGuard® CSF*** is switched off.

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8.12 Demonstration mode

The device has a demonstration mode ("Demo mode"), which may only be used for the purpose of performing demonstrations and for teaching! The Demo mode can be recognized through the red flashing "Demo" indicator to the upper left of the display (to the right and beside ICP/P_{CSF}).
One automatically comes to the Demo mode when a special, unsterile demonstration tube set is connected.
Note: In the Demo mode, the device will turn off automatically after a certain period of time without previous warning! The Demo mode should NEVER be used on a patient!

8.13 System menu

Use the display control field key “Menu” to access the "System menu". However, access to the system menu is only possible if ***LiquoGuard® CSF*** is in "Pause mode". The selection bar is moved with the turn-switch. The corresponding sub-menu is selected by pressing the turn-switch. The submenus consist of several parameters that are displayed in sequence. A further parameter is always reached by pressing the turn-switch. You can now change the preset value by turning the turn-switch. A value being edited is displayed as orange during this time. If you want to accept the changed value, press the turn-switch. A text will appear in the display as a reminder: "Confirm changes with the wheel".

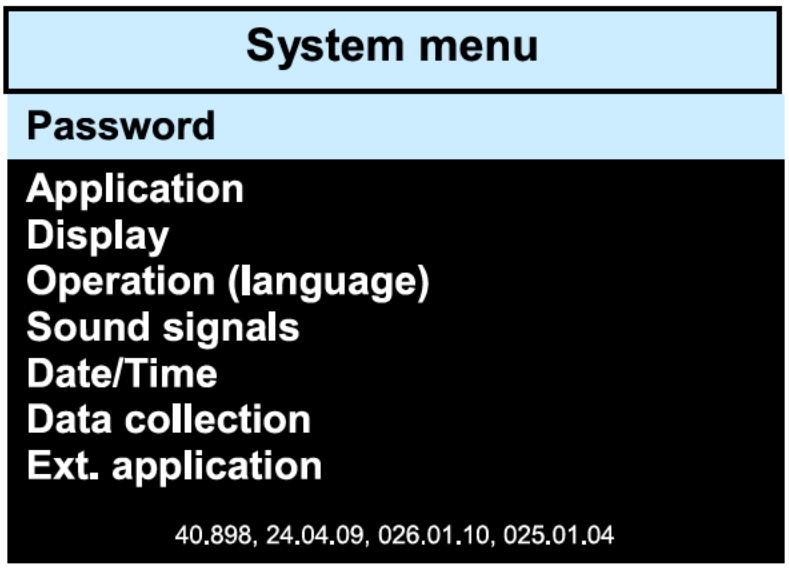

Figure 31: System menu

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Application and operation

Input of figures in the system menu is also possible in numbers. To activate this function during number input in the system menu, press the Alt key. A numeric keyboard appears in which you can enter values using the wheel. Press “END” to accept the values. Values which are too large are automatically limited by the maximum value. The Alt key therefore no longer serves as Esc at this point.

Figure 32: Numerical input

If the value is not to be adopted, leave the level with the Standby key or wait until the system menu is automatically exited - a negative confirmation tone is then sounded. You can set the time for automatic exiting (Standard 60 seconds).

8.13.1 Sub-menu Password

This point currently has no function for the operator. All menu items remain visible for the operator.

8.13.2 Sub-menu Application

The settings for the application are made in the Application sub-menu.

(1) Sampling rate memory [s]

Meaning: Time step in which a measured value is saved to memory.

Default value: 6.0 seconds
Minimum value: 0.1 seconds
Maximum value: 600 seconds

(2) Duration of volume balance [h]

Meaning: Time step for calculating the volume balance – also see page 24 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h).

Default value: 24 hours
Minimum value: OFF (set values: OFF, 2 h … 24 h, steps of 2)
Maximum value: 24 hours

(3) Flow increment

Meaning: This setting changes the increment for the operating field "Flow" (ml/h).

Default value: 1.0
Minimum value: 0.1
Maximum value: 10.0

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(4) Pressure increment

Meaning: This setting is used to change the time step for the operating fields "P-max / P-min / P-Set" (mmHg).

Default value: 1.0
Minimum value: 1.0
Maximum value: 10

(5) Duration Audio pause

Meaning: This setting sets the time for the shortest possible duration of "Audio paused".

Default value: 20 minutes
Minimum value: 1 Minute
Maximum value: 20 minutes

(6) Define application

Meaning: This can be used to reset the type of application during an application.

Possible parameter settings: lumbar, ventricular
(No default value, setting remains after reset)

8.13.3 Sub-menu Display

The settings for the display are made in the "Display" sub-menu.

(7) Range diagram

Meaning: The pressure axis in measuring mode is automatically scaled according to the alarm limits. In order to display a larger range, 20 % more than the upper alarm limit and 20 % less than the lower alarm limit are shown. The percentage is always related to the upper alarm value.

Default value: 20 %
Minimum value: 0 %
Maximum value: 100 %

Example: P-min = 5 mmHg, P-max = 25 mmHg, the diagram ranges from 0 mmHg (5-5) to 30 mmHg (25+5).

(8) Timeout backlight [s]

Meaning: In order to save power or to have a darker screen during night operation, the background lighting automatically switches into the darkest setting after an adjustable time (seconds). If this function is not wanted, the parameter can be set to OFF. During battery operation, the display is always darkened after 5 seconds.

Default value: OFF
Minimum value: OFF
Maximum value: 600 seconds

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(9) Brightness Display

Meaning: The brightness of the background lighting of the display is preset here. The value directly affects the display as it is changed so that the user can find the correct setting more easily. Setting is made in 4 steps.

Default value: 4
Minimum value: 1
Maximum value: 4

(10) Colour mode

Meaning: You can select a colour mode setting between 1 and 0.

"1" " means "dark" display background colour
"0" " means "light" display background colour
(Default value: “dark” display background colour)

8.13.4 Sub-menu Operation (language)

The "Operation" sub-menu contains functions that relate to the behavior of the unit with respect to the user.

(1) Language (language)

Meaning: The display language can be set here, and further languages can be stored.

Default value: ENGLISH
Value (depending on configuration): DEUTSCH, ENGLISH, Français, Svenska

(2) Operation Timeout [s]

Meaning: Settings or key activations are exited after a set time in seconds, independent of the level or in which parameters the input is carried out. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the input can only be exited by pressing the service screen "Standby" or "Alt". This time does not apply to the system menu.

Default value: 10 seconds
Minimum value: 1 second
Maximum value: 120 seconds

(3) Timeout menu [s]

Meaning: The system menu is closed after the preset time in seconds, independent of the level or the parameter currently being entered. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the system menu can only be exited by pressing the service screen "Standby" or "Alt".

Default value: 60 seconds
Minimum value: OFF
Maximum value: 600 seconds

8.13.5 Sub-menu Sound signals

The operator cannot change the volume of the activation signal.

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8.13.6 Sub-menu Date/Time

The system clock of ***LiquoGuard®*** can be set or changed respectively in this sub-menu.

(1) Date format

Meaning: Setting the date format

Default value: DD.MM.YYYY
Possible parameter settings: DD.MM.YYYY; MM/DD/YYYY; YYYY-MM-DD

(2) Clock: Year

Meaning: Setting of the current year

Minimum value: 2001
Maximum value: 2099

(3) Clock: Month

Meaning: Setting of the current month

Minimum value: 1
Maximum value: 12

(4) Clock: Day

Meaning: Setting of the current day

Minimum value: 1
Maximum value: 31, depending on the set month

(5) Clock: Hour

Meaning: Setting of the current hour

Minimum value: 0
Maximum value: 23

(6) Clock: Minute

Meaning: Setting of the current minute

Minimum value: 0
Maximum value: 59

(7) Clock: Second

Meaning: Setting of the current second

Minimum value: 0
Maximum value: 59

8.13.7 Sub-menu Data collection

(1) Decimal point

Meaning: Decimal markers in figure display on memory card. This setting is required for various countries.

Default value: Comma
Possible parameter settings: Comma, full stop

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(2) Data format MMC

Meaning: Setting the data format output depending on evaluation software

Default value: ASCII
Possible parameter settings: ASCII, LABpilot

8.13.8 Sub-menu Extended application

(1) Hysteresis controller [mmHg]

Meaning: This setting pre-selects a defined hysteresis for the pressure controller (target pressure curve). The hysteresis is symmetric to the target value, i.e. a target value of 12 mmHg and a hysteresis of 0.5 mmHg starts the pump at a pressure higher than 12.5 mmHg and will pump until the pressure is lower than 11.5 mmHg.

Default value: 0.5 mmHg
Minimum value: 0.5 mmHg
Maximum value: 1.5 mmHg

(2) Filter time control [s]

Meaning: The measured value for display of the digital pressure value can be filtered to avoid too high pressure changes of the digital pressure value as well as a continuous on and off of the pump. In order to filter out the pulse beat, the value must be set to at least 1.0 seconds. The set value displays after which time period 63% of the new value was reached after a step.

Note: This value is coupled to the pulsation alarm during ventricular drainage. If the pulsation alarm is ON, it is activated, the value is automatically set to 1.0; if pulsation alarm is OFF, it is set to 0.0 (in order to achieve a more rapid reaction time for the pump). This can be set manually by way of the system menu, but will once again be returned to the standard values when an adjustment is made for the pulsation alarm.

Default value: 1.0 (lumbar drainage, lumbar infusion test and ventricular drainage if pulsation alarm ON); 0.0 (ventricular drainage if pulsation alarm OFF)
Minimum value: 0.0
Maximum value: 60.0

(3) Filter time display or filter time display lumb. [s]

Meaning: The measured value for display in the diagram can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. If a clearly higher value is selected instead of a time resolution of 6 seconds, we recommend setting a longer filter time to enable the display of an averaged value. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 0.0 ventricular drainage; 0.5 lumbar drainage / lumbar infusion test
Minimum value: 0.0
Maximum value: 60.0

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Application and operation

(4) Filter time history [s]

Meaning: The measured value to store the data for the history function and the memory card can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. But then the scan time for the memory must obviously be set to 0.1 seconds. For a storage time of 1 second or more you should also select a filter constant of 1 second or more, so that averaged values can be stored. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 1.0
Minimum value: 0.0
Maximum value: 60.0

(5) Average value volume [min]

Meaning: Period for the calculation of the average volume flow

Default value: 15
Minimum value: 15
Maximum value: 60

(6) System information

Meaning: The setting "Yes" is used to display system information serving Möller Medical service staff for remote diagnosis.

(7) Reset System menu

Meaning: With the setting or changing of Reset System menu to "Yes", all changed setting parameters in the system menu are reset to standard values stipulated by the manufacturer. If confirmed with "No", all settings changed by the operator will be retained.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Troubleshooting

***LiquoGuard®* CSF may not be opened by the operator!**

This chapter describes some problems which may occur in connection with ***LiquoGuard® CSF*** Several possible solutions are listed for each problem. The first proposed solution is generally the most suitable. If the problem is not resolved, work through the proposed solutions in the order listed until the fault is rectified. ***LiquoGuard® CSF*** must always be switched off during connection or disconnection of connectors, with the exception of the tube set. If this does not remove the error, please contact the Möller Medical service division: service@moeller-medical.com.

Problem	Solution
Not functional, the display is switched off. Or ***LiquoGuard® CSF*** cannot be activated.	***LiquoGuard® CSF*** is not correctly connected to the AC power supply. Check power supply, switch on any multiple sockets, and check feed line. If these possibilities can be excluded, the error must be corrected by the service centre.
Pump does not rotate.	Pump is in "PAUSE" mode
Moistness penetrated the connectors	Pull AC power chord. Allow connectors to dry.
The device issues a rhythmic beep	Indicates an alarm. Press the Standby key 3 times in succession. If the device returns to this condition repeatedly, the device should be checked by Service.

If these measures do not eliminate the problem, the device should be inspected by Möller Medical service personnel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10 Service

The need for instant attitude of the unit service documents can be requested from the manufacturer at authorized service partners.

If the solution to a problem cannot be found, please contact the responsible service centre of Möller Medical.

Each return delivery of ***LiquoGuard® CSF*** must exclude risk of infection by a previously conducted disinfection procedure. The disinfectant may not be sprayed into the memory card slots.

Consumable materials should be disposed of in accordance with hospital guidelines.

Service Information

Never open the device if it is connected to the power supply. Attention - even then internal unit parts can still be voltaged.

Möller Medical service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
D – 36043 Fulda
Phone: +49 (0) 661 / 9 41 95 - 0
Fax. +49 (0) 661 / 9 41 95 - 850
http://www.moeller-medical.com
E-mail:info@moeller-medical.com

Service
Phone: +49 (0) 661 / 9 41 95 - 108
Fax. +49 (0) 661 / 9 41 95 – 850
E-mail:service@moeller-medical.com

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11 Accessories

The products described here represent only a small selection of the equipment available for ***LiquoGuard® CSF***. The currently valid list of equipment (including the prices) can be requested from Möller Medical on a separate Order form (neurochirurgie-vertrieb@moeller-medical.com; +49-(0)661-94195-185).

11.1 Tube set for LiquoGuard®

REF.-No.: 00003639 (1500 mm/59.06 inch)
1 cmpl packed

REF.-No.: 00003640 (2000 mm/78.74 inch)
1 cmpl packed

11.2 Other accessories

Liquor bag for **LiquoGuard ®**	Item no.: **00 003 638**
Pillows for **LiquoGuard ®**	Item no.: **00 002 701**
2GB Memory Card for **LiquoGuard ®**	Item no.: **00 002 700**
USB SD MMC card reader for **LiquoGuard ®**	Item no.: **00 003 190**
Fixing claw for **LiquoGuard ®**	Item no.: **00 002 672**
Analog Adapter 6V for **LiquoGuard ®**	Item no.: **00 003 034**
Analog Adapter 5V for **LiquoGuard ®**	Item no.: **00 003 035**
Analog adapter 4V for **LiquoGuard ®**	Item no.: **00 003 112**
Connection cable for Datex Ohmeda S5 for **LiquoGuard ®**	Item no.: **00 003 012**
Connecting cable to Marguette Hellige. Solar 8000 for **LiquoGuard ®**	Item no.: **00 003 013**
Connection cable for Phillips Intelliview MP30 / MP50 / MP70 for **LiquoGuard ®**	
Connection cable for Dräger Infinity / bridge	Item no.: **00 003 012**
HemoMed for **LiquoGuard ®**	Item no.: **00 003 128**
Connecting cable to Hellige Servocad 904 5th generation for **LiquoGuard ®**	Item no.: **00 003 172**
Connection cable for Nihon Koden for **LiquoGuard ®**	Item no.: **00 003 193**
Connection cable for Siemens ® 9000XL for **LiquoGuard**	Item no.: **00 003 012**

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Accessories

Transport case for **LiquoGuard ®**	Item no.: **00 003 102**
Patient demo for **LiquoGuard ®**	Item no.: **00 003 062**
Demo drainage hose for **LiquoGuard ®**	Item no.: **00 003 264**
Instructions GERMAN for **LiquoGuard ®**	Item no.: **20 007 862**
Instructions ENGLISH for **LiquoGuard ®**	Item no.: **20 007 863**
Instructions FRENCH for **LiquoGuard ®**	Item no.: **20 008 572**
Instructions SWEDISH for **LiquoGuard ®**	Item no.: **20 008 573**
Instructions SPANISH for **LiquoGuard ®**	Item no.: **20 008 794**
Instructions ITALIAN for **LiquoGuard ®**	Item no.: **20 009 439**
Instructions DUTCH for **LiquoGuard ®**	Item no.: **20 009 440**

Not all accessories are available in the US.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

12 Option: Lumbar Infusion Test

The option Lumbar Infusion Test is not available in the US.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 3

STERILIZATION VALIDATION REPORT

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda · Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MöllerMedical

(b)(4)

[redacted]

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda · Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

(b)(4)

[redacted]

APPENDIX 4

MECHANICAL TREATMENT REPORT

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 5

LABELS FOR THE LIQUOGUARD CSF SYSTEM

Back to **List of Appendices**

Back to **Chapter 2.5 – Question 5 – Device and Packaging Labeling**

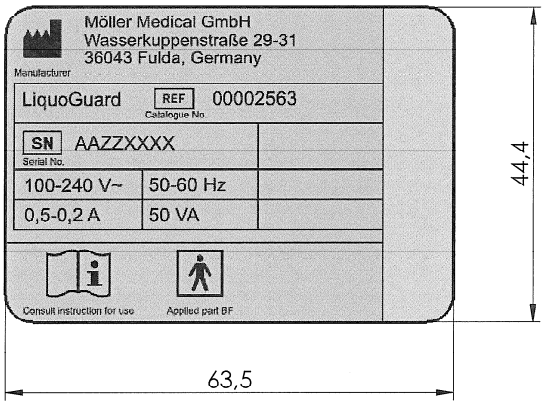
Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM – DEVICE LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP001-002 01 01-00 0-4



Aufschlüsselung der Seriennummer:

AA = Herstelljahr d.h.: Für Herstelljahr 2004 ist AA = 04
ZZ = Herstellmonat d.h.: Für Monat November ist ZZ = 11
XXXX = fortlaufende Gerätenummer mit 0001 beginnend unabhängig von Herstelljahr und Herstellmonat.

Schrift: Schwarz

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 013 302	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gefertigt aus: 30 000 146	Werkstoff-Nr.: (silber)
							Halbzeug:	
						Datum	Name	Typenschild
					Bearb.	25.04.13	PWE	
					Gepr.	25.04.13		LiquoGuard US
					zul. gespeichert von: pwelker		25.04.2013 10:12:34	
					Vertraulich/Confidential Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.			LDP001-002 01 01-00 0-4	Blatt 1 von 1
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP001-002 01 01-000			Ers. für:

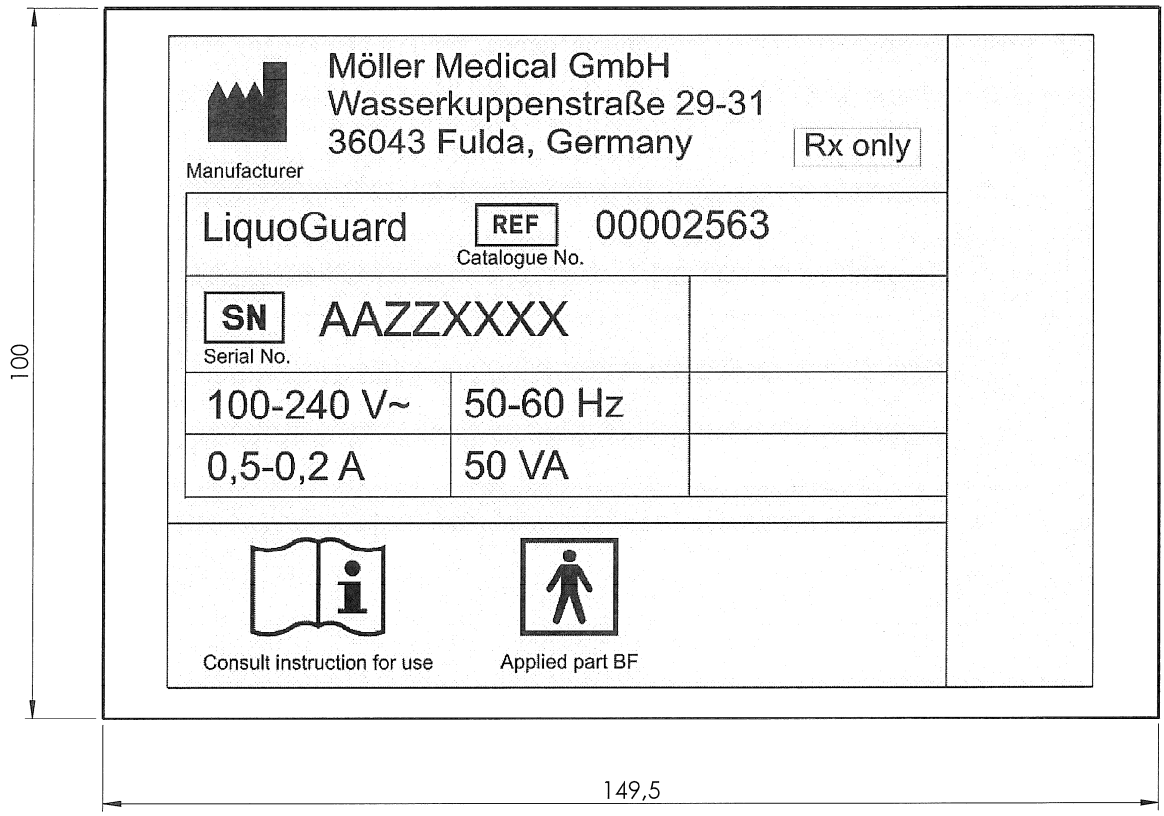
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016



Aufschlüsselung der Seriennummer :

AA = Herstelljahr d.h.: Für Herstelljahr 2013 ist AA = 13
ZZ = Herstellmonat d.h.: Für Monat April ist ZZ = 04
XXXX = fortlaufende Gerätenummer mit 0001 beginnend unabhängig von Herstelljahr und Herstellmonat.

Schrift : Schwarz

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com	Art.-Nr. 20 013 303	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1 Werkstoff: gef. aus: 30 004 755 Halbzeug:	Gewicht: Volumen: Werkstoff-Nr.:
	Datum	Name	Kartonaufkleber	
	Bearb. 24.04.13	PWE	LiquoGuard US	
	Gepr. 24.04.13			
	zul. gespeichert von: pwelker	25.04.2013 09:53:36		
	Vertraulich/Confidential Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung Ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.		LDP001-002 00 01-00 0-4	Blatt 1 von 1
Zust. Änderung KB-Nr. Datum Name	Dateiname:LDP001-002 00 01-00 0 - Kartonaufkleber LiquoGuard		Ersetzt für:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 6

LABELS FOR THE LIQUOGUARD CSF SYSTEM TUBING SET, 1500MM

Back to **List of Appendices**

Back to **Chapter 2.5 – Question 5 – Device and Packaging Labeling**

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM TUBING SET, 1500MM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-006 00 11-00 0-4

Tube set for - CSF drainage pump
LiquoGuard®

Rx only

REF **00003639** — Catalogue No.

1500 mm — Overall length

LOT — LOT No.

STERILE EO — Sterilized using Ethylene oxide

Date of manufacture

Use by

Do not use if package is damaged

+10°C (+50°F) – +40°C (104°F) Application range

Consult instruction for use

Do not resterilize

Do not reuse, single use device

MRI — Not for use in an MRI field

PHT DEHP — Contains or presence of phthalates

Manufacturer

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

MöllerMedical

20013329 - 2013-04

105

148

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com	Art.-Nr. 20 013 329	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1	Gewicht: Volumen:
			Werkstoff: bez.:Druckerei Mergard	Werkstoff-Nr.:
			Halbzeug: JAC script weiß, Klebstoff D131 80g/m²	
	Datum	Name	Verpackungsaufkleber	
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	Gepr. 25.04.13		Schlauchset "LiquoGuard" 1500mm US	
	zul. gespeichert von: pwelker	25.04.2013 09:38:31		
	Vertraulich/Confidential		LDP002-006 00 11-00 0-4	Blatt 1 von 1
Zust. / Änderung / KB-Nr. / Datum / Name	Dateiname:LDP002-006 00 11-00 0 - labels		Ers. für:	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM TUBING SET, 1500MM – PACKAGING LABELING: VARIABLE DATA

(NO CHANGES)

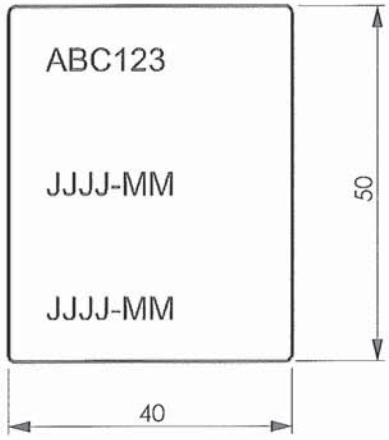
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(a) Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 687	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:
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						Datum / Name	Aufkleber	
					Bearb. 28.03.07 LW			
					Gepr. 15.03.12		für Schlauchset "LiquoGuard"	
					zul. gespeichert von: ahorwart	15.03.2012 11:05:01		
					Vertraulich/Confidential			
b	Haltbarkeit	KO3769	15.03.12	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Es sind alle Rechte vorbehalten insbesondere Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP002-001 00 09-00 b-4	Blatt 1 von 1
a	Chargenbez. geä.	KO 467	07.02.11	MU-De				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-001 00 09-00 0 - 4		Ers. für: LDP002-001 00 09-00 a-4	

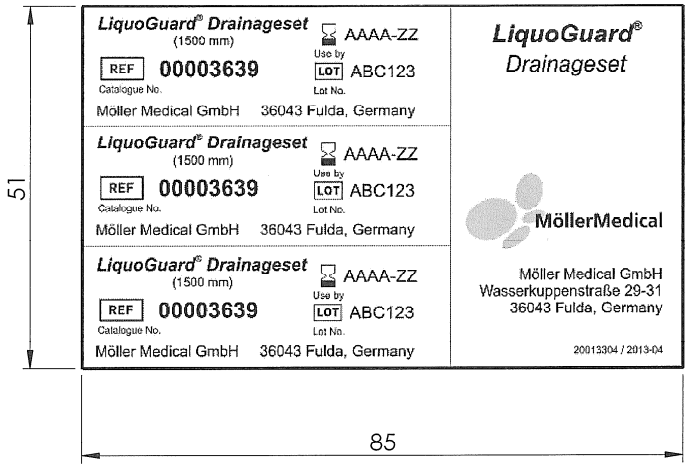
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM TUBING SET, 1500MM – PATIENT STICKERS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016



Haltbarkeit des Produktes = 2 Jahre 11 Monate

AAAA = Angabe des Jahres
ZZ = Angaben des Monats

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com	Art.-Nr. 20 013 304	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1 Werkstoff: gef. aus: 70 000 889 Halbzeug:	Gewicht: Volumen: Werkstoff-Nr.:
	Bearb. 22.04.13 PWE Gepr. 22.04.13 zul. gespeichert von: pwelker 29.04.2013 11:30:33		Patientenaufkleber Schlauchset "LiquoGuard" US 1500mm	
	Vertraulich/Confidential Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.		LDP002-006 00 12-00 0-4	Blatt 1 von 1
Zust. Änderung KB-Nr. Datum Name	Dateiname:LDP002-006 00 12-00 0 - Patientenaufkleber US 1500mm		Ersetzt für:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

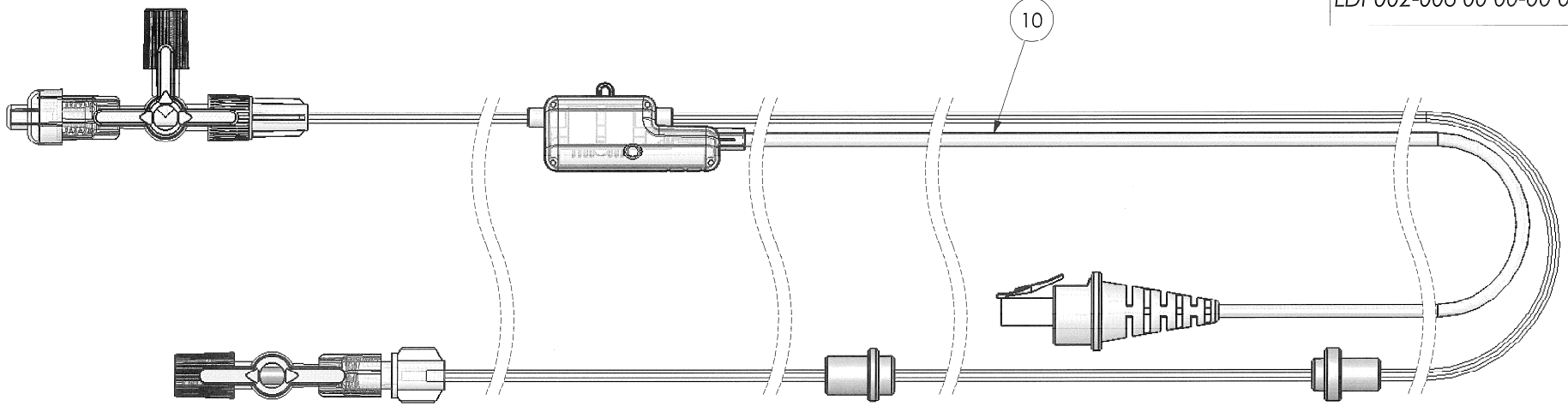
Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

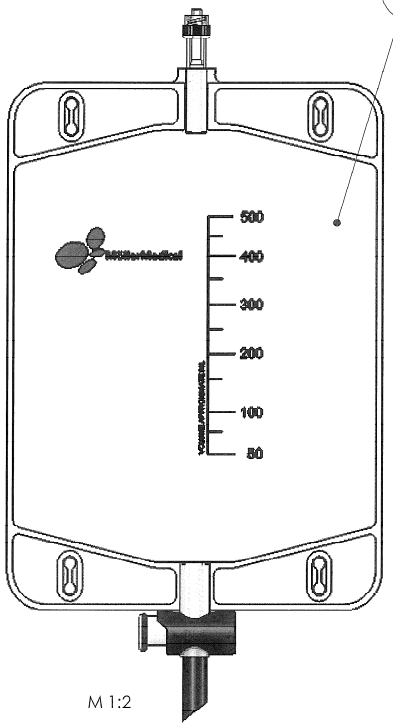
LIQUOGUARD CSF SYSTEM TUBING SET, 1500MM – PACKAGING SPECIFICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-006 00 00-00 0-3





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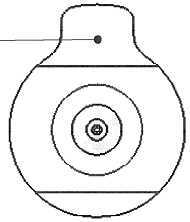

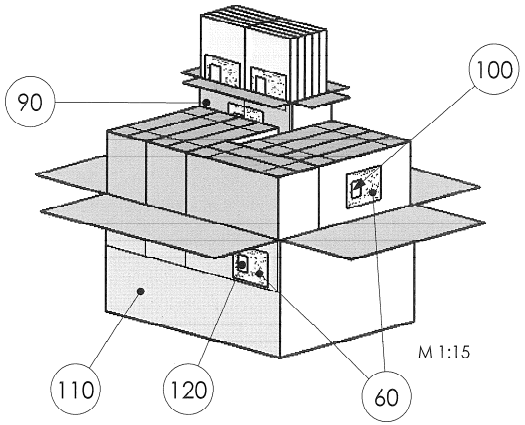

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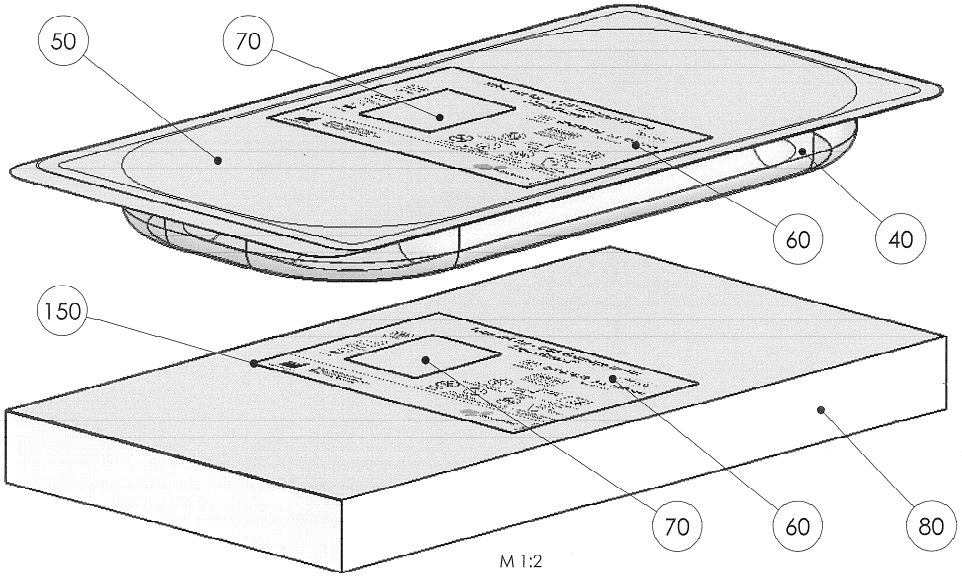

M 1:2

130 **Patientenaufkleber**

140 **Gebrauchsanweisung US**

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 00 003 639	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1 Werkstoff: Halbzeug:
						Datum	Name
					Bearb.	30.04.13	PWE
					Gepr.	30.04.13	
					zul. gespeichert von:	pwelker	30.04.2013 12:17:37
					Vertraulich/Confidential		
					Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.		
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-006 00 00-00 0 - Schlauchset kpl. verpackt US		

Gewicht: Volumen:

Werkstoff-Nr.:

Schlauchset 1500 mm (VPE = 1 Stck.)

"LiquoGuard" US mit Zubehör / kpl. verp.

LDP002-006 00 00-00 0-3

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 7

LABELS FOR THE LIQUOGUARD CSF SYSTEM TUBING SET, 2000MM

Back to **List of Appendices**

Back to **Chapter 2.5 – Question 5 – Device and Packaging Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM TUBING SET, 2000MM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Tube set for - CSF drainage pump
LiquoGuard®

Rx only

REF **00003640** — Catalogue No.

2000 mm — Overall length

LOT — LOT No.

STERILE EO — Sterilized using Ethylene oxide

Date of manufacture

Use by

Do not use if package is damaged

+10°C (+50°F) – +40°C (104°F) Application range

Consult instruction for use

Do not resterilize

Do not reuse, single use device

Not for use in an MRI field

PHT DEHP — Contains or presence of phthalates

Manufacturer

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

MöllerMedical

20013329 - 2013-04

105

148

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com	Art.-Nr. 20 013 328	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1	Gewicht: Volumen:
			Werkstoff: bez.: Druckerei Mergard	Werkstoff-Nr.:
			Halbzeug: JAC script weiß, Klebstoff D131 80g/m²	
	Datum	Name	Verpackungsaufkleber	
Bearb.	24.04.13	PWE		
Gepr.	24.04.13		Schlauchset " LiquoGuard " 2000 mm US	
zul. gespeichert von: pwelker		24.04.2013 12:27:18		
Vertraulich/Confidential			LDP002-007 00 04-00 0-4	Blatt 1 von 1
Zust. / Änderung / KB-Nr. / Datum / Name			Dateiname: LDP002-007 00 04-00 0 - label	Ers. für:

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

LIQUOGUARD CSF SYSTEM TUBING SET, 2000MM – PACKAGING LABELING: VARIABLE DATA

(NO CHANGES)

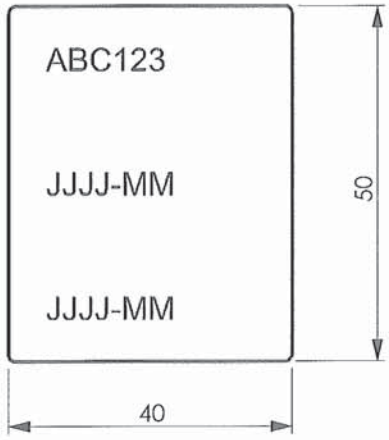
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(a) Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 008 687	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht: Volumen:
							Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:
							Halbzeug: Rollen - Haftetiketten 50 x 40 mm	
						Datum / Name	Aufkleber	
					Bearb. 28.03.07 LW			
					Gepr. 15.03.12		für Schlauchset "LiquoGuard"	
					zul. gespeichert von: ahorwart	15.03.2012 11:05:01		
					Vertraulich/Confidential			
b	Haltbarkeit	KO3769	15.03.12	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Es sind alle Rechte vorbehalten insbesondere Patent-, Gebrauchsmuster Eintragung vorbehalten.		LDP002-001 00 09-00 b-4	Blatt 1 von 1
a	Chargenbez. geä.	KO 467	07.02.11	MU-De				
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname:LDP002-001 00 09-00 0 - 4		Ers. für: LDP002-001 00 09-00 a-4	

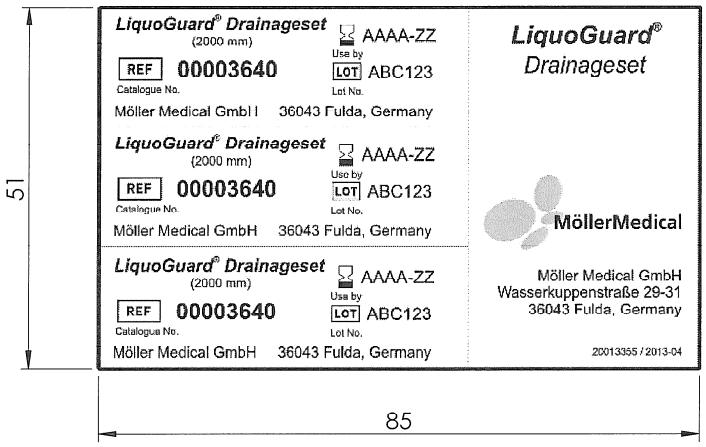
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

LIQUOGUARD CSF SYSTEM TUBING SET, 2000MM – PATIENT STICKERS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016



Haltbarkeit des Produktes = 2 Jahre 11 Monate

AAAA = Angabe des Jahres
ZZ = Angaben des Monats

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com	Art.-Nr. 20 013 355	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1	Gewicht: Volumen:
			Werkstoff: gef. aus 70 000 889	Werkstoff-Nr.:
			Halbzeug:	
	Datum	Name	Patientenaufkleber	
	Bearb. 29.04.13	PWE		
	Gepr. 29.04.13		Schlauchset"LiquoGuard"US 2000mm	
	zul. gespeichert von: pwelker	29.04.2013 11:54:34		
	Vertraulich/Confidential		LDP002-007 00 05-00 0-4	Blatt 1 von 1
Zust. Änderung KB-Nr. Datum Name	Dateiname:LDP002-007 00 05-00 0 - Patientenaufkleber US 2000mm			

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

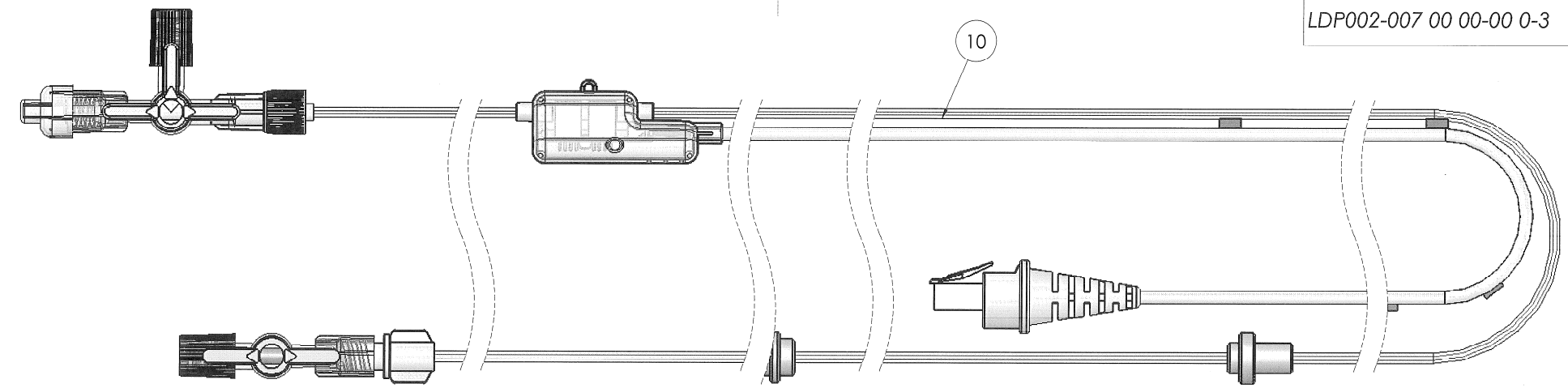
Rec[redacted]er FOIA request 2015-10257; Released by CDRH on 07/08/2016

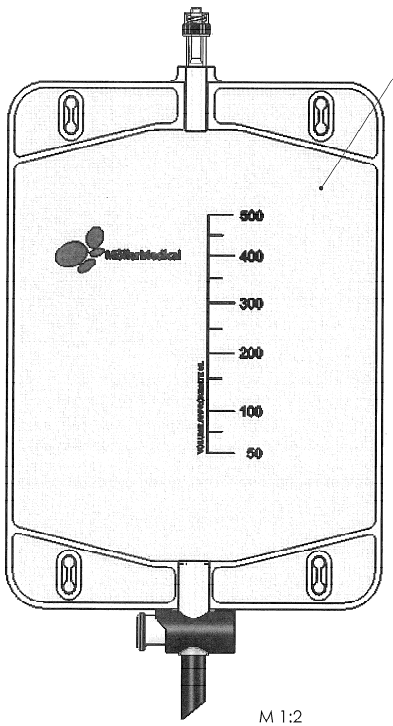
LIQUOGUARD CSF SYSTEM TUBING SET, 2000MM – PACKAGING SPECIFICATION

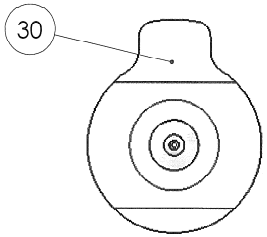
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

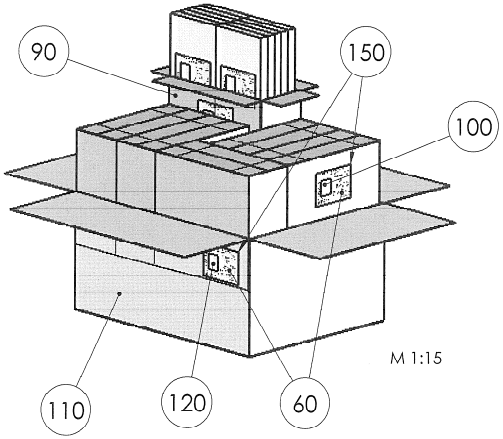
Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

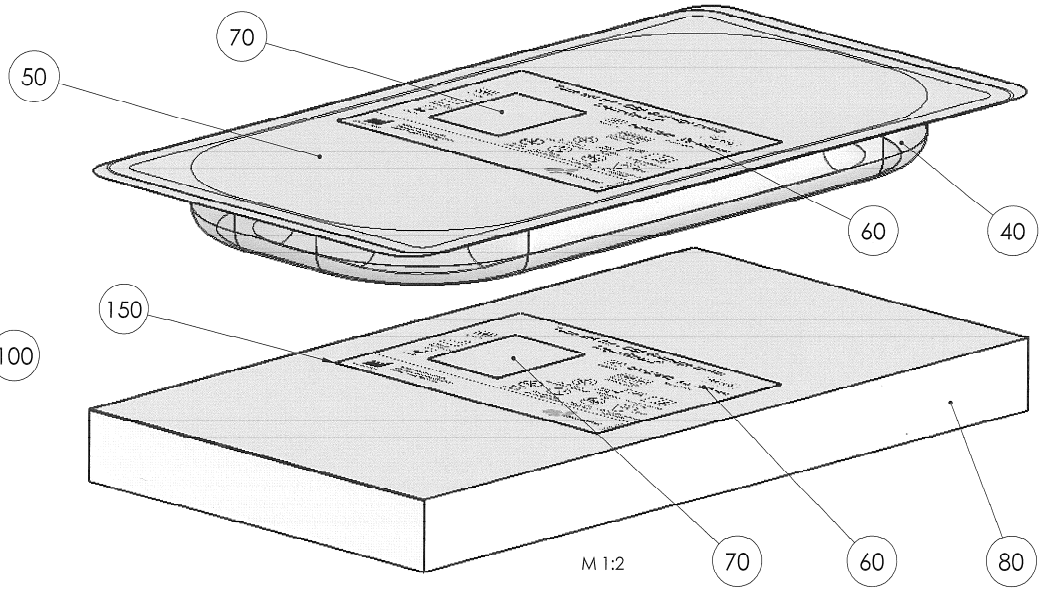
LDP002-007 00 00-00 0-3











130 **Patientenaufkleber**

140 **Gebrauchsanweisung US**

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 00 003 640	Allgemeintol. DIN ISO 2768 mK	Maßstab 1:1
							Werkstoff:
							Halbzeug:
					Datum	Name	
					Bearb. 29.04.13	PWE	Schlauchset 2000 mm (VPE = 1 Stck.)
					Gepr. 30.04.13		"LiquoGuard" US mit Zubehör / kpl. verp.
					zul. gespeichert von: pwelker	30.04.2013 13:16:30	
					Vertraulich/Confidential		LDP002-007 00 00-00 0-3
					Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster Eintragung vorbehalten.		
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP002-007 00 00-00 0 - Schlauchset kpl. verpackt		Blatt 1 von 1

Gewicht: Volumen: Werkstoff-Nr.:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 8

SHORT INSTRUCTION FOR LIQUOGUARD CSF SYSTEM TUBING SETS

Back to **List of Appendices**

Back to **Chapter 2.5 – Question 5 – Device and Packaging Labeling**

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Drainage Set *LiquoGuard*®

US

Safe for use in connection with CSF drainage pump *LiquoGuard*®

ATTENTION:

Observe the *LiquoGuard*® operating instructions.
Do not use product if package is damaged.

REF	Catalogue number
	Number of units in package
	Overall length
	Date of expiration
	Date of manufacture
LOT	Lot Number
STERILE EO	Sterilized using ethylene oxide
	Do not reuse, single use device
	Consult Instruction for Use
+40° C / +10° C	Application range
MRI	Not for use in an MRI field
STERILIZE	Do not resterilize
	Do not use if package damaged
	Manufacturer

REF **00003639** — **1500 mm**

REF **00003640** — **2000 mm**

ATTENTION:

To use this tube set with the CSF drainage pump *LiquoGuard*®, please perform the following steps:

1. Remove the tube set from the package and clip the adhesive electrode to the pressure sensor housing.
2. Connect the drainage bag to the tube set.
3. Insert the tube set into the pump. Ensure that the connecting pieces are correctly seated in the guides. Turn the pump rotor counter-clockwise by three rotations. Check whether the pump tube was correctly threaded.
4. Turn the stop cock of the 4-way manifold by 180° in the direction of flow from the pump to the catheter and remove the protective cap on the catheter side.
5. Connect the sensor cable to the pump.
6. Connect the catheter to the tube set.
7. Attach the pressure sensor housing to the patient.

During all steps observe the instructions displayed on the ***LiquoGuard***® as well as the operating instructions of the ***LiquoGuard***® operating manual.

Single-use: Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.

ATTENTION:

Always close the 4-way stop cock between the tube set and the catheter before removing or replacing the tube set in the pump. The tube set must be replaced after 120 hours of operation.

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36043 Fulda, Germany

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30005537 2013-05 A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

APPENDIX 9

SOFTWARE DOCUMENTATION

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SOFTWARE DESCRIPTION

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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LiquoGuard – Detailed Software Description

(b)(4)

[redacted]

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LiquoGuard – Detailed Software Description

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[redacted]

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LiquoGuard – Detailed Software Description

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[redacted]

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LiquoGuard – Detailed Software Description

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[redacted]

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LiquoGuard – Detailed Software Description

(b)(4)

[redacted]

REVISION LEVEL HISTORY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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LiquoGuard – Software History

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LiquoGuard – Software History

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LiquoGuard – Software History

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

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LiquoGuard – Software History

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LiquoGuard – Software History

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LiquoGuard – Software History

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LiquoGuard – Software History

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[redacted]

UNRESOLVED ANOMALIES

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LiquoGuard – Device Anomalies

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Date: November 20, 2012

Contact person: Grant Geckeler
Free lance consultant
4375 Prado Road, Suite 103
Corona, CA 92880
Phone: +1 714 283 1683
Fax: +1 714 637 2460
E-mail: ggeckeler@geoinc.org

To: Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda
GERMANY

Subject: K121248/S1 Liquoguard
Cc: Record

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information provided. Therefore, this 510(k) will be placed on telephone hold. To complete the review of your submission, we require the following information:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Binoy Mathews at (301) 796-6475. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 11

STERILITY VALIDATION REPORT

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 12

STERILITY VALIDATION REPORT

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 1

INDICATION FOR USE STATEMENT

Back to **List of Appendices**
Back to **Chapter 4. Indication for use Statement**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

March 26, 2012

Indications for Use

510(k) Number (if known): TBD

Device Name: LiquoGuard CSF System

Indications for Use:
The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

121

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APPENDIX 10

LABELS FOR THE LIQUOGUARD CSF TUBING SET, 2000MM

Back to **List of Appendices**
Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIQUOGUARD CSF TUBING SET, 2000MM – PACKAGING LABELING

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LDP002-003 00 04-00 f-4

Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 911

REF.: 92 008 568

L: 2000 mm

+40°C (104°F)
+10°C (+50°F)

STERILE EO

MRI PHT DEHP

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

20008691 - 2010-03

Achtung! Originalablage des PDF's für Fertigung : Dokumentenablage _Gültig

MöllerMedical Wasserkuppenstrasse 29-31 · 36043 Fulda Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com					Art.-Nr. 20 008 691		Allgemeintol.	Maßstab 1:1	Gewicht: Volumen:
								Werkstoff: bez.: Druckerei Mergard	Werkstoff-Nr.: 14,8 cm x 10,5 cm
								Halbzeug: JAC script weiß, Klebstoff D131 80g/m²	
						Datum	Name	Verpackungsaufkleber	
					Bearb.	29.03.07	LW		
f	kpl. überarbeitet	KO3262	01.03.10	MÖ-Da	Gepr.	01.03.10		Schlauchset "LiquoGuard" 2000 mm	
e	Logo + Anschrift	KO 3010	29.09.08	AH	Norm				
d	neues Logo	KO 2981	03.07.08	AH	aLgspeichert von	sdehler	02.03.2010 15:43:18		
c	Text überarbeitet	KO 2835	17.03.08	LW	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadenersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmustereintragung vorbehalten.			LDP002-003 00 04-00 f-4	Blatt 1 von 1
b	hinzu	KO 2801	15.01.08	LW					
a	Art.-Nr. hinzu	KO 2735	04.12.07	LW					
Zust.	Änderung	KÄ-Nr.	Datum	Name	Dateiname: LDP002-003 00 04-00 f-4			Ds. Nr. LDP 00 00 00 04 00 ag	

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250

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LIQUOGUARD CSF TUBING SET, 2000MM – PACKAGING LABELING: VARIABLE DATA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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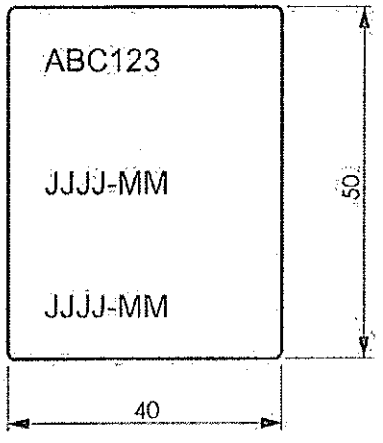
LDP002-001 00 09-00 b-4

Chargenbezeichnung (FKLeitz des Fertigproduktes) — ABC123

Herstelldatum — JJJJ-MM

Verwendbar bis — JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

b	Haltbarkeit	KO3769	15.03.12	HOR					
a	Chargenbez. geö	KO 467	07.02.11	MÜ-DO					
Zust.	Änderung	KN-Nr.	Datum	Name					

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Art.-Nr. 20 008 687

Allgemeintol. DIN ISO 2768 m

	Datum	Name
Bearb.	28.03.07	LW
Gepr.	15.03.12	B. Mo
zuletzt gespeichert von: ahorward		15.03.2012 11:05:01

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Dateiname: LDP002-001 00 09-00 b-4

Maßstab 1:1 | Gewicht: | Volumen:

Werkstoff: gef. aus: Art.-Nr. 30 002 734 | Werkstoff-Nr.:

Halbzeug: Rollen - Haftetiketten 50 x 40 mm

Aufkleber

für Schlauchset "LiquoGuard"

LDP002-001 00 09-00 b-4

Blatt 1 von 1

Ers. für: LDP002-001 00 09-00 b-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIQUOGUARD CSF TUBING SET, 2000MM – PATIENTS STICKER

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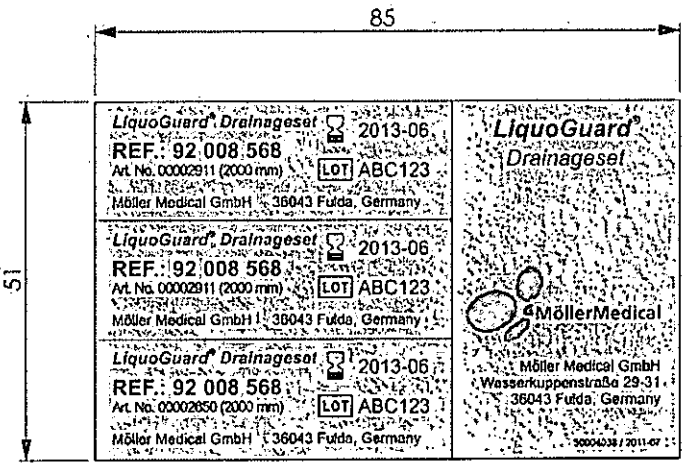
LDP002-003 00 05-00 e-4



Haltbarkeit des Produktes = 1 Jahr 11 Monate

MöllerMedical Wasserkuppenstrasse 29-31 · 36043 Fulda Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com					Art.-Nr. 30 004 038	Allgemeintol.	Maßstab 1:1 · Gewicht: · Volumen:
							Werkstoff: gef. aus: 70 000 889 · Werkstoff-Nr.:
							Halbzeug:
					Datum	Name	Patientenaufkleber
					Bearb. 29.01.08	LW	
					Gepr. 29.07.11		Schlauchset "LiquoGuard" 2000mm
e	4-fig. in 3-fig. Aufkl. geä.	KO 3577	29.07.11	MÜ-De	zuletzt gespeichert von: sdehler	29.07.2011 10:12:59	
d	Größe Ref.-Nr., Art.-Nr., Datum geändert	KO 3105	16.03.09	HOR	Vertraulich/Confidential		
c	Größe, 4 Aufkleber	KO 3058	07.01.09	HOR	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadensersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmustereintragung vorbehalten.		LDP002-003 00 05-00 e-4 · Blatt 1 von 1
b	Logo + Anschrift	KO 3010	29.09.08	AH			
a	neues Logo	KO 2981	03.07.08	AH			
Zust.	Änderung	KO-Nr.	Datum	Name			Stückliste: LDP002-003 00 05-00 e-4

Questions? Contact FDA/CDRH/OCE/DIO at CDRH-EOLSTATUS@fda.hhs.gov or 301-796-8118

254

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 13

ACCELERATED AGING TEST REPORT

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 15

DEVICE HAZARD ANALYSIS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 16

SOFTWARE REQUIREMENT SPECIFICATION

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 17

SOFTWARE ARCHITECTURE DESIGN

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 18

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 19

SOFTWARE DESIGN SPECIFICATIONS

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 2

TRUTHFUL AND ACCURACY STATEMENT

Back to **List of Appendices**
Back to **Chapter 6. Thruthful and Accuracy Statement**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

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Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

April 04, 2012

Premarket Notification
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as general manager of Möller Medical GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Dr. Christoph Traxler, General Manager
(Typed Name)

4 APRIL 2012
(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 20

SOFTWARE DESIGN SPECIFICATIONS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 21

SOFTWARE DESIGN SPECIFICATIONS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 22

SOFTWARE DESIGN SPECIFICATIONS OPERATION

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 23

SOFTWARE DESIGN SPECIFICATIONS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 24

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 25

SOFTWARE DESIGN SPECIFICATIONS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 26

SOFTWARE DESIGN SPECIFICATIONS

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 27

SOFTWARE DESIGN SPECIFICATIONS MEASUREMENT

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 28

SOFTWARE DESIGN SPECIFICATIONS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 29

TRACEABILITY ANALYSIS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 3

PRODUCT MATERIALS
LIQUOGUARD CSF TUBING SET

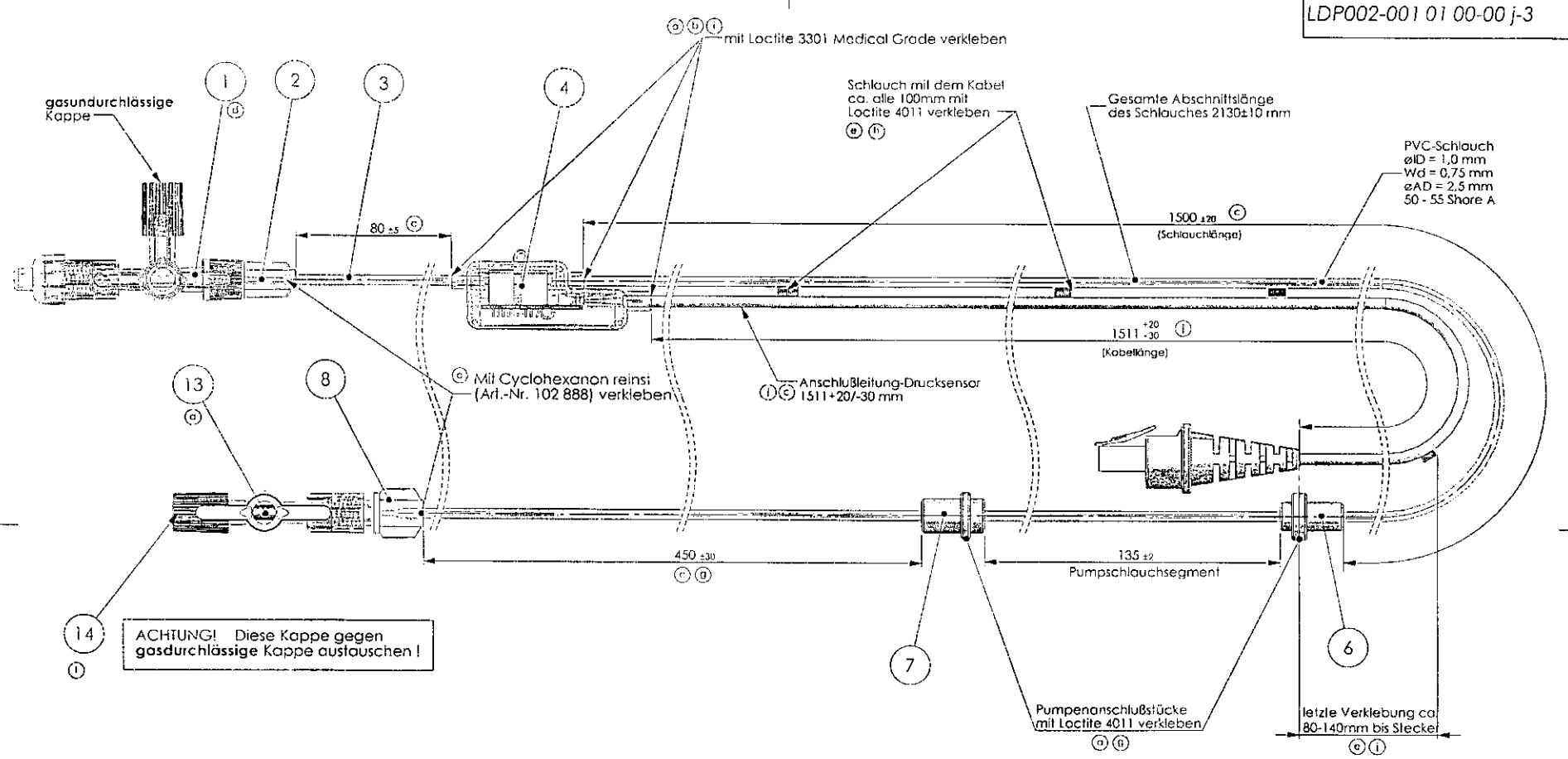
Back to **List of Appendices**
Back to **Chapter 11. Device Description**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-001 01 00-00 j-3



Verklebung - Druckdicht 1 bar

MöllerMedical Wassertruppenstrasse 29-31 · 35043 Fulda Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com	Art.-Nr. 20 007 836	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht:	Volumen:
			Werkstoff:	Werkstoff-Nr.:	
			Halbzeug:		
		Datum / Name	Schlauchset 1500 mm "LiquoGuard"		
		Bearb. 16.12.05 LW			
		Gepr. 31.03.08			
		Norm			
		freigegeben: schäfer 23.06.2010 15:59:14	LDP002-001 01 00-00 j-3	Blatt 1 von 1	
i gefindert	KO 294	26.03.08 LW			
i Kleber geändert	KO 268	19.06.07 LW			
Zust. Änderung	KB-Nr.	Datum Name	Dateiname: LDP002-001 01 00-00 0-3	Ers. für: LDP002-001 01 00-00 i-3	

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Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MöllerMedical

Material of the LiquoGuard CSF Tubing Set (LDP002-001 01 00-00 j-3):

No.	Part	Material
1	4-way-cock (neutral)	Polycarbonate
2	Luer-Lock (male)	Glued with cyclohexanon
3	Tubing (2,5mm x 1,0mm)	PVC 50-55 Shore A
4	Housing of pressure sensors, including the pressure sensor and the connecting cable	Makrolon glued with Loctite 3301 Medical Grade, Freescale MPX2011DT1 for medical application, Polyurethane
6	Pump adapter (broad)	Makrolon glued with Loctite 4011
7	Pump adapter (small)	Makrolon glued with Loctite 4011
8	Luer-Lock (female)	Glued with cyclohexanon
13	1-way-cock (blue)	Polycarbonate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 30

SOFTWARE DEVELOPMENT PLAN

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 31

SOFTWARE VERIFICATION AND VALIDATION

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 32

ELECTROMAGNETIC COMPATIBILITY, DIN EN 60601-1-2

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 33

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

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APPENDIX 34

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 35

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 36

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

(b)(4) Test Report

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 37

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

(b)(4) Test Report

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 38

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

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Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 39

TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

(b)(4) Test Report

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 4

PACKAGING CONTENTS OF THE LIQUOGUARD CSF TUBING SET

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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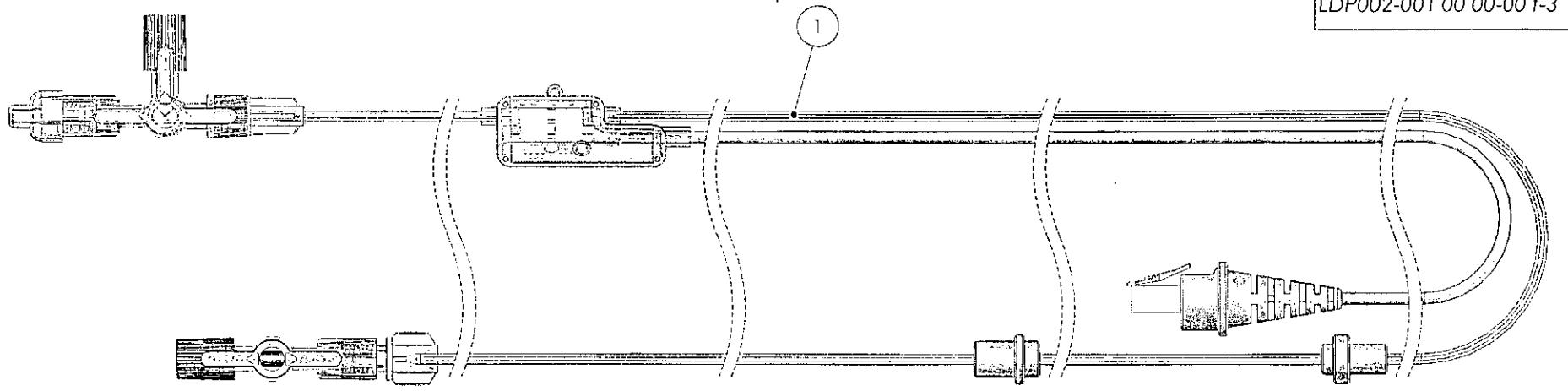

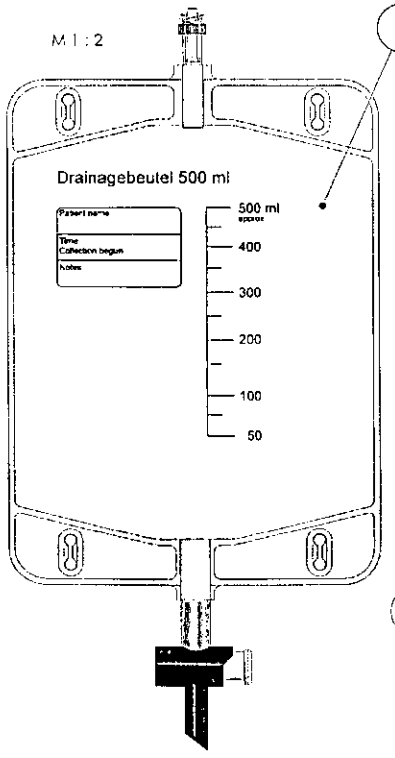

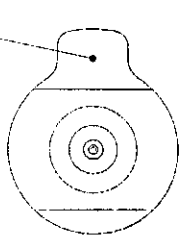

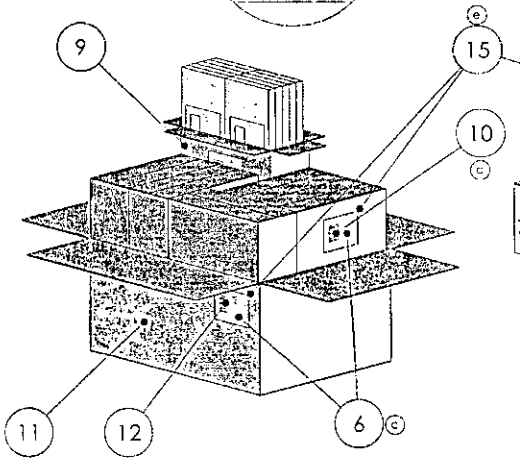

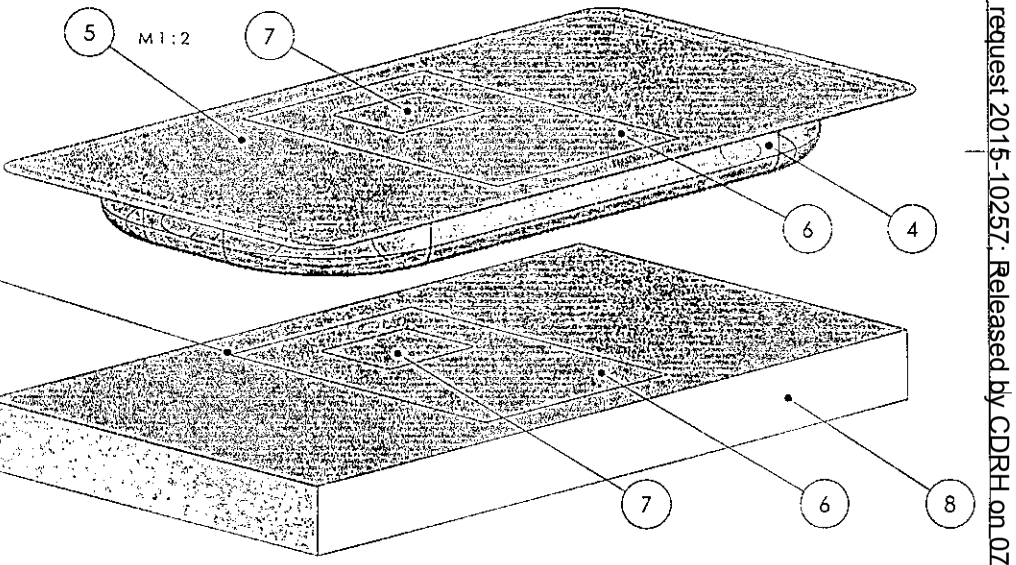

d 13 Patientenaufkleber

d 14 Gebrauchsanweisung - Heft, mehrsprachig

Zust.	Änderung	KB-Nr.	Datum	Name	
f	Pos. 6 geändert	KO3262	03.03.10	MB-DC	
e	hinzu	KO 2694	19.07.07	LW	
d	hinzu	KO 2618	03.04.07		
c	Aufkleber geändert	KO 2563	06.02.07	LW	
b	überarbeitet	-	04.07.06	LW	
a	überarbeitet	-	23.05.06	OF	

MöllerMedical
Wasserkuppenstrasse 29-31 · 36043 Fulda
Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com

Art.-Nr. 00 002 650

Allgemeintol. DIN ISO 2768 m

	Datum	Name
Bearb.	27.04.06	LW
Gepr.	03.03.10	
Norm		

Ersetzt in: SYSTEM 04.03.2010 10:08:53

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Dateiname: LDP002-001 00 00-00 0-3

Maßstab 1:1 | Gewicht: | Volumen:

Werkstoff: | Werkstoff-Nr.:

Halbzeug:

Schlauchset 1500 mm (VPE = 1 Stck.)
"LiquoGuard" mit Zubehör / kpl. verp.

LDP002-001 00 00-00 f-3

Blatt 1 von 1

Ers. für: LDP002-001 00 00-00 e-3

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Möller Medical GmbH

Wasserkuppenstr. 29-31, D-36043 Fulda · Postfach 1737, D-36007 Fulda
Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
E-Mail: info@moeller-medical.com · Web: www.moeller-medical.com

MöllerMedical

Packaging of the LiquoGuard CSF Tubing Set (LDP002-001 00 00-00 f-3):

No.	
1	LiquoGuard CSF Tubing Set
2	CSF drainage bag
3	ECG-electrode (note: only used for attaching)
4	Blister (PETG), packaging
5	Tyvek, packaging
6	Labeling on packaging (LDP002-001 00 11-00 f-4)
7	Labeling on packaging with individual data (manufacturing date, LOT, shelf life)
8	Secondary packaging (cardboard)
9	Packing for 10 tube sets
10	Labeling on packaging for 10 tube sets
11	Packaging for 120 tube sets
12	Labeling on packaging for 120 tube sets
13	Labeling for patient data (LDP002-001 00 12-00 d-4)
14	Operating manual for tube set (30 004 036)
15	Indication button for EO Sterilization

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

(b)(4) Test Report

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

[redacted]

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) Test Report

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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APPENDIX 5

COPIES OF THE 510(K) SUMMARIES FOR EQUIVALENT DEVICES

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K030289

HERMETIC PLUS™
EXTERNAL CSF DRAINAGE SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Hermetic Plus™
External CSF Drainage System

510(k) SUMMARY

FEB 2 6 2003

Submitter's name and address:

Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Donna R. Wallace
Director, Regulatory Affairs
(609) 275-0500

Date summary was prepared:

January 24, 2003

Name of the device:

Proprietary Name:	Hermetic Plus™ External CSF Drainage System
Common Name:	External CSF Drainage System
Classification Name:	Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The Hermetic Plus™ External CSF Drainage System is substantially equivalent in function and intended use to the unmodified External CSF Drainage and Management Systems which has been cleared to market under Premarket Notification 510(k) K972994.

Intended use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure, to monitor cerebrospinal fluid, and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Device Description:

The Hermetic Plus™ External Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients. The systems connect to a ventricular or lumbar catheter via a luer connection to a patient line and ultimately to a drainage bag. The patient line is connected to a graduated burette that is then connected to the drainage bag. CSF can be collected and measured in the burette and subsequently emptied into the drainage bag by opening the stopcock placed in line between the burette and the drainage bag. An antimicrobial vent is included in the burette cap. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The

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antimicrobial vent used on the Hermetic Plus™ systems will allow better drainage of the CSF to the drainage bag and will resist occlusion after contact with CSF without the need for clamping the burette vent tube.

The Safety Locking Knob of the Hermetic Plus™ system will now contain a titanium screw component and the cord lock of the suspension cord has been changed to an all plastic component.

Safety

The Hermetic Plus™ External CSF Drainage Systems have been demonstrated to be MR safe* when used in the Magnetic Resonance (MR) environment.

*MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb. 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."

Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The systems have been tested for strength of bonded components, leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

Conclusion

The Hermetic Plus™ External CSF Drainage System is substantially equivalent to the unmodified External CSF Drainage Management Systems. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

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K032817

EXTERNAL DRAINAGE SET

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K032817

OCT - 6 2003

External Drainage Set

510(k) SUMMARY

Submitter's Name and Address:

Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France

Contact Person and Telephone Number:

Anne Bigeard
Regulatory Affairs Specialist
Integra NeuroSciences Implants S.A.
2905 Route des Dolines
06921 Sophia Antipolis
Cedex, France
Telephone: 33 4 93 95 56 00

Authorized Agent in the United States:

Judith E. O'Grady
Integra LifeSciences Corporation
Sr. Vice President Regulatory, Quality and Clinical Affairs
311 Enterprise Drive
Plainsboro, NJ 08536, USA
Telephone: 609-936-2311

Date Summary was Prepared:

September 9, 2003

Name of Device:

Proprietary Name:	External Drainage Set
Common Name:	External CSF Drainage Systems
Classification Name:	Central Nervous System Shunts and Components JXG

Substantial Equivalence:

The External Drainage Set is substantially equivalent in function and intended use to the Unmodified External Drainage Set which has been cleared to market under Premarket Notification 510(k) K910853.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K032817

Intended Use:

The External Drainage Sets are intended for cerebrospinal fluid (CSF) drainage, sampling and collection.

Device Description:

The External Drainage Set is designed for cerebrospinal fluid (CSF) drainage, sampling and collection. The system connects to a ventricular or lumbar catheter via a Luer connection to a patient line.

The graduated cylinder of the External Drainage Set is attached to an IV pole and may be moved up and down to change positioning of the graduated cylinder by using the Velcro straps. CSF can be collected and measured in the graduated cylinder and subsequently emptied to the drainage bag by opening the stopcock placed in-line between the graduated cylinder and the drainage bag.

A hydrophobic vent filter is included in the graduated cylinder cap of the External Drainage Set. This vent filter allows air to enter the graduated cylinder to facilitate drainage from the graduated cylinder to the drainage bag while protecting the system from contamination.

Safety:

The External Drainage Set is provided sterile. The External Drainage Set has been tested for tensile strength of bonded components, pressure and leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids in compliance with the Needlestick Safety and Prevention Act, H.R.5178.

Conclusion:

The External Drainage Set is substantially equivalent to the unmodified External Drainage Set. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K061568
CODMAN® EDS 3™
CSF EXTERNAL DRAINAGE SYSTEM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

Ko 61568

Codman
a Johnson & Johnson company

SEP 29 2006

510(k) Summary

Submitter: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person: Jocelyn Raposo
Regulatory Affairs Specialist II
Phone Number: (508) 828-3421
Fax Number: (508) 828-2777

Date Prepared: June 2, 2006

Proprietary Name: CODMAN® EDS 3™ CSF External Drainage System
Common Name: External CSF Drainage System
Classification Name: Central nervous system fluid shunt and components

Predicate Device: K902257 External Drainage System II
K910938 External Drainage System II
K954021 External Drainage System II

Device Description: The EDS 3 system is designed to collect cerebral spinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and the patient. Collecting CSF from the patient is performed in efforts to reduce elevated intracranial pressure (ICP).

Intended Use: Use of the EDS 3 system is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

Performance Data: The fundamental scientific technology of EDS 3 is the same as EDS II. Bench testing was performed for the EDS 3 system. The modified device was deemed acceptable according to the acceptance criteria; therefore, the safety and efficacy of the product was not affected.

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K962928

MULTI-PARAMETER MONITOR (MPM)

INTRACRANIAL PRESSUER MONITORING SYSTEM

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K962928

DEC 20 1996

PREMARKET NOTIFICATION
510(k) SUMMARY

1. SUBMITTER:

Camino NeuroCare,™ Inc.
5955 Pacific Center Blvd.
San Diego, CA 92121

Donna L. Free (Contact Person)
Phone: 619-455-1115
Fax: 619-455-8298

2. DEVICE NAME:

Trade Name:	a.	Micro-Ventricular Pressure-Temperature Monitoring Kit (110-4HMT) Parenchymal Pressure-Temperature Monitoring Kit (110-4BT)
	b.	Multi-Parameter Monitor (MPM)
Common Name:	a.	Intracranial Pressure and Temperature Monitoring Kit
	b.	Multi-Parameter Monitor
Classification Name:	a.	Intracranial Pressure Monitoring System
	b.	Intracranial Pressure Monitoring System

3. PREDICATE DEVICE:

Camino NeuroCare™ Intracranial Pressure-Temperature Monitoring Kit:

Model 110-4BT is equivalent to:
Camino, Intracranial Pressure Monitoring Kit, Model 070, 853864C
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

Model 110-4HMT is equivalent to:
Camino, Micro Ventricular Pressure Monitoring Kit, Model 110-HM, K914735
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

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3. PREDICATE DEVICE:

Camino NeuroCare™ Multi Parameter Monitor:

Model MPM is equivalent to:
Camino, Direct Pressure Monitor, Model V420, K893232
SpaceLabs, Patient Monitor, Model Alpha PC Patient Computer, K842616.

4. DEVICE DESCRIPTION:

The Intracranial Pressure-Temperature Monitoring System consists of a catheter and monitor. The catheter is a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. The Camino catheter has a miniature transducer and thermistor at the distal tip. The pressure transducer is identical to the Camino predicate device. The design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. The transducer is 4F, fiber optic with a pressure measurement range of -10 to 250 mmHg and a temperature measurement range of 30°C -40°C.

The Multi-Parameter Monitor (MPM) is a compact, portable device for use with Camino Pressure-Temperature catheters. The MPM measures Intracranial Pressure (ICP), Intracranial Temperature (ICT) and calculates Cerebral Perfusion Pressure (CPP). The MPM provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport. The monitor is equipped with an high ICP alarm. The dimensions are 274 mm x 216 mm x 89 mm and weighs 4.3 Kg.

5. INTENDED USE:

Model 110-4BT:
Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:
Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

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Intended to be used with an external drainage system as indicated by individual manufacturers.

6. SUBSTANTIAL EQUIVALENCE:

Pressure:
The ICP/T catheter and monitor have the same indication statements for monitoring pressure as Camino's predicate devices.

Temperature:
Predicate temperature-sensing devices include the Electromedics, Model 2403, Temperature Probe, K813459A. The predicate probes are used to measure the temperature of a target organ or tissue. Camino's temperature probe has the same use.

Nevertheless, the ICP/T has a difference in the indication statements in regard to temperature. The difference refers to the tissue in which the temperature is taken. For example, the Electromedics predicate catheter is labeled for general temperature use. Other indications include general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care, and neonatal care. The Camino probes have similar labeling in that they are for general uses that may include surgery, critical care, pediatric care and head injured patients. The Electromedics probe is labeled to take a patient's temperature in the esophagus, on the skin surface, in cardioplegia systems and in the myocardium. The Camino pressure-temperature probe is labeled to be used in the brain, with either parenchyma or ventricular placement.

Monitor:
The ICP/T monitor and both predicate monitors display pressure.
The ICP/T monitor and SpaceLabs monitor display temperature.
The ICP/T monitor and SpaceLabs monitor display Cerebral Perfusion Pressure (CPP).
The ICP/T monitor and both predicate monitors display a waveform.
The ICP/T monitor and both predicate monitors display trends.
The ICP/T monitor and both predicate monitors comply with UL Medical Equipment standards.
The ICP/T monitor and the predicate monitors comply with AAMI/ANSI Safe Current Limits standards.

7. PERFORMANCE TESTING:

Camino NeuroCare conducted animal studies to support substantial equivalence. We conducted a comparative study of the subject (test) device measuring intracranial temperature compared with a predicate device, located along side the test device, also measuring intracranial temperature over a varied temperature range. The temperature measurements were ± 0.4°C between the test device and predicate device in the 10 animals tested. These data support the claim of substantial equivalence.

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8. CONCLUSIONS

The contact area of the Camino probe is of the same design, has the same materials, and it is inserted into the body in the same manner as predicate Camino probes. Thus, the questions of safety are the same. The diagnostic effect of temperature probes for general use is to provide temperature information to a physician for whatever use he or she may choose, based on the user's training and experience. The effectiveness of a temperature probe for diagnostic or monitoring use is determined by its ability to deliver an accurate temperature reading. This is the same standard that was used for predicate devices, some of which were cleared for organs and tissues which may have been different form those for which existing predicate devices were cleared.

Based on the above information Camino NeuroCare™ Inc., concludes that the ICP/T Monitoring system demonstrates substantial equivalence to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

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(b)(4) [redacted]

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(b)(4) [redacted]

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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TEST REPORT (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4) [redacted]

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(b)(4) [redacted]

(b)(4) [redacted]

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TEST REPORT (b)(4) [redacted]

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(b)(4) [redacted]

(b)(4) [redacted]

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TEST REPORT (b)(4) [redacted]

EXTERNAL CONNECTIVITY

(b)(4) [redacted]

(b)(4) [redacted]

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APPENDIX 6

CLINICAL EVALUATION ACCORDING TO MEDDEV 2.7.1

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Clinical evaluation for LiquoGuard

Literature route, acc. to MEDDEV 2.7.1

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Author of the summarized clinical evaluation

Personal data

Dr. med. Bernd Manfred Hölper, born 8. February 1969 in Gießen, married to Dr. med. Dörthe Inge Hölper (neè. Beinroth), 2 children (Elisabeth Clara and Alexander Bernd)

Education and basic military servicet

1975 - 1979	Krofdorf-Gleiberg Primary School
1979 – 1980	Gießen Grammar School (Landgraf-Ludwig-Schule Gießen)
1980 – 5/1989	Ignaz-Günther-Gymnasium Rosenheim, Completion 5/1989 (University Entrance, average grade A)
6/1989 – 9/1990	Training as keyboard radio operator and telecommunications technician, Air Force in Pinneberg/Lengries

Tertiary Education

10/1990 – 3/1996	Medical degree at the Georg-August University in Göttingen
8/1992	Intermediate examination
3/1996	2nd part of the examination
4/1996 – 4/1997	Practical Year: Surgery and Internal Medicine at the Reinhard-Nieter Hospital in Wilhelmshaven and Neurology at the Nordwest Hospital in Sanderbusch
21. April 1997	Completion of medical studies with a "B" average.

Dissertation

2. 7. 1997	Granting of the Degree of a Medical Doctor at the medical faculty of the Georg-August University in Göttingen with the dissertation "Computer simulation and analysis of two artificial neuronal networks oriented to neurobiological models" (Supervision: Prof. Dr. H.-O. Reiber), Grade "A".

Function as physician in practical studies

5/1997 – 9/1998	Active as intern in the neurosurgical clinic of the Fulda Clinic for a duration of 18 months

Research in Richmond/Virginia USA

10/1998 –3/1999	Research at the Commonwealth University of Richmond, Virginia (USA), Neurological Surgery in Prof. R. Bullock and Prof. A. Marmarou's work group, research on intracranial pressure and cerebral metabolism

Function as assistant physician

4/1999 – 3/2005	Active as assistant physician in the neurosurgical clinic of the Fulda Clinic
2002	Awarded the scientific prize of neurological sciences
2001 - 2003	Course participant (European Association of Neurosurgeons)

Examination for specialist

9. 3. 2005	Recognition as neurosurgical specialist at the provincial medical chamber, Hesse

Function as Specialist

Since 3/2005	Active as neurosurgical specialist at the neurosurgical clinic of the Fulda Clinic.

Research focus

Intracranial pressure measurement and intracerebral metabolism in neurosurgical intensive care, evaluation of intracranial sensors (see author's publication index), evaluation of algorithms and assessment of medical data aided by artificial intelligence (neuronal nets), development of image fusion algorithms.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Scientific activity and author's publication index

Book (first author)

Hölper, B.M., Soldner F., Behr R.: Kompendium Neurochirurgie. proINN-Verlag, Rosenheim, 2006

Publications (peer review)

1. Hoelper BM, Reinert MM, Zauner A, Doppenberg E, Bullock R: rCBF in Hemorrhagic, Non-Hemorrhagic and Mixed Contusions after severe head injury and its Effect on Perilesional Cerebral Blood Flow. Acta Neurochir (2000) [Suppl] 76: 21-25
2. Hoelper BM, Soldner F, Choné L, Wallenfang T: Effect of Intracerebral Lesions Detected in Early MRI on Outcome After Acute Head Injury. Acta Neurochir (2000) [Suppl] 76: 265-268
3. Reinert M, Hoelper B, Doppenberg E, Zauner A, Bullock R: Substrate Delivery and Ionic Balance Disturbance After Severe Human Head Injury. Acta Neurochir (2000) [Suppl] 76: 439-444
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Product name

LiquoGuard is a CSF drainage system, which is connected to an already existing intrathecal CSF drainage with the possibility to measure CSF pressure while simultaneously draining the CSF. The volume of drained CSF hereby depends on the CSF pressure measured by the system and on the maximum drainage volume defined by the operator.

Product manufacturer

The manufacturer of the product LiquoGuard and its set of consumables is Möller Medical GmbH & Co KG, Wasserkuppenstr. 29-31, 36043 Fulda, Germany.

Purpose

The LiquoGuard system consists of disposable consumables (CSF drainage system) and a control/pump unit. The purpose of the system is to measure CSF pressure in the CSF drainage system and to remove CSF at a determinable quantity via a surgically installed intrathecal CSF drainage, which was selected and installed by medical staff independent of the LiquoGuard system and whose indication does not depend on the use of the LiquoGuard system.

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Indications

Pathophysiological principles for the indication of intrathecal space puncture
The nervous system (brain, meninges) is surrounded by cerebro-spinal fluid (CSF) (6, 20). The production and resorption of CSF is in a stable balance (6, 10). Diseases or injuries to the nervous system or its surroundings e.g. hemorrhages, infections, tumors, cranio-cerebral injury or deformities can disrupt the balance between CSF production and resorption; a collection of CSF in the brain or in the meningeal area can then lead to increased pressure on the nervous system, which could lead to irreversible damage, severe permanent damage or even to death (1, 9, 10, 12-14, 18-20, 22, 24). In order to avoid this potentially life-threatening situation, CSF is drained to the outside (intrathecal CSF drainage) (7, 10, 13, 23). Analogue to this, lumbar CSF drains are used, which are not installed for the correction of a life-threatening situation, but serve the correction of a CSF fistula or the diagnosis of a chronic pathological collection of CSF (normal pressure hydrocephalus).(2, 3, 7, 15, 23)

"Gold Standard" for the treatment of dysfunctional CSF circulation
The essential basis for intrathecal CSF drainage is the installation of a drainage system in the CSF space. This is performed via ventricle drainage (usually consisting of silicon or polyurethane) or a stainless steel cannula (e.g. Duisburg needle) (7). Lumbar drainage is achieved by inserting a thin silicon catheter into the intrathecal space (2). Both procedures represent today's "Gold Standard" for intrathecal CSF drainage in dependence of the disease and therapy objective (10, 13). A CSF drainage system is connected to this CSF conductor, independent of the use of the LiquoGuard system. This CSF drainage system is either a system already established on the market or it may be the LiquoGuard system. All operative steps to install the intrathecal CSF drain must be carried out according to the respective indication, independent of the CSF drainage system used later.

Indication for temporary intrathecal liquor drainage
Fundamentally, the LiquoGuard system does not change the indication for intrathecal liquor drainage in any patient, nor does it influence the therapeutical concept, type of treatment, therapy objectives or therapy duration. The LiquoGuard system constitutes a liquor drainage system, whose most important characteristics comply to other liquor drainage systems on the market. Therefore the listed indications for liquor drainage must be understood in the broadest sense, without presupposing the use of the LiquoGuard system or a comparable liquor drainage system, as these systems are interchangeable with each other at all times without the need for a change in therapy or further surgery.

- **Communicating hydrocephalus:** This summarizes all clinical pictures in which liquor production is temporarily in disproportion to liquor resorption, usually during cerebral hemorrhage (subarachnoid hemorrhage, intraventricular hemorrhage), encephalitis and cranial-cerebral injuries. In most cases the cause is resorption dysfunction by obstruction of the Paccioni granulation. There is no alternative treatment to intrathecal liquor drainage for these clinical pictures.
- **Non-communicating hydrocephalus:** Liquor drainage is impaired by a partial or complete occlusion of the liquor draining paths. This may occur through masses (tumors, cysts, hemorrhage, congenital malformation) near

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the foramen Monroi, the 3rd ventricle, the aquaduct, the 4th ventricle or the foramen Monroi and the foramina Luschkae.

- **Therapy-resistant cerebral swelling:** The application of liquor drainage may be indicated in therapy-resistant cerebral swelling caused, for example, by cranial-cerebral injury, cerebral hemorrhage or subarachnoid hemorrhage or by cerebral swelling due to tumors, inflammation or hypoxia, in order to reduce intracranial pressure and to bypass trepanation (the removal of a cranial bone).

Treatment alternatives to CSF drainage

- **Endoscopy:** In a few cases of non-communicating hydrocephalus, endoscopic windowing (e.g. of the lamina terminalis) may be created to communicated with the external CSF paths. However, this is not indicated in all cases of non-communicating hydrocephalus, can only be performed by a few, specially trained neurosurgeons who possess the appropriate equipment (endoscope) and who are available at the required time. However, external CSF drainage cannot be replaced by endoscopic windowing for all clinical pictures of non-communicating hydrocephalus.
- **Therapy-resistant cerebral swelling:** After exhausting all medicinal forms of therapy, the removal of a part of the cranial bone can lead to effective relief of the intracranial pressure. The indication as to when external CSF drainage or cranial bone removal is performed depends on the primary disease, etiopathology, brain swelling dynamics, patho-physiological mechanisms, the patient's age, his overall condition, the prognosis and ventricle width and must be individually decided by the neurosurgeon. As the surgical risk of CSF drainage is considerably lower than that of cranial bone removal, CSF drainage at the appropriate medical indication and tenability is preferred to removal of cranial bone.
- **Shunt implantation**: As a shunt represents an implantable, permanent CSF drainage system and external CSF drainage represents temporary CSF relief, shunt implantation is no alternative treatment option to CSF drainage.

Contraindications

The contraindications do not apply to the use of a liquor draining system such as the LiquoGuard system, but to the application of intrathecal liquor drainage itself. As, however, liquor discharge is only applied in connection with liquor drainage, contraindications described below are in connection with the application of external liquor drainage only.

- **Absolute operative contraindications:** Coagulopathy, thrombocythemia.
- **Relative operative contraindications:** In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does the simultaneous intake of intrathecal antibiotics in the case of ventriculitis.
- **Indication for permanent liquor drainage:** If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculo-peritoneal shunt or a ventriculo-atrial shunt.

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PRODUCT DESCRIPTION

LiquoGuard system components
The LiquoGuard system consists of two components:

1. **Disposable tubing set:** CSF drainage system with male Luer lock connection (3-way cock) to connect to an already surgically installed intrathecal CSF drainage. Distal to the proximal Luer lock connection (3-way cock) is an attached pressure measurement device, in which two piezo-resistant pressure sensors, attached independent of one another, measure CSF pressure within the tube lumen. Both sensors are embedded in a die-cast component; a connection from the tube lumen to the outside does not exist. An attachment clamp is installed in the die-cast component enabling the attachment to a standard electrode with a press-stud. A cable anchored and connected to the pressure sensor electronics can be connected to a confusion proof socket in the LiquoGuard device. A compressible tubing system is distally integrated to the pressure sensors, which can be inserted into a rotor pump. A CSF collecting bag with a reflux valve is attached to the distal end of the tubing system via a 3-way cock.
2. **LiquoGuard device:** LiquoGuard consists of a casing with a transport attachment (bed, crossbeam, round rod) containing the dually installed evaluation electronics of pressure sensors, drive electronics for the rotor pump incl. the rotor pump, drive electronics for the monitor incl. the monitor, process electronics for input via keyboard and operating wheel, the internal power source (battery) incl. mains connection, the display for illustration of various values and data, alarm light emitting diodes, the loudspeaker for audible alarm emittance, the card slot for the insertion and removal of the memory card, the internal memory electronics and the connecting socket for external power supply as well as pressure sensors.

LiquoGuard system functionality
The CSF drainage system is inserted into the rotor pump by lifting the safety flap, whereby the arresting pins in the pump have been designed to be confusion-proof. After connecting the pressure sensor cable to the LiquoGuard device and after switching on the LiquoGuard device, zero calibration must be carried out on both pressure sensors. The CSF drainage system can then be connected to the previously and surgically installed intrathecal CSF drainage. Intrathecal CSF drainage is not a component of the LiquoGuard system; all approved intrathecal CSF drainage systems available on the market may be used. An indication for the installation of intrathecal CSF drainage does not depend on the use of the LiquoGuard system (consumable goods or LiquoGuard device). The housing with the integrated pressure sensors must be attached at the assumed CSF zero height. In the case of intracranial application an adhesive electrode is attached to the head near the audible tract, the external anatomic landmark of the foramen Monroi, in the case of intrathecal spinal application at the height of the proximal end of the catheter. In accordance with current literature, alignment of the zero point in intracranial application should be at the height of the foramen Monroi; the zero point in intraspinal application is at the height of the intrathecal catheter end (10). The casing with its integrated pressure sensors can be clipped to this adhesive electrode. Setting

Setting of therapy-specific parameters
A therapy during reclining CSF drainage is performed irrespective of the CSF drainage system only once CSF has been drained. In this respect CSF drainage

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under all clinical conditions is only required as of a positive intrathecal pressure. The height of the positive intrathecal pressure, as of which CSF is drained, depends on the disease and etiopathology and is determined individually by medical staff, entered as CSF target pressure into the LiquoGuard device via the suitable input interfaces and shown in the display. The pressure sensors continuously record CSF pressure. If the CSF target pressure is exceeded, the rotor pump is started. CSF is removed by the rotation of the pump, conveyed through the CSF drainage system and pumped into the CSF collecting bag. The pump stops once the pressure in the drainage system returns to the specified target pressure. This control keeps the patient's CSF pressure within a pre-defined range (predefined target pressure ± Hysteresis, resulting from the regulation, whereby the height of hysteresis is adjustable, e.g. 0.5 mmHg). As the closed measurement system enables continuous CSF pressure measurement, CSF drainage over and above the target pressure is not possible. The volume and speed of CSF drainage can be controlled by rotational speed and run-time of the pump. The CSF target volume parameter specified by medical staff is used in this respect. This parameter limits the maximum delivery rate and simultaneously defines the speed of CSF drainage. If the intrathecal pressure lies above or below the upper or lower CSF pressure alarm limit, an optical and audible alarm is triggered.

Diagnosis-specific parameters

The LiquoGuard system displays the diagnosis-specific parameter "intrathecal pressure" (ICP) and the drained volume of CSF.

- **Intrathecal CSF pressure:** After zero point calibration performed at startup of the disposable consumable articles, the two pressure recorders of the tubing set integrated into one casing are attached at foramen Monroi level. The CSF pressure column between the intrathecal catheter and the pressure sensors is the existing intracranial pressure. This pressure is not only the control pressure for the LiquoGuard's rotor pump but also represents the Gold Standard for determining intracranial pressure (10, 13). Further diagnostic and therapeutical measures depend on this measurement value. As each set of consumables can be used only once due to an internal electronic registration, repeat pressure measurement or one during application (with existing pressure) is not possible.
- **Drained CSF volume:** The diameter of the tube inserted in the rotor pump and the rotation of the rotor pump defines the volume of drained CSF. This volume is electronically displayed (ml/min, ml/h, ml/24h). The collecting bag also has a measurement scale which enables reading and controlling of the drained liquid volume. The drained CSF volume can indicate an imbalance between CSF production and CSF resorption. The therapeutical consequences may be a permanent CSF drainage (shunt) for the patient.

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Literature research on comparable products with the same purpose (including reasons of comparability)

Literature selection

External CSF drainage has been an established and standardized procedure in neurosurgery for many years, and beyond question in the entire current neurosurgical literature. As the LiquoGuard system does not represent a change in intrathecal drainage, its indication and therefore a possible increase in complications, generally acknowledged textbooks are used in literature evaluation with regard to CSF drainage effectiveness. Data sources for the creation of a literature overview were Medline, Pubmed, including the database of the National Center for Biotechnology Information (NCBI, www.ncbi.nlm.nih.gov) as well as library indexes on neurosurgical textbooks. Additionally, current convention reports of the Deutsche Gesellschaft für Neurochirurgie (DGNC) during the last five years were taken into consideration. Internet research via current search machines (yahoo, google) on intracranial pressure and CSF drainage was also carried out. Overview work from the most important and most renowned neurosurgical textbooks were used for citations on the topic of CSF drainage. Book articles were cited for respective questions regarding the accuracy of pressure sensors, which summarize numerous clinically recognized articles and were written by globally recognized specialists in their respective fields. As CSF drainage is an established, standardized method, book articles were mostly reverted to in connection with indication. Due to the utilization of large overview work published by different authors and various publishers worldwide, there is no indication that important, even negative literature was not used and would therefore distort literature research. No literature sources were explicitly excluded. Citations with an unfavorable or negative evaluation, which limit the use of the LiquoGuard system, are unknown. All used publications stem from recognized, scientific publications and were written by acknowledged experts. The objective of a literature evaluation is the illustration on the necessity of CSF drainage and the illustration of existing CSF drainage systems and pressure measurement systems, their technical details and compliance to the LiquoGuard system.

External CSF drainage

External CSF drainage is comprised of two systems: a catheter/cannula (intrathecal CSF drainage) inserted into CSF space and a CSF drainage system attached to this intrathecal CSF drainage (10, 17).

Intrathecal CSF drainage

The removal of CSF requires the surgical installation of an approved catheter or cannula into intrathecal space. This operative procedure is required for respective indications (subarachnoid bleeding, cerebral hemorrhage, brain tumors, inflammation of CSF paths, displacement of CSF-efferent paths due to tumors and swelling, cranio-cerebral injuries) and undisputed in the entire neurosurgical literature as well as life-saving in many cases.(1, 9, 10, 12-14, 18-20, 22, 24) Although the insertion of intrathecal CSF drainage is a prerequisite for using the LiquoGuard system, it does not change the indication of intrathecal CSF drainage due to its comparability with previous systems. All intrathecal CSF drainage catheters with female Luer lock connections approved for intrathecal CSF drainage, which can be connected to available CSF drainage systems, can also be connected to the LiquoGuard system. The use of intrathecal CSF drainage is in complete compliance and comparability with regard to the application of the system.

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CSF drainage system
All CSF drainage systems are connected to the intrathecal CSF drainage and serve the measurement of the intrathecal pressure as well as the removal of CSF.(10, 17)(10, 17) A CSF drainage system consists of various components which in their totality result in a functional system. These system components of systems established on the market are described below and compared to the LiquoGuard drainage system. The procedure is carried out under the same clinical condition, for the same clinical purpose of CSF drainage at the same part of the body on comparable patients (including age, anatomy, and physiology). CSF is identical; the same materials are brought into contact with the same human body fluids (CSF). Technically speaking, the identical version (Luer lock connection) with the same design exists if we compare the LiquoGuard system with existing CSF drainage systems.

CSF drainage tube system to pressure measurement system: All CSF drainage systems are connected to an intrathecal CSF drainage (10, 17). Current CSF drainage systems as well as the LiquoGuard drainage system consist of a transparent plastic tube system with an attached 3-way cock or an alternative CSF drainage facility. This applies to CSF drainage systems as well as to the LiquoGuard system; both systems are completely comparable with one another regarding this construction stage of the entire CSF drainage system. The tubing system is technically comparable, CSF drainage facilities (3-way cock) are identical, biological properties are appropriate (CSF) and clinical conditions (indication to remove CSF via connection (3-way cock) are the same.

Pressure measurement system
Pressure measurement in existing systems is conducted via a pressure sensor integrated into the CSF drainage system or connected to the lumen of the drainage system via a 3-way cock (10, 17). Correct intracranial pressure measurement requires that the tubing system is distally closed, as an open system cannot create pressure and the CSF will flow in direction of the open system (10, 17). The alignment of the pressure measurement system must be at zero point level (in the case of intrathecal intracranial application this would be the foramen Monroi (8)) in all systems (in previous CSF drainage systems as well as in the LiquoGuard drainage system). Display of pressure in previous systems was enabled by connection to the sensor system at a patient monitor, whereby the LiquoGuard system displays the pressure directly via the display integrated in the LiquoGuard device. Existing pressure measurement systems and the display of the measured pressure are based on the same sensor technology as the piezo-resistant LiquoGuard pressure measurement system (8, 21) and are therefore technically comparable as they measure the pressure of the same biological body fluid in the same clinically comparable patients.

CSF drainage tube system from pressure measurement system to CSF collecting bag
In established systems, CSF is transported to a droplet chamber or a collecting bag on the distal side of the pressure measuring system. To measure the intracranial pressure, the two existing CSF drainage systems must be distally closed to enable reliable pressure measurement. Once the pressure defined by medical staff has been

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reached, the CSF drainage system will be distally opened. Now CSF can drain via the drainage system into the collecting bag, whereby the drop-by-drop addition of CSF from the tubing system into the collecting bag must be set to the zero reference line (intracranial at foramen Monroi). The system must be opened distal to the external air so that the air displaced by inflowing CSF can escape within the collecting bag. Once CSF flow is suspended (target pressure is reached) the system is closed and pressure measurement is continued. Opening and closing intervals depend on the speed of the renewed intracranial pressure increase. In the LiquoGuard system CSF drainage occurs in analogue manner. The closing mechanism for the completion of correct intrathecal pressure measurement is carried out by the rotor pump instead of the 3-way cock or a crimp connection in the LiquoGuard system. If the measured intrathecal pressure rises to a pressure defined by medical staff (target pressure reached) the rotor pump is activated via its electronics and pump rotation leads to CSF removal with transportation of CSF to the collecting bag. If the pressure decreases to target pressure (analog to CSF flow suspension in existing systems), the rotor pump will stop and CSF drainage is suspended. Clinically, the same purpose is pursued under the same conditions, the same patient population and the same indication, i.e. the measurement of intrathecal pressure and the removal of CSF as of a definable pressure level. Both procedures therefore result in the identical clinical effect, the intrathecal pressure decrease as a result of CSF drainage. A biological comparability exists between the systems, as the same human liquid (CSF) is drained using the same materials. Technical comparability exists in the fact that both systems are primarily closed and remove CSF up to reaching a target pressure once a certain intrathecal pressure, measured with the same measurement technology has been reached. Whether CSF is drained by a positive intrathecal pressure via an overflow system (previous established systems) or via a rotor pump, is negligible, as further CSF drainage is prevented once the CSF target pressure has been reached. With regard to the function of the system there are no differences.

CSF volume control

Control of CSF to be drained is on a visual basis in existing system, by persons operating the system reading the CSF level within the collecting bag prior to CSF drainage, then opening the CSF drainage system and waiting until the appropriate CSF volume has drained into the collecting bag. The LiquoGuard system does provide visual control as an analog possibility, as an appropriately comparable scale has been attached to the collecting bag, but the calculation of CSF volume from the rotation of the pump and the diameter of the drainage tube inserted in the pump is more exact and simpler.

Illustration and measurement of CSF pressure and CSF volume

In existing systems, the pressure recorder is attached to the installed patient monitoring system in an appropriate stationary unit like arterial pressure measurement. The illustration of intrathecal pressure is then possible via this patient monitor. In the LiquoGuard system the intrathecal pressure is displayed in the LiquoGuard device itself. Furthermore, and unlike previous systems, the LiquoGuard system permits trend display of previously measured values and data storage (without patient information) onto a suitable memory medium, as well as data transfer to a patient monitoring system. Compliance is therefore given, but the LiquoGuard system provides additional functions.

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Alarm limits for ICP

In existing systems as in the LiquoGuard system, the upper and lower alarm limit of intrathecal pressure can be defined. Both systems activate a comparable visual and audible alarm once alarm limits are reached. In existing systems this is carried out via the patient monitor, whereas the LiquoGuard system has integrated alarm functions, whereby the alarm functions can also be activated via the connected patient monitor.

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Assessment criteria to prove the efficiency and safety of the product

The fact that intrathecal CSF drainage is applied in the same way by both the existing systems as well as the LiquoGuard system makes an assessment of intrathecal CSF drainage unnecessary. The efficiency of intrathecal CSF drainage is globally undisputed. It represents a routine procedure as therapy for intracranial pressure increase (1, 9, 10, 12-14, 18-20, 22, 24).

Expected effect of a CSF drainage system

The expected effect of a CSF drainage system consists of enabling sterile CSF extraction in identifiable quantities via an intrathecally inserted cerebro-spinal fluid drainage in case of intrathecal pressure increase beyond a certain threshold (target pressure) and when a pressure sensor is connected to be able to measure intrathecal pressure reliably by appropriate means ("Gold standard" for intracranial pressure measurement) (5, 8, 13, 21).

Both established systems and the LiquoGuard System make intrathecal CSF pressure measurement possible via integrated pressure measurement in the CSF drainage system. (7, 11, 21, 23) In order to enable pressure measurement, a pressure sensor must be integrated in the tube system or in the ventricle drainage region and zero-point calibration executed for both systems.

For intracranial pressure measurement in conventional systems, the tube system is closed distal to the pressure sensor. Only then does a closed pressure distal position exist, which can be used for intracranial pressure measurement. However, it is not possible to drain any CSF from these systems during this period. In the case of an intrathecal pressure increase in excess of a defined value, CSF extraction takes place by opening the system - for conventional systems by means of the differential pressure between the intrathecal catheter and the height of the distal CSF drainage system tube which leads to the CSF collecting basin. However, if the CSF drainage is open, reliable and correct pressure measurement for existing systems is not possible. Quantification of the CSF volume withdrawn is made visually for these systems, using a measurement scale which is attached to the CSF collection bag.

The LiquoGuard System records intrathecal pressure via the external attachment of pressure sensors at the level of the respective reference point. It is neither necessary to open nor to close the CSF drainage system because, if the target pressure is exceeded, CSF is withdrawn using the rotor pump and when target pressure is achieved CSF withdrawal stopped. As opposed to the existing systems, continuous intrathecal pressure measurement is possible, providing additional safety for the patient during CSF drainage as opposed to risks. The quantification of CSF withdrawn is also visual, using a measurement scale which is attached to the CSF collection bag. However, in addition, the amount of CSF withdrawn can be calculated using the number of rotations of the rotor pump and the tube diameter, providing two alternative methods for CSF quantification.

All in all, the use of the same correcting variables (target pressure, CSF quantity) and the same measurement systems (intrathecal pressure measurement via an externally attached piezo-resistant pressure sensor) for both systems (existing CSF drainage systems and LiquoGuard System) provide comparable effectiveness with regard to intrathecal pressure reduction and the quantity of CSF withdrawn.

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Assessment of the safety of CSF withdrawal

With regard to the period of CSF withdrawal, the quantity of CSF withdrawn differs between the existing systems and the LiquoGuard System.

The CSF quantity for existing systems during the course of time is dependent on the diameter and length of the CSF drainage system, the length and diameter of the intrathecal CSF drainage, the viscosity of the CSF, the height of the distal drainage system (target pressure), the ratio between the patient's CSF production and CSF absorption and the current prevailing intrathecal pressure. It is not possible to determine the CSF drainage amount exactly over the course of time using these systems as the additional times for the named factors cannot be determined (e.g. the CSF absorption rate). Therefore discontinuous CSF withdrawals are necessary, leading repeatedly to slow pressure increase (system closed) and quick pressure loss (distally open system). This can result in quick pressure loss in conventional systems, which can lead to an undesired quick pressure drop with the risk of an aneurysm rupture, especially in case of vascular malformation (aneurysm). Moreover for existing systems opening the system distally is dependent on the presence of a person who operates the drainage system closure mechanism. Hence intrathecal pressure can increase until the respective staff opens the system. As the controls of the rotor pump in the LiquoGuard system always depend on the currently measured intrathecal pressure and the respective target pressure, undesired fast changes in pressure and pressure reductions are impossible due to permanently controlled CSF drainage. There is no clinical indication for discontinuous CSF withdrawals, making continuous CSF drainage whilst maintaining the target pressure the therapeutic objective in all cases.

Moreover, it is also possible to quantify the exact CSF amount to be withdrawn over the course of time because, despite the unknown factors, the amount of CSF to be withdrawn depends on the diameter of the tube system and the rotational speed of the rotor pump and whether both influencing factors are known. The existing CSF drainage systems do not enable a time-based depiction of the CSF drainage amount. It is possible to read out the CSF amount in the drip chamber, however time-based references cannot be established in as far as the drip chamber is not emptied at very short time intervals, also restricting accuracy (low readout accuracy for low CSF amounts) (7). The CSF drainage system LiquoGuard enables highly precise measurement of the CSF feed rate with high time-based resolution, a balance for every hour or every 24 hours and depiction of the continuous feed rate. These parameters can be applied for controlling the pump (setting the maximum total feed rate per hour), not otherwise possible if using conventional systems without incurring personnel costs. This additional parameterization of the discharge flow with a time-based course may be of special significance for certain clinical pictures and concerns, in particular, withdrawal from ventricle drainage. In order to reduce the CSF feed rate, the height distance between foramen Monroi and the drip chamber of an open system is increased here. However this also means that pathological and thus high-risk high intracranial pressure might have to be tolerated. LiquoGuard can avoid this risk by reducing the CSF feed rate and increasing the upper alarm limit slightly, still maintaining CSF drainage, even if within a restricted scope.

Existing systems have a CSF collecting basin which must have an external opening via an air filter. Blocking up, unintentional or deliberate (e.g. whilst transporting patients) closure of the air filter hinders CSF drainage because the air must escape through the incoming CSF. By contrast, an external opening via an air filter is not required for the LiquoGuard System because the rotor pump transports the extracted

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CSF to the collection bag. In this way the risk of an unwanted insufficient CSF drainage can be considerably reduced using the LiquoGuard System. As the insertion of the LiquoGuard tube set in the rotor pump works confusion-proof in one direction, pumping in the opposite direction (distal to proximal) due to user error is not possible. Nonetheless, even if there is a rotor pump malfunction and the rotational direction of the pump is incorrect, the risk of danger to the patient is very low because only the CSF amount actually in the tube system is discharged retrograde and this can also occur in conventional systems in a similar manner if the distal end of the CSF discharge system is attached higher and due to the hydrostatic pressure CSF can run retrograde to the intrathecal CSF drainage. As the LiquoGuard System provides constant pressure monitoring, danger to the patient due to increased intrathecal pressure due to retrograde CSF flow can be ruled-out. This is not possible distally if conventional systems are used and CSF drainage is open. This means that by using the LiquoGuard System the risk of danger to the patient due to retrograde CSF flow is considerably lower than in existing systems.
CSF drainage is only possible when using existing systems when the ventricle drainage is opened, the 3-way cock is open and the air filter for the CSF collecting basin is opened (10, 17). Unintended closure of the CSF drainage system at any one of these points leads to a system occlusion which may remain unnoticed. In contrast, an occlusion of the LiquoGuard CSF drainage system is noticed as there is no CSF pulsation (occlusion proximal to the pressure sensors) or through an increase of the intrathecal pressure values (occlusion distal to the pressure sensors) auf. This leads to direct recognition of danger to the patient if the LiquoGuard System is used and the possibility to avert it, thus minimizing the risk of danger to the patient.
However, the systems used to date have had different disadvantages, caused physically with regard to the open system with an air filter when CSF drainage is desired. As conventional drainage is a distally open system (external pressure compensation is possible in the CSF collecting basin via an air filter), it is not possible to measure CSF pressure in a distally opened external tube system correctly (7, 21). CSF drainage is controlled using the height of the distal tube system which must always be set in accordance with the patient's height (7, 11, 17, 21). A change in the height of the intrathecal catheter in relation to the distal tube system inevitably causes a change to the differential pressure (target pressure) which remains unnoticed if distal CSF drainage takes place in the current systems. This means that the risk for the patient that either an uncontrolled high amount of CSF (differential pressure lower than wanted, distance between intrathecal CSF drainage and external drainage lower) or too low a CSF quantity (differential pressure higher than wanted, distance between intrathecal CSF drainage and external drainage higher) is drained. The LiquoGuard application can reduce this risk considerably because the pressure sensor attached externally to the patient at the height of the intrathecal catheter is carried along when the patient moves, thus averting any pressure changes. This formation not only decreases the amount of work for medical staff in its clinical application and daily routine - it also reduces the risk of incorrectly high or low CSF drainage.(4)

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Assessment of pressure measurement safety

Existing CSF drainage systems possess two varieties of pressure measurement with CSF drainage. The Gold Standard describes the attachment of a pressure sensor to the ventricle drainage and alignment at foramen Monroi level (10, 11). However, pressure measurement is only possible with a tubing system closed distal to the pressure sensor, this arrangement does not permit simultaneous drainage and pressure measurement (16). What is disadvantageous and risky to the patient is that an open system and therefore a deactivated pressure measurement does not guarantee the observation of a tube occlusion or a disconnection. The second variety permits measurement of brain pressure via a pressure sensor directly inserted in the ventricle system, attached at the tip of the ventricle drainage (16, 21). In this case the distal catheter part is open and permits CSF drainage. However, as simultaneous CSF drainage creates an open system, the value of the intraventricular pressure measurement is determined by the height of the drip chamber. Both systems currently available normally work with only one pressure measurement. This means that in case of a technical pressure sensor fault the measurements would lose their reliability, usually a technical redundancy for the safety of the patient does not apply. The CSF drainage system LiquoGuard permits simultaneous pressure measurement and CSF drainage in a closed system. All previously existing risks of unnoticed dysfunctional CSF drainage (disconnection, catheter occlusion) are therefore solved and lead to considerable improvement of patient safety. As this is a closed system, pressure measurement is possible with simultaneous CSF drainage. Simultaneous pressure wave analysis also permits statements on the functionality of ventricle drainage, which is also not possible with the pressure sensors attached to the tip of the ventricle drainage. As both pressure sensors as well as the device-internal processing are redundant in the catheter system, the risk of a technical error measurement as in previous systems can be virtually excluded, as a drift of both sensors in the same direction (positive/negative) in the exact same time resolution with identical amplitude can be classified as unlikely.

All pressure sensors require zero-point calibration before application. In this respect, existing systems do not differ from the LiquoGuard system. However, previous systems permit further zero-point calibrations, which denote two significant risks: 1. the system must be open to air, which promotes germ entry into the tubing system; 2. erroneous, subsequent zero-point calibration with adjoining liquid column can cause an erroneous, low pressure measurement, which can lead to erroneously low intrathecal pressure measurements. As zero point calibration in the LiquoGuard system can only be performed once during initialization of the system and as calibration is recorded in the sensory memory, a second, perhaps erroneously low calibration is impossible. This significantly increases patient safety.

Wrong attachment of the sensor in connection with the zero point (usually foramen Monroi) or unobserved detachment of the pressure sensor can lead to incorrect intrathecal pressure values. This could also lead to erroneous measurement of high intrathecal pressures resulting in CSF drainage. However, as the connection tube between CSF drainage and the pressure sensor is short, pressure difference is only marginal and has no significant influence. In contrast, the CSF collecting bag in existing systems can detach itself from the attachment clamp and fall to the ground. As the connection tube between intrathecal CSF drainage and CSF collecting bag is long, there is a risk of significant pressure differences, which could denote a hazard to the patient. This risk can be significantly reduced due to the technical properties of the LiquoGuard system.

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Safety assessment in CSF drainage occlusion
To ensure correct CSF drainage it must be guaranteed that the entire tubing system, starting at the ventricle catheter to the drip chamber, is not closed (e.g. by 3-way cocks, kinks in the tube, displacement of the inner tube lumen by blood coagulation, etc.) and that pressure balance in the drip chamber to the outside is guaranteed (air filter connected and not jammed, clamp at air filter open).(17) Air filter jamming in particular is difficult to recognize in previous systems, as an external visual inspection (all connections open) does not recognize malfunction and can only be noticed and corrected during air filter exchange or pressure measurement. Recognition of a situation potentially critical for the patient is not possible in previous systems. As pressure measurement is always simultaneously connected to drainage in the new LiquoGuard system, continuous pressure monitoring is possible. An occlusion proximal to pressure sensors is immediately recognized by the absence of the appropriate CSF pressure curve and an alarm is triggered. The occlusion distal to the pressure sensor system is measured by an increase in CSF pressure and an alarm is generated when the upper pressure limit specified by the physician is exceeded. In both systems the removal of a distal tube occlusion and a positive pressure difference between intrathecal pressure and target pressure to the achievement of the target pressure removes a comparable volume of CSF. All in all, the risk of an unnoticed system occlusion can be reduced by the additional measuring systems integrated in LiquoGuard and continuous pressure measurement during CSF drainage without creating additional risks in the application.

Safety assessment to maintain CSF target pressure
All previous systems are based on a distally open tubing system; the desired CSF pressure is set via height adjustment in the drip chamber of the CSF drainage (16, 21, 23). The problem is that when the position of the patient's head is changed (e.g. bed position, self-mobilization of the patient such as sitting up, turning, etc) the height of the drip chamber must be readjusted. If this is not performed, an undesired, large volume of CSF may drain (drip chamber too low in relation to patient's head) or too little CSF is drained (drip chamber too high). This results in serious risks to the patient, as overdrainage with reduced ventricle pressure may cause rupture of bridge veins and transtentorial herniation (clamping) (17). Too little drainage can cause increased CSF pressure and lead to pressure damage in the nervous system (22). The LiquoGuard CSF drainage system avoids these risks as follows: both pressure sensors are configured in such a way that they can be attached at the height of the patient's foramen Monroi by adhesive electrodes. Positioning of the height of the rotor pump and collecting bag is therefore completely independent of patient position. The pressure sensor follows all changes in the position of the head. However, this is only possible if the pressure sensors have been correctly attached to the head. As the proximal connection piece to the ventricle catheter is very short, the pressure difference in case of detachment and suspension in relation to previous systems (drip chamber falls to the ground) is limited. All in all, the system's independence from patient position leads to a significant reduction in risk to the patient and to much easier handling in the daily clinical application.

Safety assessment for disconnection during CSF drainage system application
The disconnection of the tubing system in all previous systems, occurring occasionally during permanent lumbar CSF drainage (patient removes proximal tubing system during change in position or disconnects it when disorientated) leads to spontaneous emptying of CSF to the outside with the risk of a negative CSF

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pressure (risk of herniation, hemorrhage) and CSF infection (no existing sterility, open CSF drainage serves as port of germ entry(17)). As permanent lumbar drainage is commonly applied in wards without a monitoring unit, the disconnection is only recognized after longer periods of time and after loss of significant CSF volumes(2)(17). The LiquoGuard drainage system can detect the problem immediately by measuring acute pressure reduction caused by disconnection in the catheter system and signal an appropriate alarm. The risk to the patient caused by unrecognized CSF drainage over longer periods of time is significantly reduced by the use of the LiquoGuard system.

Safety assessment for sterility of CSF drainage systems

For physical reasons, existing systems require an external system opening for CSF drainage. An air filter must be connected to the CSF collecting container, which can lead to cross-contamination. This risk can be reduced by using the LiquoGuard system, as it is a closed system and does not require the use of an air filter.
Existing systems can be reused contrary to the determination of suitability, whereas multiple use or re-sterilization in the LiquoGuard system is impossible due to single zero point calibration. This excludes the risk of unintentional multiple use of disposable products. All other consumable goods in contact with human body fluids are comparable to the LiquoGuard system and do therefore not denote any additional risk of infection.

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Summary

Verification of effectiveness

The LiquoGuard CSF drainage system is a tube system with integrated redundantly designed pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CNS drainage. The intrathecal CSF drain is used independent of the LiquoGuard system, and the products approved for intrathecal CSF drainage and pressure measurement can be connected to the LiquoGuard system. The indication for insertion of an intrathecal drainage will not be affected by using the LiquoGuard system. As the control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing systems and the LiquoGuard system, the measuring sensors are comparable and the effective mechanism and the function of the CSF extraction by means of a target value-controlled rotor pump in the LiquoGuard system is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard system offers comparable effectiveness to existing CSF drainage systems. Thus both systems similarly enable CSF drainage as a treatment up to target pressure in order to reduce intrathecal pressure, which makes it possible to treat intrathecal pressures leading to a perfusion deficit of the central nervous system. There is technically similar to standard shunt valves with regard to the automated pressure-related CSF flow control. Such devices usually work by tensioning a valve via a spring tension and can be adjusted from outside mechanically, magnetically or by any other suitable method, depending on the design. At a certain preset CSF pressure definable from outside, the valve opens and allows the CSF to flow, until the CSF pressure is below the preset pressure, causing the valve to close automatically (5, 7). This active pressure-controlled CSF drainage is realized in the LiquoGuard system in an analogue way.
By using the LiquoGuard system, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in both systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement.

Risk evaluation of the system

Intrathecal pressure measurement

In the LiquoGuard system, the technical requirements for pressure measurement are comparable to the existing CSF pressure measurement systems that work via a liquid column communicating to the intrathecal space. Both the positioning of the pressure sensors in the tube system as well as the orientation of the pressure sensor in relation to the intrathecal catheter is comparable. Contrary to other systems, however, the LiquoGuard system is designed such that the pressure measurement is performed twice, and in the event of measuring a differing pressure between both sensors, an alarm is activated enabling the malfunction of a sensor to be noticed immediately. Since a faulty measurement of the intrathecal pressure can pose a risk for the patient (excessive CSF pressure risking a compression and perfusion deficit of the CNS, insufficient CSF pressure risking a tensile stress on CNS structures

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leading to hemorrhages, vessel ruptures and shear injuries), the double measurement with mutual control of both pressure sensors allows the significant reduction of the risk of faulty pressure measurement in comparison to existing systems. The prevention of pressure equalization to ambient air pressure with already inserted systems, with the consequence of a wrong high or wrong low intrathecal pressure reading, further increases the safety of the patient in the LiquoGuard system.

CSF extraction
The LiquoGuard system, contrary to existing systems, allows continuous pressure measurement even during CSF extraction. Therefore, there are no further additional risks associated with using the LiquoGuard, but rather the risk of an uncontrolled CSF extraction under existing systems (wrong difference height set, patient moves during CSF extraction with open system, height of CSF drainage bag changes during CSF extraction, CSF drainage system is disconnected while drainage is in progress) can be significantly reduced by using the LiquoGuard system. Thus the risk of excessive CSF pressure risking a compression and perfusion deficit of the CNS, or of insufficient CSF pressure risking a tensile stress on CNS structures leading to hemorrhages, vessel ruptures and shear injuries can be reduced by using LiquoGuard. Hemorrhages (13, 17) caused by the application of intrathecal CSF drainage are not affected by the used CSF drainage system; there is no increased hemorrhage risk by using the LiquoGuard system. Other risk sources for the patient such as wrong catheter positions (11, 17) are also not related to the CSF drainage system and pose an independent risk that is neither reduced nor increased by using the LiquoGuard. .

Quantification of the CSF extraction volume
A comparable visual determination of the extracted CSF volume by reading the quantity of CSF on scales attached to the drainage bags, allows a basic CSF volume determination with both existing CSF drainage systems and the LiquoGuard system. Additionally, the LiquoGuard system can compute the extracted CSF volume by means of the number of rotations of the rotor pump and the tube diameter, thereby allowing not only a safety-relevant redundancy of the CSF volume determination, but also a quantification of the CSF volume in high time resolution.

Closed vs. open CSF drainage system: Existing systems allow reliable intrathecal pressure measurement with a closed CSF drainage system, and CSF drainage with an opened CSF drainage system. If the CSF drainage system is occluded distally from the pressure measurement (clogging of tubing system, tube closed by 3-way cock, clogging or closing of air filter at the CSF drainage bag) and the pressure measurement is not connected to the liquid column, a very high CSF pressure may build up without being noticed. This can lead to a severe risk for the patient, as it may result in a compression of the CNS with the danger of a perfusion deficiency. The risk of an unnoticed CSF pressure increase can be significantly reduced due to the continuous CSF pressure measurement with the closed system (LiquoGuard system), no air filter is required, and the CSF pressure measurement is possible simultaneously and independently from each other at any given time. The risk of a malfunction of the rotor pump control in the LiquoGuard system through a faulty pressure measurement is highly unlikely due to the double pressure measurement design.

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Disconnection and occlusion of the CSF drainage system
With existing systems in closed status as well as with the LiquoGuard system, during connected liquid column, any disconnection of the system with CSF leak can be immediately noticed due to a rapid drop in pressure at the pressure sensors below the lower pressure limit. Contrary to the LiquoGuard system, where it is possible to recognize a disconnection even under CSF drainage conditions, this is not possible with the existing systems under deactivated pressure measurement during CSF drainage. Here the danger is that CSF can leak out unnoticed in large quantities with the risk for the patient that due to insufficient CSF pressure there is a risk of tensile stress on CNS structures leading to hemorrhages, vessel ruptures and shear injuries. This risk can be significantly reduced by using the LiquoGuard system, without any identifiable additional risks for the patient. An occlusion proximal to the pressure sensors will lead to a suppression of pressure pulsations, which in existing CSF drainage systems can be visually displayed via a patient monitor connected to the pressure sensor, and in the LiquoGuard system both via a connected patient monitor as well as via the display of the LiquoGuard device. Contrary to existing systems, however, the LiquoGuard system is computing the pulsations and triggers an acoustic and visual alarm above or below defined alarm parameters. This will make the clinical staff aware of a possible system occlusion proximal to the pressure sensors. There are no other additional risks involved for the patient, but the risk of an unnoticed intrathecal pressure increase with the consequence of a compression and perfusion deficiency of the CNS can be significantly reduced by the LiquoGuard system in comparison to the existing systems. An occlusion distally from the pressure sensors will in both systems equally cause the CSF drainage to be suspended. With existing systems, this situation may remain unnoticed if the pressure sensor is not connected to the liquid column (e.g. by connecting the pressure sensors via 3-way cock). With the LiquoGuard system, a distal occlusion will lead to a measurable pressure increase, which will trigger an acoustic and visual alarm when the upper alarm limit for the CSF pressure measurement is exceeded. Therefore, the continuous CSF pressure measurement by means of the LiquoGuard affords a significant improvement of the CSF pressure monitoring with a decrease in the patient risk.

CSF system sterility
Handling the connection of the CSF drainage system to the CSF drain is comparable in all CSF drainage systems, here there are no identifiable additional risks by using the LiquoGuard. However, with an open system a bacterial contamination through the air filter might occur, which is not possible with a closed system (LiquoGuard). Additionally, the rotor pump prevents a CSF reflux from the tube/drainage bag system into the intrathecal space, which further reduces the infection risk. Any multiple use of the tube system with a possible germ contamination is virtually impossible due to the electronic protection and unique zero calibration of the pressure sensors. All in all there are no indications of any increased infection risk by using the LiquoGuard system; there are rather significantly less points of entry for a bacterial contamination of the system with the LiquoGuard system. Using the LiquoGuard system has no influence on the principle risk of an infection of the CSF drainage system (8, 17).

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Conclusion

It has been shown in the existing recognized literature that the CSF drainage is a recognized and established method in neurosurgery for many years for the diagnostic and treatment of patients with diseases of the CNS. The risks associated with the surgical insertion of a CFS drain are not depending on the CSF drainage system chosen and thus not on the use of the LiquoGuard system. The objective of intrathecal pressure measurement and CSF extraction is achieved both by existing CSF drainage systems as well as by the LiquoGuard system in comparable effectiveness. Contrary to existing systems, however, by using the LiquoGuard system, the risks of erroneous pressure measurement, sensor fault, and false pressure measurement by changing the reference height of the patient, unnoticed catheter occlusion and catheter disconnection as well as the infection risk can be reduced.

Biologically, the identical material is used for the drainage (CSF). Neither insertion technique, material nor the indications are influenced or altered by using the LiquoGuard. Therefore, there is no difference in the surgical risks for inserting the relevant ventricular or lumbar drainage when using the LiquoGuard. The intrathecal drainage is inserted with the identical patient population at the same place in the body (ventricular system, lumbar CFS system) (7, 13). The pressure measurement is performed by piezo-resistive pressure sensors that are established and described for the use in intracranial pressure measurement (10, 11, 21). Fundamental risks that do not depend on the method of CSF drainage and occur after insertion of a CSF drain (ventricular catheter, permanent lumbar drainage catheter) are described in major trials; these are infections (8, 17), hemorrhages (13, 17), wrong catheter positions (11, 17), occlusions (17), overdrainage (17).

The surgical procedures will not be changed in any way; also the indications for a surgical intervention remain unchanged. No material risk can be identified, as existing systems are made of comparable material and are used as soon as sterile catheter material becomes available.

In summary, from a functional point of view existing systems are identical to the LiquoGuard system (CSF drainage, pressure measurement), but the pressure-controlled CSF drainage via a rotor pump (LiquoGuard) offers a clear reduction of technical, application-specific and patient-specific risk sources, without generating new risk sources at the same time. All patient-relevant risks of usual systems can be significantly reduced by using the LiquoGuard. There is no additional risk to users or third parties..

Fulda, 23. August 2006

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Annex: Bibliography

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APPENDIX 60

LIQUOGUARD CSF SYSTEM CLINICAL TRIAL

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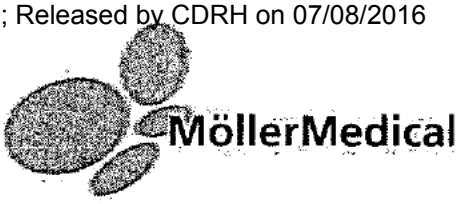

LiquoGuard vs. drip chamber – A non-inferiority trial Protocol

(b)(4)

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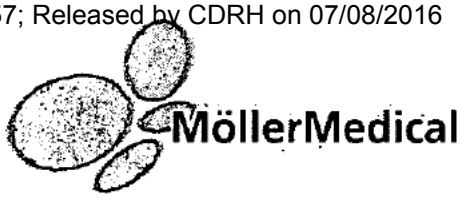

LiquoGuard vs. drip chamber – A non-inferiority trial Report

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(b)(4) Test Report

[redacted]

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(b)(4) Test Report

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(b)(4) Test Report

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(b)(4) Test Report

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APPENDIX 61

LIQUOGUARD CSF SYSTEM PUBLICATIONS

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B.M. HOELPER

CLINICAL STUDY REPORT OF A NEW PRESSURE AND VOLUME CONTROLLED CSF DRAINAGE SYSTEM (LIQUOGUARD)

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Clinical study report of a new pressure and volume controlled CSF drainage system (LiquoGuard®)

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Summary.

Introduction. Lumbar and ventricular CSF drainage is applied in various indications in neurosurgery. Until now, open hydrostatic systems mostly including a dripping chamber were used. This report presents first experimental and clinical experience using a new, closed CSF drainage system capable of simultaneously draining CSF and measuring CSF pressure (LiquoGuard®).

Material and Methods. CSF pressure is measured by a dual external pressure sensor device taped at an anatomical reference point of the patient and CSF is drained by a peristaltic pump. For ventricular application, drainage is pressure controlled, while in lumbar drainage a constant flow rate can be defined. For experimental evaluation, hydrostatic pressure as well as comparison to an independent pressure sensor technique was calculated for static pressures and pressure changes. During clinical application, intraventricular pressure measured by the new system was compared to established ICP devices (internal and external pressure transducers) in 16 patients. Lumbar drainage with constant flow rate was performed in 4 patients.

Results.

Experimental data comparing the LiquoGuard® pressure sensor to hydrostatic pressure levels and pressure measured by an calibrated pressure measurement device revealed in ranges < 100 mmHg a high accuracy with deviation of 0 – 3 mmHg. Ventricular CSF pressure also was comparable to established sensors (Raumedic Neurovent and standard external pressure transducer). Calculated drained volume differed from measured volume within the drainage bag < 5 % if total CSF amount was > 100 ml. Slit ventricle syndrome was detected early by loss of CSF pulsation, oscillating CSF pressure and reduction of CSF outflow. Catheter occlusion was stated if CSF pressure remained low in contrast to slit ventricle syndrome.

Discussion.

Both experimental and clinical data indicates that the new device allows a precise external CSF pressure measurement with low sensor drift along with the possibility to

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drain CSF simultaneously due to a closed drainage system. This results in several clinical advantages: Adjustment of a dripping chamber is not necessary any more leading to enhanced patient safety and mobility. Lumbar drainage is facilitated by a constant flow rate. Critical conditions such as slit ventricle syndrome or catheter occlusion can be detected by the integrated CSF pulsation detection in addition to alterations in CSF pressure and outflow. Therefore, the system can facilitate handling of ventricular and lumbar drainage and might enhance safety for the patient.

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I INTRODUCTION (BACKGROUND AND RATIONALE)

Lumbar and ventricular drainage of CSF is a daily routine method in neurosurgical practice (3, 5, 10, 18) in several indications. Ventricular CSF drainage might be needed in situations caused either by obstruction of CSF outflow (e.g. by subarachnoid haemorrhage, obstruction of CSF flow by tumor or blood as well as infectious diseases) of distrubtion of CSF resorption (1, 4, 5, 9-11, 13-15, 17, 19). Furthermore, lumbar CSF drainage is needed to treat CSF fistulas or establish diagnosis in normal pressure hydrocephalus (6). However, several important disadvantages occur with current ventricular and lumbar systems. For pressure controlled CSF drainage, permanent alignment of the dripping chamber to anatomical reference points is necessary. Furthermore, reliable measurement of ICP is possible only in a closed drainage system: by positioning the dripping chamber for example above the reference point, only the hydrostatic pressure difference between the fluid level inside the tube and the pressure sensor is measured. Other nursing problems such as disconnection and occlusion of the CSF drainage are frequently registered with long time delay. Additional, technical inconsistencies of pressure measurement due to sensor malfunctions (e.g. sensor drift) and incorrect handling (wrong zero leveling, incorrect adaptation to the monitoring system) might cause wrong ICP readings. By this, the patient might be without surveillance of CSF pressure and imprecise determination of drained CSF volume. In lumbar drainage, nowadays it is very difficult to achieve a continuous CSF flow over time, since CSF outflow depends on position of the catheter, pressure difference between catheter and dripping chamber, positioning of the patient and CSF-dynamics (CSF production, resorption and outflow).

The presented new system (LiquoGuard®) is an externally closed system which might allow drainage of CSF parallel to CSF pressure measurement. Technically, in contrast to the dripping chamber the system is externally closed by a peristaltic pump and by this it allows simultaneous CSF drainage and pressure measurement. Therefore, there should be no need for a dripping chamber due to pressure controlled drainage. Additional, continuous CSF flow especially in the use of lumbar drainage might be possible.

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II STUDY OBJECTIVE AND DESIGN

Study Objective

Purpose of this study was to evaluate if dripping chambers can be replaced by the LiquoGuard® system without any clinical changes and if the LiquoGuard® system is reliable concerning the applicability, accuracy of CSF drainage and CSF pressure measurement. The intend of the LiquoGuard® device to minimize most sources of error mentioned above due to the closed fluid system is evaluated. Furthermore, clinical practice in mounting the pressure sensors at the reference point is studied. In addition, LiquoGuard® is observed in the following clinical situations: catheter disconnection, catheter occlusion and collapsed ventricles. The accuracy of both sensors and the frequency of inconsistencies between both sensors (sensor drift) will be analyzed. For lumbar drainage, the ability of the LiquoGuard® system to drain CSF continuously and the accuracy of drained fluid volume are further examined.

Study Design

For 20 Patients requiring external CSF drainage (ventricular or lumbar) instead of the usually applied dripping chamber the external CSF drainage system LiquoGuard® is used with the same intend to treat. Since the presented new system (LiquoGuard®) is a externally closed system which allows drainage of CSF parallel to CSF pressure measurement, the ICP will be compared to an independent alternative ICP and the calculated CSF volume is compared to the collected CSF volume.

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III SAFETY AND EFFECTIVENESS PARAMETERS

A. Key Safety Parameters

CSF pressure. Most important for ventricular CSF drainage is the correct adjustment of intraventricular pressure. This is performed either externally by adjusting the dripping chamber or by mounting (either taping or fixing by suture) of the ICP pressure sensors (LiquoGuard®). By this, LiquoGuard® must allow to drain comparable CSF volumes to maintain intraventricular CSF pressure. To exclude increased ventricular CSF pressure due to inadequate drainage, an additional external pressure sensor was installed parallel to the LiquoGuard® CSF pressure sensors. Furthermore, alarm functions are activated if CSF pressure is out of physiological ranges.

Drained CSF volume. The CSF volume drained by LiquoGuard® was calculated by the device and displayed. Furthermore, the amount of collected CSF was measured afterwards. To exclude a larger deviation of drained CSF volume, it was possible to read the collected volume outside the drainage bag. Therefore, assuming that a withdraw of a larger amount of CSF might lead to a decrease of CSF pressure, additionally the CSF pressure was measured and a lower CSF pressure alarm was predefined. By this, the drainage of larger CSF amounts should be registered.

B. Key Effectiveness Parameters

Aim of each ventricular and lumbar CSF drainage is to allow CSF flow from the CSF space to an external reservoir, either with determination of the CSF pressure (most ventricular drainage systems) or of the CSF volume (most lumbar drainage systems). Therefore, the effectiveness of the LiquoGuard® system has to be determined by its ability to withdraw CSF from the intrathecal space (ventricular or lumbar), either controlled by the CSF pressure or by the volume. Since the withdrawn CSF can be sampled in the drainage bag, the effectiveness of the LiquoGuard®-System can be measured directly and immediately during clinical practice.

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IV PATIENT ENROLEMENT

A. Inclusion Criteria

In the study, neurosurgical patients with the need of a ventricular or lumbar drainage were included. All patients underwent an operative procedure to introduce an external drainage catheter into the CSF space. However, this was done independent of the use of a conventional system or the LiquoGuard® system. Indications with the need of an external drainage are subarachnoid hemorrhage, intraventricular hemorrhage, head trauma, ventriculitis, CSF fistula and normal pressure hydrocephalus.

B. Exclusion Criteria

Since the operative procedure to apply an external drainage device does not differ between the conventional drainage systems and the evaluated system, no additional operative or nursing step must be done. Therefore, there are no exclusion criteria that can be assumed to be exclusion criteria for the use of the LiquoGuard® system which differ from the exclusion criteria for all external CSF drainage systems. For completion, relative exclusion criteria for external lumbar or ventricular drainage (both conventional dripping chamber and LiquoGuard® system) are pathologies in haemeostasis, coagulopathies, and severe infections disease. However, in many cases CSF drainage has to be applied immediately in life threatening situations.

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V STUDY MATERIALS AND METHODS

A. Description of Device

The LiquoGuard® system (Moeller Medical, Fulda, Germany) consists of a device including a peristaltic pump, inputs for pressure sensors, and several external interfaces. The external drainage system consists of a tube with two integrated pressure sensors. The tube can be inserted into the peristaltic pump and the sensors are connected to the pressure sensor interface. After zeroing of the sensors, CSF drainage can be immediately started and current ICP, CSF pulsation (for ventricular drainage) as well as withdrawn CSF volume are displayed. Sensor information provided by the manufacturer is a sensor accuracy ± 0,375 mmHg, long-term drift of < 1 mmHg and a total system deviation of < 2 mmHg, manufacturer states that the volume calculated by the device deviates ± 15% in maximum. Upper and lower ICP alarm threshold can be set. For ventricular drainage, pulsation of the CSF is detected, displayed and loss of pulsation leads to an activation of an alarm function.

B. Patient Entry

For evaluating the possibility of continuous CSF drainage, the LiquoGuard® system was connected the ventricular drainage in 16 patients and lumbar drainage in 4 patients. In ventricular application, the LiquoGuard® pressure sensor was taped to the patient head at the level of the foramen Monroi and ICP was measured by an additional intraventricular applied pressure sensor catheter (Raumedic Neurovent®) or by an external pressure transducer connected to the external tubing system by a three way connector.

C. Surgical Procedure

For application of the LiquoGuard® CSF drainage system no surgical procedure is needed. However, the application of each external CSF device requires an operative procedure independent on the use of the external drainage system. For ventricular drainage, a burr hole was performed according to standard landmarks (about 2 cm lateral of the superior sagittal sinus and 0.5 cm anterior to the coronal suture, mostly right-sided). After incision of the dura, a ventricular catheter was introduced with a

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length of about 5-6 cm into the ventricular system until CSF dropped out of the drainage. Then, the catheter was either tunneled and sutured to the skin or was fixed by a PEEK bolt (Raumedic). For lumbar drainage, a standard lumbar drainage kit (Integra) was used. The intrathecal space was approached in the level of L3/4 or L4/5 by a Touhy-Needle and the lumbar catheter was introduced in cranial direction with a length of 5-15 cm. Externally, the catheter was sutured to the skin and additionally taped.

D. Postoperative Care

After ventriculostomy, ICP was adjusted to 10-20 mmHg depending on the disease of the patient and according to the previous standard of the height of the dripping chamber. Drained CSF volume was set in the range between 5 to 25 ml/h for ventricular drainage. Upper alarm was set at 20 – 40 mmHg, lower alarm at 0-5 mmHg according to the patient's disease. ICP measured by the external independent pressure sensor was either recorded automatically every minute or manually by the nursing staff every half hour along with the ICP displayed by the LiquoGuard®, Drained CSF volume was collected and measured every 24 hours for balance. Furthermore, the complete drained CSF volume was measured and simultaneously the volume calculated and displayed by the LiquoGuard® was recorded.

For lumbar drainage, flow rate was set to 5 – 13 ml/h, upper pressure alarm at 40 – 70 mmHg, lower pressure alarm at 0 - 5 mmHg. Pressure from LiquoGuard® and the additional pressure sensor was time locked collected for the complete monitoring time.

Each alarm of the LiquoGuard® had to be prompted by the nursing staff. In cases of an exceeding ICP either the CSF flow rate was increased or other standard steps (medical treatment of elevated ICP or diagnostic procedures) were performed. In cases of an ICP below the lower alarm the threshold was either further lowered, the position of the patient was altered or the mounting of the ICP sensor was checked. In cases of a pulsation alarm and/or a low ICP without visible CSF pulsation, continuity of the ventricular or lumbar catheter was checked and in case of an obstruction the catheter was flushed.

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E. Patient Follow-up

Each patient was followed up during the time of treatment and several days after treatment routinely for clinical signs of CSF infections. However, since the treatment is finished after withdrawing of the ventricular or lumbar catheter, no further follow-up is required and was performed concerning the external CSF drainage system.

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VI STATISTICAL METHODS

After collection of ICP data, the difference between both values was calculated and statistically evaluated for significant differences (Mann-Whitney-U Test). CSF volume was displayed by the LiquoGuard® with hourly and daily balance and total drained CSF amount. The withdrawn CSF volume colleted in the drainage bag was measured and the difference was calculated. All statistical Analysis was performed by using SPSS (V. 12.0).

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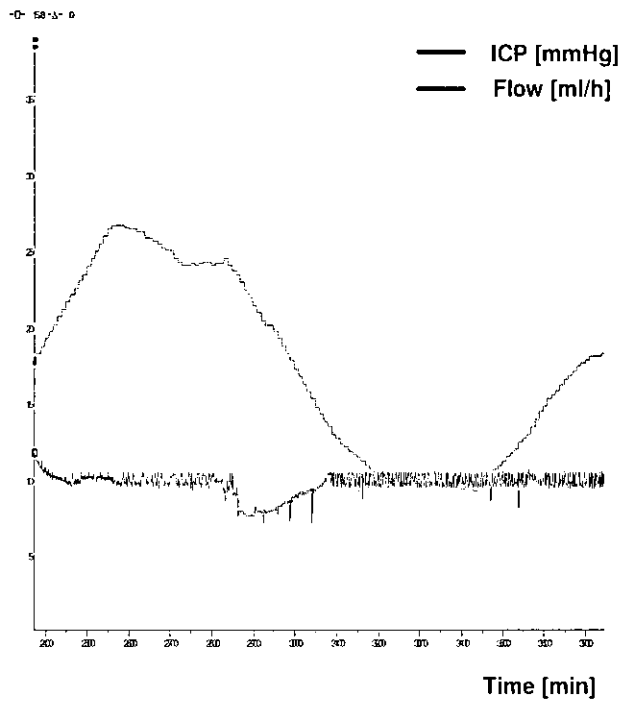
VII RESULTS

Replacement of dripping chamber.

In 20 patients, previous applied dripping chamber was replaced by the LiquoGuard® system (both in ventricular for 16 patients and lumbar application in four applications). After setting of the parameters (desired ICP, maximal CSF drainage in ml/h and alarm limits), in all patients CSF drainage was continued analogous to the dripping chamber. In 16 patients, the self-adhesive pad mounted at the head of the patient had to be replaced, no complications were seen during this procedure. In clinical routine, a standard setting with a maximal flow rate of 20 ml/h is sufficient in most cases. Flow rates of 5 – 20 ml/h are also frequently seen in external dripping chambers.



This graph depicts the flow of CSF (blue line) controlled by the LiquoGuard® system. The ICP was kept at 10 mmHg or below representing the functioning of the system to maintain ICP in predefined range.

For patient transport, mostly the dripping chamber is switched off which might lead to an intermittent increase of ICP. Since the LiquoGuard® system runs on recharchable batteries, there is no need to disconnect the drainage system and thus drainage is also possible during transportation. Furthermore, also during angiography, CT and transport into the OR a continuous CSF drainage is possible which might lead to a better surveillance of the patient and might minimize the risk of ICP peaks during transport without any recognizable negative consequences for the patient.

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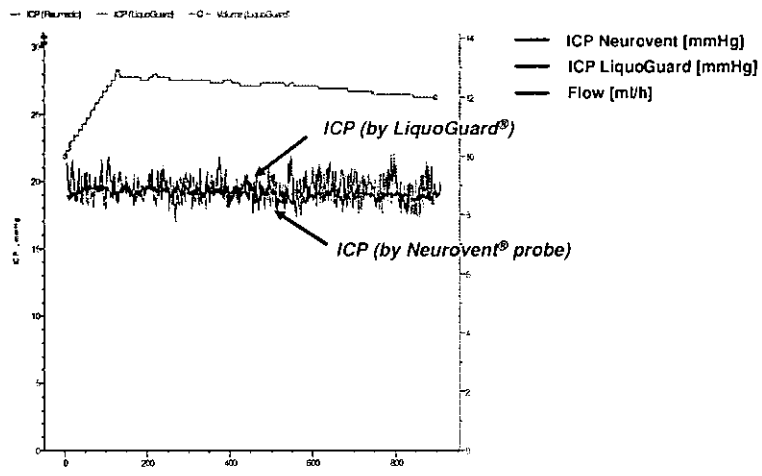
ICP measurement

In ventricular application, ICP measurements between LiquoGuard® and an alternative pressure measuring method differed in a range of 0 – 3 mmHg. The maximal deviation was found between the LiquoGuard® pressure sensor readings and the compared external pressure transducer with 3 mmHg, while differences between the Raumedic Neurovent® and the LiquoGuard were below 3 mmHg. No statistical difference was found during measuring periods between external ICP or intraventricular Raumedic Neurovent® probes and the LiquoGuard® ICP values.



ICP measured by LiquoGuard® (blue line) and an comparable intraventricular system (Raumedic Neurovent® probe, black line) showed absolutely comparable ICP values with deviation < 1 mmHg. The red line indicates the CSF flow controlled by the LiquoGuard® system.

No sensor malfunction was observed in these measurements, however in 4 patient a second disposable drainage system had to be connected due to an operating time of the tube of more than 5 days (as recommended by the manufacturer).

CSF volume

The differences between the drained CSF compared to the calculated volume calculated by the LiquoGuard® was < 10% and no statistical significant difference was found if total drainage volume was > 100 ml. Therefore, both accurate pressure measurement and calculated volume by LiquoGuard® can be used for clinical purpose. Critical situations such as slit ventricle syndrome were detected at a very early point in a typical pattern with loss or CSF pulsation and increasing variability or CSF pressure. Additional, catheter occlusions for both lumbar and ventricular applications were immediately detected by sudden decrease of CSF pressure and

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loss of CSF pulsation. For lumbar application, continuous CSF drainage is possible even during mobilization of the patient, while catheter occlusion, malpositioning and disconnection of the catheter were prompted by an alarm.

Collapsed ventricles.

In two patients collapsed ventricles were detected in cranial CT. Prior to CT, in both patients the ICP measured by the LiquoGuard® system altered in an oscillating fashion below the desired ICP, CSF pulsation was lost and the CSF flow rate was reduced (Figure 3). Pausing of CSF drainage led to an equilibration of ICP at pathological levels (> 35 mmHg) with CSF pulsation.

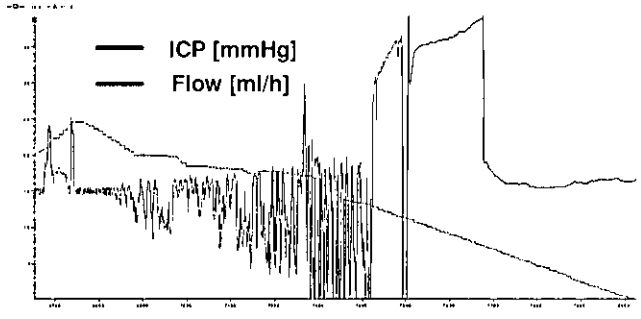

Figure 3. Decrease of CSF outflow or production from the ventricles leads to decrease in CSF flow displayed by the LiquoGuard® (as seen in the blue line) indicating a clinical situation which might be due to collapsed ventricles. Since CSF flow is very low, the amount of drained CSF by the LiquoGuard® is also in very low ranges and a withdraw of small amount of CSF leads to sudden and high changes in ICP. This can be seen in an increase of ICP oscillation, here in the range between 0 and 20 mmHg.

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Catheter occlusion.

Several intermittent occlusions of the lumbar and ventricular catheters occurred. Mostly, occlusion was caused by obliteration of the internal lumen of the tube, but in two patients CSF drainage was not possible due to partial withdrawal of catheter to an extradural position. In all situations, CSF pressure was very low (0 – 2 mmHg), CSF pulsation and flow was not detectable (figure 4). Flushing the tube by a small amount of sterile isotonic saline solution ended immediately the occlusion in cases not caused by extradural catheter position.

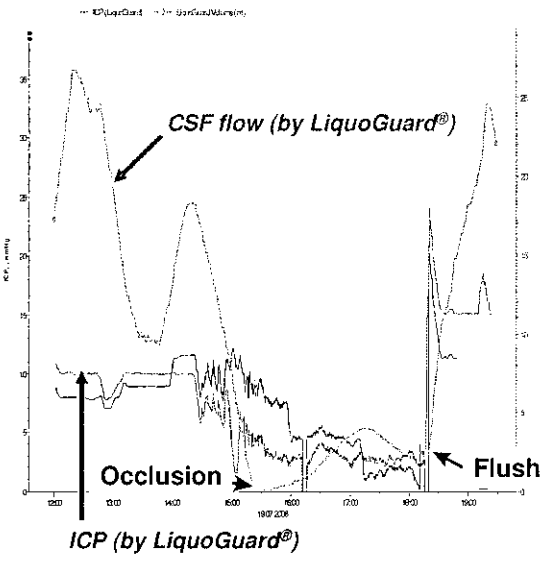

Figure 4. Typical presentation of a catheter occlusion which immediately leads to an reduction of CSF flow (red line) and a decrease of ICP. The ICP decrease is caused by withdrawing of CSF by the LiquoGuard® system without efflux of CSF from the ventricular system.

Clinical.

For evaluating the possibility of continuous CSF drainage, the LiquoGuard® system was connected to ventricular drainage in 16 patients and to lumbar drainage in 4 patients. In ventricular application, the LiquoGuard® pressure sensor was taped to the patient head at the level of the foramen Monroi and ICP was measured by an additional intraventricular applied pressure sensor catheter (Raumedic Neurovent®) or by an external pressure transducer connected to the external tubing system by a three way connector. ICP was adjusted to 10-20 mmHg depending on the history of the patient, drained volume was set in the range between 10 to 25 ml/h. Upper alarm was set at 35 – 40 mmHg, lower alarm at 5 mmHg. For lumbar drainage, flow rate was set to 5 – 13 ml/h, upper pressure alarm at 40 – 60 mmHg, lower pressure alarm at 2 - 5 mmHg. Pressure from LiquoGuard® and the additional pressure sensor was time locked collected for the complete monitoring time. Additional, the drainage volume was colleted and measured in a calibrated cylinder for further comparison to

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the LiquoGuard®. Any occurring alarms, handling problems by the nursing staff were documented.

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VIII DISCUSSION / CONCLUSIONS

Experimental work showed a very stable and reliable pressure measurement by the LiquoGuard® which works in the ranges provided by the manufacturer (complete deviation of the pressure < 2 mmHg). No differences were found in hydrostatic pressure differences and in continuous increase and decrease of pressure. The deviations of the pressure sensor is comparable to other external applied CSF pressure sensors (8, 21) and drift is even lower compared to miniaturized sensors applied into the intradural space (2, 7, 8, 12, 16) Therefore, the applied sensor seems to be suitable for low pressure seen in intracranial and lumbar applications. In clinical setup, ventricular pressure was also measured with high reliability compared to commercially available external and internal pressure sensors. Sensor drift seen in most sensors applied intracranially is negligible and malfunction of one pressure sensor can be detected easily due to the dual architecture of the system. There is only one commercially available system (Raumedic Neurovent duo, 16) offering the possibility to measure two pressures, but in contrast to this the LiquoGuard® compares the two measured pressures continuously. The slight difference between the pressure measured by the LiquoGuard® compared to the external pressure sensor was due to slight differences in positioning the sensor related to the level of the foramen Monroi. The LiquoGuard® pressure system can be taped using an ECG electrode to the patient head, the risk of deviation concerning the measured pressure might be reduced, since usually the external pressure transducer is either fixed at the holding device with is mounted at the bed or directly fixed on the pillow. The fixation of the LiquoGuard® pressure system directly at the patient allows for lumbar and ventricular application a continuous adaptation, the risk of measured pressure which is not corrected to the anatomical reference point of the patient is therefore minimized. In two patients, symptoms of intracranial hypotension relieved after changing the lumbar drainage from discontinuous to continuous manner.

The calculation of drained CSF volume gives further diagnostic information especially for diagnosis of critical situations such as slit ventricle syndrome and catheter occlusions. Furthermore, other therapeutically strategies might be modified using this parameter such as indication for CSF shunting and withdrawing the external ventricular drainage. Detection of CSF pulsation might indicate easily catheter occlusion and slit ventricle syndrome and offers easy and early additional information

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to the neurosurgical staff, since catheter occlusion can not be detected by a pressure sensor mounted at the tip of the catheter. The only limiting factor might be if air comes into the drainage which then might lead to deviations between calculated and measured CSF volume. However, since ICP curve will be dumped by air, ICP pressure pulsation will be reduced.

In conclusion, this new system offers new possibilities for neurosurgical patients for treatment in both, lumbar and ventricular application. The dual pressure sensor technique, independence to a dripping chamber and possibility to drain CSF and measure the CSF pressure simultaneously offers an additional safety and mobility for the patient.

IX APPENDICES

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CONTINUOUS CONTROLLED LUMBAR SPINAL FLUID DRAINAGE FOR PPREVENTION OF SPINAL ISCHEMIA DURING THORACOABDOMINAL SURGERY OF THE AORTA

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"Der interessante Fall"
(Feature article)

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Continuous controlled lumbar spinal fluid drainage for prevention of spinal ischemia during thoracoabdominal surgery of the aorta

Despite various therapeutic applications, attempts to substantially reduce ischemia associated neurological failures following thoracoabdominal aorta surgery have been unsuccessful. The challenge is to find better methods to determine and improve spinal cord perfusion. In addition to the use of shunts, left heart bypasses using pump systems, lowering body temperature, MEP monitoring, as well as clamp-and-repair techniques and inclusion of the spinal arteries in the reconstruction of the aorta, other suitable methods include fluid drainage systems such as the continuous closed variant (LiquoGuard) proposed.

Method

The current practice of lumbar drainage involves manual, irregular fluid withdrawal. The application of LiquoGuard by Möller Medical GmbH, enables for the first time, a continuous, pressure-controlled fluid drainage. Furthermore, in contrast to the established drop-chamber systems, this drainage system is closed and sterile (**Fig. 1**).
The fluid flow is controlled by a pre-programmed spinal pressure and a set maximum flow rate. Excessive drainage is avoided since underpressure never occurs. A pre-operative, time-consuming adjustment of the pressure transducer is not required since the sensor unit can be secured to the nape of the patient quickly and easily.

Case history

A 65-year old patient underwent surgery for a symptomatic thoracoabdominal aortic aneurysm Crawford Type III. A large, penetrating ulcer (PAU) on the right side indicated a high risk of perforation. A tubular prosthesis had previously been implanted as a result of an infrarenal abdominal aortic aneurysm. Due to the specific position of the TAA in the visceral segment of the aorta, an endovascular procedure was excluded.
The operation technique consisted in a left thoracoabdominal, extraperitoneal approach with an internal aorto-aortal shunt implantation. Resection of the aneurysm was performed by using a tubular prosthesis, with the inclusion of the spinal arteries TH 11 and 12, as well as all visceral arteries. Cooled, pharmacological rinsing perfusion was temporarily performed on an intestinal artery and a renal artery respectively. After successful reconstruction of the aorta, the internal shunt was removed and the thoracolaparotomy wound closed.
Prior to anaesthetisation, the patient received a thoracic peridural catheter to ensure analgesia. Another catheter was inserted in the L4/5 spinal region for lumbar drainage and incorporated with the LiquoGuard system. The drainage tube was fitted into the pump. The pressure sensor connector was connected to the pump and a zero balance performed. The interspinal pressure limit was set at 10 mmHg. The continuous flow rate was set at a mean value of 20 ml per hour and the application started. The system operated in a continuous and smooth manner throughout the duration of the surgery. Manual intervention was not required, thus ensuring that the system was permanently sterile, unlike conventional methods of manual fluid withdrawal via drop-chamber systems. Interspinal pressure peaks were particularly evident during aortic cross-clamping (**Fig. 2**). However, the pressure never exceeded 12 mmHg. The flow rate set avoided pressure peaks occurring from the outset.

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During the duration of the surgery, a total of 25 ml of fluid were drained by the LiquoGuard system without the need for intervention by the anaesthetist.

With a total drainage of 174 ml during the post-operative stage, the catheter was smoothly removed after 72 hours.
The patient indicated no post-operative neurological failure following a brief weaning stage. None of the feared side effects of lumbar drainage were noted.

Discussion

Spinal ischemia is a complication arising during thoracoabdominal aortic surgery. Over the past 25 years the incidence rate has ranged between 5 and 20% [7, 14]. Neurological failures such as sensorial deficit, paraparesis and paraplegia have resulted. As with so-called hybrid procedures, even modern techniques such as endoluminal stent-graft implantation in the treatment of thoracoabdominal aneurysmata (TAAA), constitute a risk of neurological failures, albeit to a lesser degree [2]. The paraparesis and paraplegia incidence rates are 4.2% and 8.5% respectively [21].
Often further complications arise during post-operative procedures, thus increasing patient morbidity. In particular, higher incidence in pneumonia and increased reintubation resulting from diaphragmatic respiratory impairment, are reported. Other examples include renal failure, urinary passage infections and major decubitus ulcers. The mortality rate with full paraplegia is recorded at about 20% [18]. Even in cases of anastasis, a complete recovery is the exception rather than the rule.
The protection of the spinal cord, therefore, is important during thoracoabdominal aorta reconstruction. The most common neurological safeguard is measuring the fluid pressure in the lumbar spinal canal and draining spinal fluid [17]. Since cross-clamping of the thoracic aorta causes increased pressure in the spinal canal, continuous lumbar drainage can reduce spinal cord compartment lesions. This increased intrathecal pressure is further strengthened by a secondary reperfusion-related tissue oedema resulting from a disturbance of the blood-spinal cord barrier [13]. The spinal cord oedema also impacts on the microcirculation. Spinal perfusion is influenced by the ratio of the spinal perfusion pressure to the tissue pressure in the osseous compartment.
Clinical data recorded in prospective randomised studies on the protection derived from spinal fluid drainage, indicate the neuroprotective advantages of spinal cord fluid drainage during and after thoracic aorta cross-clamping; these studies, however, have been repeatedly challenged [6, 8, 18]. Intraoperative spinal canal pressure monitoring is, therefore, recommended. In the event that the pressure limit of 15 mmHg is exceeded, fluid can be removed through a lumbar drainage in lying position in order to reduce the spinal pressure and raise the perfusion pressure in the spinal cord [3, 4, 12, 16]. The intraspinal pressure limit should not exceed 10 to 12 mmHg [4, 9]. Post-operative drainage monitoring is continued for another 72 hours in order to prevent a secondary pressure increase [1, 11, 17].
Temporary side effects and permanently manifest complications due to cerebrospinal fluid drainage are seldom reported in conjunction with thoracoabdominal aortic procedures. Catheter-associated meningitis (1.2%) and catheter fracture (1.8%) can be caused by the common intermittent fluid withdrawal in drop-chamber systems. Intraspinal haematoma (3.2%) and intracranial subdural haematoma due to excessive manual drainage (3.5%) are also reported [5, 10, 15, 20, 22]. From an anaesthesiological and legal perspective, therefore, indications in favour of lumbar fluid drainage are to be considered crucial [20]. In 2000, Coselli et at. [7] indicated a reduction in paraplegia and paraparesis of 80% in patients with thoracic aorta aneurysms where lumbar fluid drainage had been performed.

Conclusion

Fluid drainage within a sterile system (LiquoGuard) can minimise the incidence of temporary side effects and permanently manifest complications resulting from the particular surgical method, allowing for a broader application.

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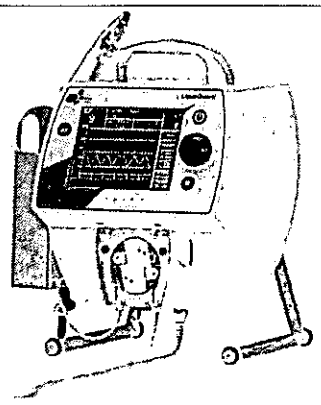

Fig. 1 LiquoGuard

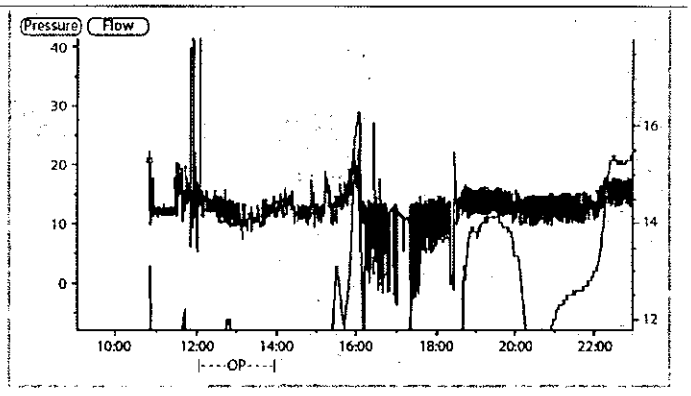

Fig. 2 Fluid pressure and flow during surgery and during the post-operative stage

Abstract

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Continuous controlled lumbar spinal fluid drainage for prevention of spinal ischemia during thoracoabdominal surgery of the aorta

Abstract

Spinal ischemia is an unresolved problem in thoracoabdominal surgery of the aorta. As a result, neurological failures such as sensory deficits occur, as well as paraparesis and paraplegia. Therefore, protection of the spinal cord during thoracoabdominal surgery is a major challenge. The most commonly used method of neurologic surveillance is measurement of spinal fluid drainage and cerebrospinal pressure in the lumbar spinal canal. Complications such as meningitis or spinal catheter fracture can be caused by intermittent fluid withdrawal in the drop-chamber system. Further complications include intraspinal hematoma and intracranial subdural hematoma due to excessive manual drainage. So far, cerebrospinal fluid drainage systems have been manual and unbalanced. Using LiquoGuard (Möller Medical), continuous pressure-controlled cerebrospinal fluid drainage has been enabled for the first time. Furthermore, this drainage system is closed and sterile, in contrast to established drop-chamber systems.

Keywords
Spinal ischemia · Thoracoabdominal surgery · Lumbar drainage · LiquoGuard

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Conflict of interest: The author declares that no conflict of interests exists.

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AUTOMATICAL PRESSURE- AND FLOW-CONTROLLED VENTRICULAR CSF DRAINAGE LIQUOGUARD®: TWO YEARS OF EXPERIENCE WITH OVER 50 CHILDREN IN PEDIATRIC NEUROSURGERY AND EPILEPSY SURGERY

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Behandlungszentrum Vogtareuth
Schön Kliniken

Automatical Pressure- and Flow-Controlled Ventricular CSF Drainage LiquoGuard®: Two Years of Experience with over 50 Children in Pediatric Neurosurgery and Epilepsy Surgery

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Klinik für Neurochirurgie und Epilepsiechirurgie, Behandlungszentrum Vogtareuth

Introduction:
At the clinical centre Vogtareuth (Fig. 1), a department of neuropediatry as well as departments for neurosurgery and epilepsy surgery is in operation. The fields of pediatric neurosurgery and epilepsy surgery are cooperating very closely. Many of the jointly treated patients are suffering from complex forms of hydrocephalus, or need at least a transient post-surgical external CSF drainage. With the legacy open ventricular CSF drains using drip chambers, the handling was unsafe in many cases, in particular on the normal care station, and complications (e.g. overdrainage) occured in some cases (Fig. 2). To ensure better patient safety, we have been using the LiquoGuard®-System (Möller Medical), since 2006 in some test cases, and since 2007 systematically.

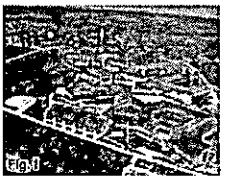

Fig. 1

Fig. 2
After functional right hemispherectomy, a CSF overdrainage of about 200ml, caused by uncontrolled mobilization, led to a expanding hygroma on the opposite side. The hygroma left had to be treated by a subdural drainage.

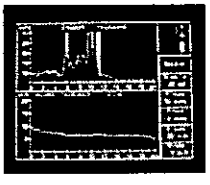

Fig. 3
History presentation (LiquoGuard®-System) of an artificial ICP increase, caused by screaming of the child (above).
The CSF flow remained constant throughout this phase. An overdrainage – as is common with legacy ventricular drains using drip chambers – did not occur.

Material and Method:
Since 2007, the common external CSF drains (drip chambers that have to be level-adjusted in relation to certain anatomical reference points) have been replaced by the LiquoGuard® system (Möller Medical) with almost all neuropediatric-neurosurgical patients. Particularly in epilepsy surgery, in connection with surgeries when a hydrocephalus condition was diagnosed, or resections of several cerebral lobes and extended opening of the ventricular system was required, this system was systematically used. Further application areas were verification of hydrocephalus diagnoses and external drains in connection with shunt infections and shunt-related complications. In total, the LiquoGuard® system was used on more than 50 children. We have analyzed and evaluated the data with regard to drainage-associated complications.

Results:
In none of the over 50 cases, the LiquoGuard® system caused any complications. Neither any overdrainage, nor any overdrainage-related complication that required surgical treatment, occurred. The advantages became even more visible, the more uncooperative, restless or mobile a child was. Neither coughing, crying/screaming (Fig. 3), unintended change of position, epileptic seizures or extreme mobility (Fig. 4) led to uncontrolled CSF losses. In these situations, had the child been treated with a drip chamber, a continuous supervision by nurses or parents would have been mandatory, since only the instantaneous closing of the drain would have prevented unintended loss of CSF.
With transient post-surgical use of the LiquoGuard® system, it was possible to remove the external drains earlier. The daily drained volumes were in some cases significantly lower, since no intended CSF losses came on top of the actually required CSF drainage volume.

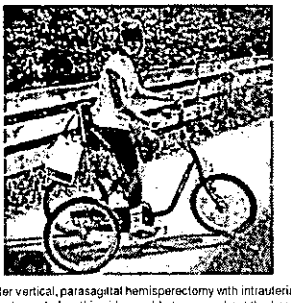

Fig. 4
Ten days after vertical, parasagittal hemisperectomy with intrauterine media infarct and hydrocephalus, this girl was able to move about the hospital grounds by bicycle with active external CSF drainage and LiquoGuard® system (visible on the bicycle carrier).

Discussion:
Especially in the neuropediatric normal care station, the significant advantages of the LiquoGuard® system as compared to a drip chamber-based system were most obvious. Patient safety with a running external ventricular drainage was increased, while supervision and nursing effort was reduced. A continuous ICP measurement supplemented supervision, especially with children in the early post-surgical phase. Overdrainage-related complications did not occur. Besides patient safety, patient satisfaction was also increased significantly, since even longer mobile phases were possible with a running system and no complications.

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THE CAMINO INTRACRANIAL PRESSURE DEVICE IN CLINICAL PRACTICE. ASSESSMENT IN A 1000 CASES

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Clinical Article

The Camino intracranial pressure device in clinical practice. Assessment in a 1000 cases

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Summary

Background. Intracranial pressure (ICP) monitoring has become standard in the management of neurocritical patients. A variety of monitoring techniques and devices are available, each offering advantages and disadvantages. Analysis of large populations has never been performed.

Patients and methods. A prospective study was designed to evaluate the Camino® fiberoptic intraparenchymal cerebral pressure monitor for complications and accuracy.

Results. Between 1992–2004 one thousand consecutive patients had a fiberoptic ICP monitor placed. The most frequent indication for monitoring was severe head injury (697 cases). The average duration of ICP monitoring was 184.6 ± 94.3 hours; the range was 16–581 hours. Zero drift (range, −17 to 21 mm Hg; mean 7.3 ± 5.1) was recorded after the devices were removed from 624 patients. Mechanical complications such as: breakage of the optical fiber (n = 17); dislocations of the fixation screw (n = 15) or the probe (n = 13); and failure of ICP recording for unknown reasons (n = 4) were found in 49 Camino® devices.

Conclusions. The Camino ICP sensor remains one of the most popular ICP monitoring devices for use in critical neurosurgical patients. The system offers reliable ICP measurements in an acceptable percentage of device complications and the advantage of in vivo recalibration. The incidence of technical complications was low and similar to others devices.

Keywords: Camino device; complications; fiberoptic device; intracranial pressure; ICP monitoring; zero drift.

Introduction

Continuous Intracranial Pressure (ICP) measurement forms part of the standard management of many patients with a wide range of intracranial disease. There are two systems to monitor intracranial pressure i.e., fluid-couples systems by placement of an intraventricular catheter, and non-fluid-coupled systems with a variety of devices developed over the last 20 years in which a miniature transducer is placed directly within the cranial cavity [29, 30]. The later group includes fibreoptic devices, the most popular of which is the Camino system. The system has been used widely in Europe and USA ever since Ostrup *et al.* first described it in 1987 [24]. Several experimental and clinical studies have been undertaken to evaluate accuracy, handling characteristics, and the complication rate of the Camino fiberoptic system [20, 23, 25, 27, 30]. Common complications of ICP monitors are infection, haemorrhage, and drift rate [30].

In our Hospital the Camino fiberoptic system for intracranial pressure monitoring has been extensively adopted in the last decade, in patients with severe intracranial pathology. The purpose of this study was to examine a consecutive series of 1000 patients in whom a ICP parenchymatous monitor had been placed in order to analyse the reliability, handling characteristics, and complication rate of the device in routine clinical practice.

Patients and methods

The present study was performed at the Hospital Clinic of Santiago de Compostela, a 700-bed University Hospital with a neurosurgical service for a population of approximately 950.000 in habitants. Between 1992–2004, 1000 consecutive patients had a fiberoptic ICP intraparenchymatous monitor placed. The ICP was measured with the Camino® intraparenchymal fiberoptic device (Model 110-4B), Camino Laboratories,

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San Diego, California). Data collected for all patients included age, sex, diagnosis, duration of ICP monitoring and complications. The ICP monitor was inserted either in the intensive care unit (ICU), or operating theatre (OT). The transducer was zeroed prior to insertion and located in the frontal region on the side of the pathology. The patient's head was aseptically cleaned with iodine povidone, and a small skin puncture was made approximately 2cm anterior to the coronal suture in the mid-pupillary line using a twist drill before inserting the catheter into the brain parenchyma.

No prophylactic antibiotics were administered either preoperatively or during ICP monitoring. Antibiotics were administered if indicated for other reasons such pneumonia, abdominal surgery or urinary tract infections. Coagulopathy was defined by abnormalities in the partial thromboplastin time, prothrombin activity, or platelet count. A new area of haemorrhage adjacent to the probe on CT resulting from intracranial bleeding attributed to the device was evaluated as a complication.

A CT scan was performed in 922 patients after insertion of the fiberoptic system; the position of the tip was confirmed and occurrence of hematoma related to probe insertion was evaluated. In 547 fiberoptic catheter tips were removed in an aseptic manner and sent to the laboratory for culture.

In 624 patients zero drift was measured by monitoring the pressure signal when the probe was removed and after waiting 20–30 seconds. The recorded drift of each ICP system was documented. From these values, including negative and positive numbers, the actual mean drift was calculated; in the remaining 376 patients the zero drift was not recorded after removal because the device had been removed by the nurse or during the monitoring time as the device was momentarily removed for recalibration.

The data are expressed as mean ± SD for continuous variables and relative and absolute frequencies for categorical variables. Statistical analysis was performed using Student's *t* test and linear regression analysis. Differences were considered statically significant when $p<0.05$.

Results

From January 1992 to December 2004, 1071 consecutive Camino® intraparenchymal ICP probes were placed in 1000 patients. Sixty two patients received a second parenchymal fiberoptic probe and nine patients received a third parenchymal Camino device either due to mechanical complications (n = 49) or a new surgical intervention (n = 22). Sixty one per cent were male (611 males and 389 females). Average age was 45.6 ± 15.8 years (range 11 m–88 y), and the score on the Glasgow coma scale on admission ranged from 3 to 12.

Table 1. *Indications for ICP monitor placement*

Diagnosis	No. of cases	%
Traumatic head injury	679	67.9
Subarachnoid haemorrhage	113	11.3
Intracerebral hematoma	82	8.2
After surgery	82	8.2
Hydrocephalus	21	2.1
Arteriovenous malformation	8	0.8
Meningitis-Encephalitis	5	0.5
Others	28	2.8
Total	1000	100

The causes of the neurological disease requiring ICP monitoring are summarised in Table 1. Traumatic head injury accounted for 67.9% (n = 679), followed by 113 subarachnoid haemorrhage (11.3%), 82 intracerebral hematomas, 8 arteriovenous malformations. The fiberoptic ICP monitor was placed in the intensive-care unit in 754 patients (75.4%) and in the operating room in 246 patients (24.6%). The mean monitoring time was 184.6 ± 74.3 hours (range 16–581 hours) (Fig. 1).

Zero drift

In 624 patients zero drift was measured by monitoring the pressure signal when the probe was removed, zero

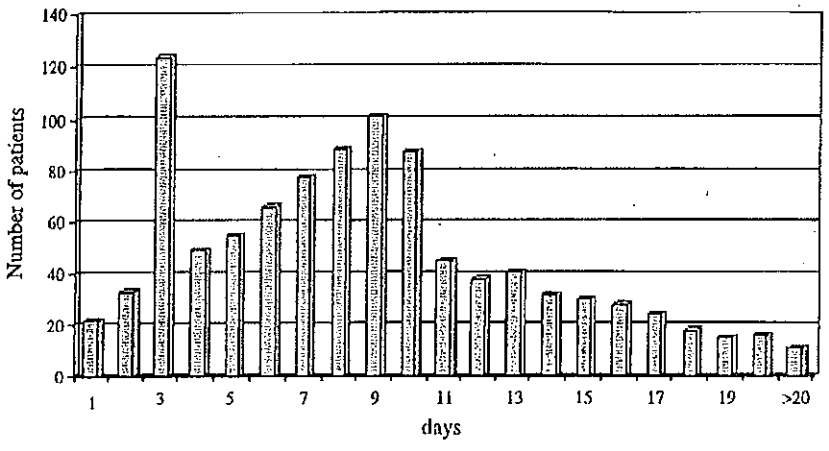

Fig. 1. Distribution of ICP monitoring duration (days)

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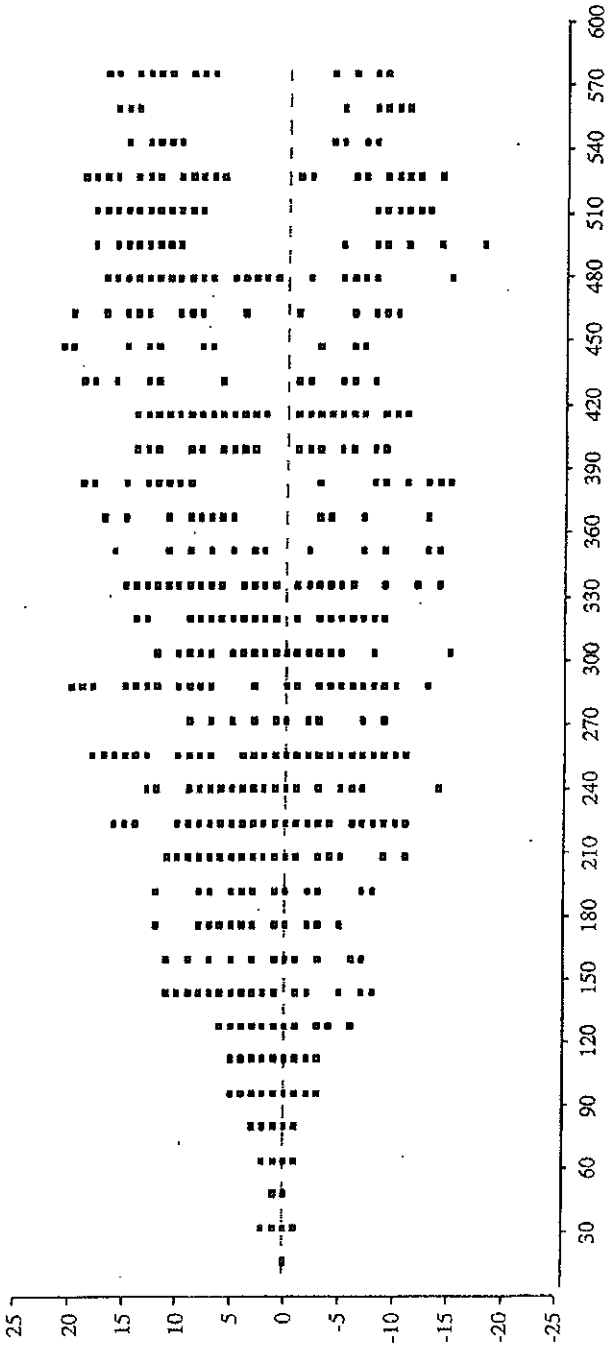

Fig. 2. Measuring time of the Camino devices versus actual drift after removal. The actual mean drift was 7.3 ± 5.1

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drift ranged from −17 to 21 mm Hg (mean 7.3 ± 5.1). In 322 sensors, a negative reading was obtained (mean 5.3 ± 3.8) ranging from −1 to −17. In 223 readings were positive (mean 8.1 ± 4.2) ranging from 1 to 21 (Fig. 2). Only 79 sensors (12.6%) showed no zero-drift (0 mm Hg reading) on removal, and mean monitoring time was 58.4 ± 8.6 hours (range 16–114 hours). No significant correlation was found between zero drift and monitoring time ($p = 0.316$), ($p = 0.211$), and ($p = 0.098$) for global, negative and positive drift.

Recalibration was performed in 94 fiberoptic devices, 11 devices were recalibrated twice during the monitoring period, of which 7 were infected.

Infection

Bacteriological analysis was performed in 547 probe tips, and cultures were negative in 91.5% of these (501 cases). Positive cultures were found in 8.5% (46 cases). Staphylococcus epidermidis was the main pathogen in this series, occurring in 22 of 46 cases (47.8%). In the remaining thirteen sensors, cultures were positive for Escherichia coli ($n = 9$), Corynebacterium ($n = 5$) (Table 2). No patients presented a cutaneous infection at the site of bolt insertion. No significant differences were found between patients who had more than one probe implanted. There was no statistical significance in the location of ICP monitor placement (OT or ICU) and the incidence of positive catheter tip cultures ($p < 0.45$).

Hemorrhagic complications: Abnormality in at least one coagulation parameter was observed in 87 patients (8.7%), and seven cases had a postoperative bleed (8%) but of no clinical relevance.

Bleeding rate in patients without coagulopathy was 1.9% (18/903). There were radiological findings in all of the cases but were clinically relevant in only 6 (0.66%) (4 intraparenchymal haemorrhage, 2 epidural haematomas). The overall (including patients with and without coagulation disorders) bleeding rate was 2.5%.

Table 2. *Microbial pathogens isolated from the probe tips*

	No. of cases	%
Staphylococcus epidermidis	22	47.9
Escherichia coli	9	19.7
Corynebacterium	5	10.9
Staphylococcus aureus	3	6.6
Haemophilus influenzae	2	4.3
Klebsiella	2	4.3
Streptococcus spp.	1	2.1
Serratia	1	2.1
Pseudomona aeruginosa	1	2.1
Total	46	100

Table 3. *Technical complications in 49 cases*

Complication	Number	(%)
Breakage of the optic fiber	17	34.7
– During nursing or transport	10	20.4
– Patient activity	4	8.1
– For unknown reasons	3	6.1
Dislocation of the screw	15	30.7
Dislocation of the probe	13	26.5
– During nursing or transport	8	16.3
– Patient activity	3	6.1
– For unknown reason	2	4
Failure for unknown reasons	4	8.1
Total	49	100

Technical complications

Complications such as breakage of the optical fiber ($n = 17$) or dislocation of the fixation screw ($n = 15$) or the probe ($n = 13$) as well as failure of ICP recording for unknown reasons ($n = 4$) were found in 49 Camino® devices (4.5%). Most of these complications occurred during nursing manoeuvres, during transport of the patient to CT scan or patient activity (Table 3).

Discussion

ICP monitoring has been used in clinical practice for more than 4 decades, but evidence from randomized controlled trials in support of this intervention is lacking [31]. The first monitoring of intracranial pressure was described by Guillaume and Janny in 1951 using an indwelling intraventricular catheter attached to an external strain gauge transducer, amplifying system, and chart recorder [12]. Its use became routine after Lundberg's publication in 1961 describing accuracy in reading normal and abnormal intracranial pressure waves [18]. In the 1970's, subarachnoid screws, and subdural and epidural monitors were described and commonly used, when appropriate, in place of ventricular puncture [13].

Intraventricular pressure is considered to be the gold standard in ICP monitoring, and is the benchmark by which all others systems are compared [17]. Although ICP monitoring has become routine, there are no guidelines regarding the choice of intraparenchymal fiberoptic or and intraventricular catheter when monitoring is desired after traumatic brain injury [1]. The choice is

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at present dictated primarily by the surgeon's personal preference since both types of monitors offer advantages and disadvantages. The most accurate method of measurement i.e., placement of an intraventricular catheter, is now seldomly used due to its invasive nature and the risk of infection as well as the availability of fiberoptic devices that can be conveniently inserted in the intraparenchymal/subdural space at the patient's bedside [7]. The advantage of the fiberoptic monitoring device system is the ease of placement i.e., it allows direct measurement of brain tissue pressure in patients with compressed or dislocated ventricles in which placement of an intraventricular catheter would be difficult and eliminates several of the problems associated with hydraulic systems [24, 25, 30, 32]. The quality of pressure waveforms obtained is higher [25] and the absolute ICP value and amplitude are not subjected to damping or to the presence of air bubbles or blood clots within the catheter. The main disadvantages of the fiberoptic transducers are their cost and that drifts in calibration cannot be readjusted once in situ [25].

The Head Injury Management Guidelines published by the Brain Trauma Foundation in 2000 recommended intraventricular ICP measurement as the first-line approach to monitoring ICP "In the current state of technology, the ventricular catheter connected to an external strain gauge is the most accurate, low-cost, and reliable method of monitoring intracranial pressure (ICP). It also allows for therapeutic cerebrospinal fluid drainage" [5]. Despite the publication of these guidelines, fiberoptic intraparenchymal pressure monitoring remains popular given that it is reliable, easy, and quickly implanted. Extensive clinical and laboratory experiences using this system has been reported with optimum results in several trials [4, 9, 20, 24, 25].

Zero-drift

The drift of ICP probes is normally calculated as the difference between the initial and final pressure after given period of time; thus, it is one of the most important parameters since it reveals deviations from the patient's real pressure [8]. The nature of the drift of ICP probes is not fully understood and may be due to the inability to measure constantly the same pressure as a result of mechanical defects of the probe and the material used [22]. The manufacturer's specification for zero drift of the Camino device is ±2 mm Hg for the first day and ±1 mm Hg/d thereafter. Czosnyka *et al.* [8] confirmed these zero-drift findings in bench test studies, although they also reported, that the temperature drift of the device was significant (0.3 mm Hg/1 °C). In our study no correlation between the duration of monitoring and zero drift ($p = 0.316$) was observed, which is contrary to the findings of previous studies which showed a linear drift pattern in a positive or negative direction [6, 21]. However, probes have often been observed to exhibit a nonlinear drift pattern, and appear to reveal positive and negative drift consecutively hence the need for a more precise way to calculate the "drift index" during long-term ICP measurements [22]. Accordingly, the drift index consists of three parameters: 1) The percentage of measurements which involve a pressure change during a 10 day period; 2) The maximum absolute pressure deviation which occurs during the ten day period, and 3) The mean absolute pressure deviation during the 10 day period. In the Camino® device the median percentage of pressure change was 1.6% of; the maximum pressure change was upto the 6 mm Hg. The median values for the mean absolute pressure changes were: Camino®: 2.9 mm Hg, and the 10 days drift measurement was: 4 mm Hg (for the Camino®) [22].

Infection

The role of prophylactic antibiotics in preventing infection associated with intracranial pressure monitoring is not well defined. Prabhu *et al.* [26] in an extensive review of the literature analyzed the indication for prophylactic antibiotics in patients with ICP monitoring; the authors reviewed 85 relevant articles but most were retrospective, nonrandomized, nonblind trials, without adequate controls or patient numbers. Appropriate indications for prophylactic antibiotics have not been clearly established, whereas the indiscriminate use of antibiotics can theoretically results in infection from resistant organisms, anaphylactic reactions, increased bleeding time, and systemic toxicity. This study does not resolve the controversy regarding the role of antibiotics with ICP monitoring and questions the efficacy of administering antibiotics during this procedure. Nevertheless, the use of PAB should be determined in relation to the infection profile of each hospital in terms of the antimicrobial spectrum, bio-availability, side effects, and the antibiotic cost-efficacy ratio. Jacobs and Westerband [14] determined the safety and efficacy of prophylactic antibiotics in head-injuries requiring ICP monitoring, and observed that patients who received prophylactic antibiotics demonstrated statistically higher septic morbidity rates (78.6% versus 31.3%), and statistically

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higher pneumonia rates (57.1% versus 18.8%) compared with patients who did not receive antibiotics. The authors concluded that the administration of prophylactic antibiotics during ICP monitoring for head-injuries was unnecessary and potentially detrimental.

Haemorrhage

Haemorrhage depends on the compartment where the device is placed, and the existence of a coagulation disorder [20]. Other authors recommend that the coagulation disorder must be corrected before placing the probe, and if this is not possible, other less invasive types of devices such as an epidural probe should be used [16]. The discrepancy in the incidences of intracranial haemorrhages following the placement of an ICP monitoring device reported in the literature is considerable, ranging from (0–15.3%). However, most studies do not distinguish between large haematomas requiring surgical evacuation and small pinpoint haemorrhages detected incidentally only on imaging [3, 21]. In our series, we found a complication rate of 2.5% (25 patients), similar to that reported in the literature [4, 21], though only 6 cases required surgical evacuation.

Recently Davis *et al.* [10] studied the risk of haemorrhagic complications due to intracranial pressure monitors in patients with abnormal coagulation parameters, and concluded that in patients with coagulations disorders haemorrhagic complications after ICP monitor placement were infrequent and the use of fresh frozen plasma to correct coagulation parameters to "normal" is not supported by the study and delays monitor placement. A study on the safety of twist-drills in 1032 cranial perforations revealed that only four procedures (0.38%) caused clinically significant bleeding attributed to the twist-drill, all of which were managed conservatively without requiring surgical evacuation [19].

Technical complications

A total of 49 cases (4.5%) of technical complications were observed in the 1071 devices inserted. Our technical complication rate is acceptable when compared with other reported rates: 25.4% Schürer *et al.* [27], 23.5% Münch *et al.* [23], 17.8% of Bavetta *et al.* [2], and 13% Jensen *et al.* [15]. Fiberoptic breakage and dislocation usually occurs during nursing procedures or medical manouvering [28] and is usually detected by a sudden loss of functioning. Münch *et al.* [23] pointed out that the rigid fiberoptic cable sticking out of the head and the fixation screw are responsible for dislocation, accidental removal of the probe and breakage of the optical fiber.

In conclusion intracranial pressure measurement with the Camino intraparenchymal device offers reliable ICP recordings in the majority of the measurements. The mean drift of the system is acceptable, and similar to others devices. The system offers the advantage of recalibration in vivo in cases with suspected erroneous readings, and permits the relocation of the device through the same twist-drill without increasing the infection risk. When used correctly, the incidence of mechanical complications and the rate of infections are very low.

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Comment

This large study by Gelabert-González *et al.* demonstrates low infection and complication rates of Camino ICP transducers. It also examines the important question of drift in the zero point. Because this is set prior to implantation and cannot easily be checked or changed afterwards, any significant drift may cause inappropriate readings to be recorded. Zeroing and recalibrating transducers are often confused. It is extremely difficult to change the calibration of a device but re-zeroing (i.e. checking the transducer is measuring 0 mmHg at atmospheric pressure) is difficult as it clearly increases the risk of infection.

The ease by which parenchymal pressure transducers can be inserted combined with low infection and complication rates adds to the evidence supporting the utility of such devices. However the zero drift characteristics may still be of concern to users. The data presented (Fig. 2) suggests than in patients monitored for less than 100 hours, at the end of the monitoring period the device did not drift more than ±4 mmHg which is clinically acceptable. However for longer monitoring periods, high levels of drift, up to ±20 mmHg, were found.

Although the authors present the results in terms of a drift index and conclude that the Camino device is reliable in the majority of measurements, this is not borne out by their results. Their data may suggest that for extended monitoring periods there are unacceptably high levels of drift that would cast doubt on the accuracy of the measurements. Douglas Miller was a great proponent of the idea that an inaccurate measurement was worse than no measurement at all. Perhaps we should remember this when monitoring ICP over extended periods with the Camino system.

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MULTICENTER CLINICAL ASSESSMENT OF THE RAUMEDIC NEUROVENT-P INTRACRANIAL PRESSERE SENSOR: A REPORT BY THE BRAINIT GROUP.

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MULTICENTER CLINICAL ASSESSMENT OF THE RAUMEDIC NEUROVENT-P INTRACRANIAL PRESSURE SENSOR: A REPORT BY THE BRAINIT GROUP

OBJECTIVE: The aim of this study was to evaluate the robustness and zero-drift of an intracranial pressure sensor, Neurovent-P (Raumedic AG, Münchberg, Germany), when used in the clinical environment.

METHODS: A prospective multicenter trial, conforming to the International Organization for Standardization 14155 Standard, was conducted in 6 European BrainIT centers between July 2005 and December 2006. Ninety-nine catheters were used. The study was observational, followed by a centralized sensor bench test after catheter removal.

RESULTS: The mean recorded value before probe insertion was 0.17 ± 1.1 mm Hg. Readings outside the range ±1 mm Hg were recorded in only 3 centers on a total of 15 catheters. Complications were minimal and mainly related to the insertion bolt. The mean recorded pressure value at removal was 0.8 ± 2.2 mm Hg. No relationship was identified between postremoval reading and length of monitoring. The postremoval bench test indicated the probability of a system failure, defined as a drift of more than 3 mm Hg, at a range between 12 and 17%.

CONCLUSION: The Neurovent-P catheter performed well in clinical use in terms of robustness. The majority of technical complications were associated with the bolt fixation technology. Adverse events were rare and clinically nonsignificant. Despite the earlier reported excellent bench test zero-drift rates, under the more demanding clinical conditions, zero-drift rate remains a concern with catheter tip strain gauge technology. This performance is similar, and not superior, to other intracranial pressure devices.

KEY WORDS: Intracranial pressure, Multicenter trials, Physiological monitoring, Technology assessment

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In the 1950s, the first practical method for the clinical monitoring of intracranial pressure (ICP) was developed, and not long after that, its clinical value was demonstrated by Lundberg (8, 10). However, despite nearly 50 years of experience with this technology, the accurate and reliable measurement of ICP in the clinical setting remains a challenge.

Catheter tip pressure sensors, which rely on the technology of miniaturization, are likely to cause less damage to tissue than larger, fluid-filled catheters. As there is no separation between the point of measurement and the pressure sensor, catheter tip sensors are not affected by hydrostatic pressure differences. However, because of the reliance on miniaturization of the sensors and the interconnecting technology, these devices are more prone to problems of robustness. Also, because the pressure sensor is at the tip of the catheter and its reference zero level cannot be checked after insertion, the technology must exhibit minimal in vivo zero-drift over several days of measurement. There are several catheter tip devices on the market which, although performing well in bench test studies, have exhibited unacceptable zero-drift, robustness, or both, in studies conducted in the clinical environment (3, 5, 13, 15–17, 19–21, 23).

To reduce the physical size of the strain gauge catheter tip, usually only a partial Wheatstone bridge (an electrical bridge circuit used to measure resistance) is used, particularly because of the difficulty of producing robust multiple electrical connections in the miniature catheter tip design. Recently, a new

ABBREVIATION: ICP, intracranial pressure

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technology has become available, the Neurovent-P (Raumedic AG, Münchberg, Germany), in which a full Wheatstone bridge is fabricated at the catheter tip together with integral miniature multiwire technology. This solution should, in theory, provide improved zero-drift characteristics. A recent 2-center study conducted in Germany studied the incidence of zero-drift, rate of placement-induced parenchymal hemorrhage, magnetic resonance imaging compatibility, and robustness of this new ICP probe (22).

As a prerequisite for a clinical trial, the BrainIT group conducted and reported on an independent bench test study of the Neurovent-P catheter, which confirmed the manufacturer's long-term zero-drift performance for this technology (4). The results of that study demonstrated that mean zero-drift, after 5 days, was very small, and long-term continuous recording of a stable pressure was very precise. The response in dynamic tests, i.e., the changes of pressure over a wide range, was excellent. The average bias of the Raumedic catheter compared with a known pressure is very small. However, controlled laboratory conditions can be a very different environment from the clinical setting, and although devices may perform satisfactorily in the laboratory, they also need to be evaluated in clinical use. The aim of this study was to evaluate the robustness and zero-drift of this technology when used in the clinical environment in a prospective multicenter trial.

PATIENTS AND METHODS

The present prospective multicenter trial involved 6 BrainIT (www.brainit.org) centers (Barcelona, Heidelberg, Monza, Newcastle upon Tyne, Uppsala, and Vilnius; see Appendix), where patients in whom ICP monitoring was clinically indicated were enrolled between July 2005 and December 2006.

This study conformed to the International Organization of Standardization 14155 Standard, "Clinical Investigation of Medical Devices for Human Subjects." The model used was one of an investigator-led study design with the BrainIT group coordinating center's host institution (Southern General Hospital, Glasgow, Scotland) acting as the study sponsor. The BrainIT group has a regional language-based coordination, data validation, and study monitoring infrastructure in place to provide the required trial monitoring.

The study hypotheses were that, during typical clinical use, Neurovent-P catheters: 1) maintain accuracy of calibration as measured by postremoval zero-drift and postremoval bench test calibration; 2) are robust, as measured by catheter/cable system failure rate; and 3) are easy to implant and set up, as measured by a structured survey questionnaire of neurosurgeons and bedside nurses involved in the implantation and use of the system.

The inclusion criteria were: 1) clinical indication for ICP monitoring using an intraparenchymal probe, in keeping with the local guidelines; 2) estimated monitoring time longer than 24 hours; and 3) minute-by-minute recording of ICP with a bedside data collection tool.

The exclusion criteria were: 1) age younger than 16 years, 2) no clinical indication for ICP monitoring, 3) coagulopathy, 4) expected monitoring duration less than 24 hours, and 5) no bedside data collection of ICP available.

Patients in whom an increase in ICP was suspected, satisfying the inclusion criteria, were monitored with an intraparenchymal pressure probe. All ICP probes were inserted through a frontal burr hole. The location was chosen according to local guidelines; in general, this was the right frontal lobe. The Neurovent-P probes were implanted either through the bolt kit or introduced with a twist drill and tunneled subcutaneously. A questionnaire was completed by the neurosurgeon after every implantation to collect information on the procedure. The probe was electrically zeroed to a patient monitor and implanted according to the manufacturer's specifications. The probe placement depth and side of placement were recorded. Minute-by-minute ICP data were collected together with the BrainIT core data as standard.

Recording of Adverse Events

During the course of the study, all adverse events and technical complications were recorded. Adverse events were defined as any undesirable clinical occurrence in a subject, whether it was considered device related or not, such as cerebrospinal fluid infection or cerebral hematoma. Cerebral hematomas were classed into 3 grades: small punctate hemorrhages or localized subarachnoid hemorrhages (I), larger bleeds that did not cause a new neurological deficit or required surgical evacuation but might alter ICP readings (II), and hemorrhages that caused a new deficit or necessitated surgical removal (III). Technical complications were defined as an event or device failure associated with no deviation from a patient's baseline health, such as measuring errors, probe dislocation or unplugging, and probe damage because of cable rupture or pronounced kinking of the sensor. We analyzed whether these complications occurred during nursing maneuvers, during transport of the patient, or for other reasons.

Data collection stopped when a clinical decision was made to remove the ICP monitor from the patient. On removal of the ICP catheter from the patient, the postremoval zero-drift was checked after a stable reading had been achieved.

After removal, all catheters were sent to Monza for bench testing. Using methods and laboratory equipment described previously (14), we tested the zero-drift and dynamic response of the system to changes of pressure in a stepwise fashion, from 5 to 20 mm Hg. Before starting each experimental run, we verified the recorded pressure value, and any sensors that were damaged after removal from the patient were discarded before bench testing. A progressively increased hydrostatic pressure was produced, starting at 0 and rising to 20 mm Hg.

Sample Size Calculation and Statistical Analysis

Evidence from previous work with the Raumedic ICP probe showed that zero-drift had been recorded as 0.2 ± 0.41 mm Hg initially, as 1.7 ± 1.36 mm Hg after monitoring was completed, and 0.6 ± 0.9 mm Hg after 5 days on bench testing (4, 22). To be able to calculate the failure rate, clinically defined as a zero-drift of ±3 mm Hg or more, it was necessary to observe at least 1 failure (1). The probability of observing a drift of ±3 mm Hg or more for different values of mean pressure and standard deviation were calculated. A sample size of 100 catheters would yield a 95% chance of including at least 1 failure if the standard deviation was 1.5, whatever the size of the mean drift, and a 95% chance of including at least 1 failure if the standard deviation was 1.0 and the mean drift was 1.3 mm Hg or more. Using this approach, we designed the study to collect data from 100 catheters. For the bench test studies, summary statistics reported include mean, median, maximum, minimum, standard deviation, and the 25th and 75th percentiles. The measured pressure for the dynamic tests was compared with the "gold standard" (hydrostatic water column). Splus 2000 software (Mathsoft, Inc., Seattle, WA) and SPSS software (Version 14; SPSS, Inc., Chicago, IL), were used to perform statistical analyses.

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TABLE 1. Patient distribution among centers, percentage of bolt use, depth of introduction, site of introduction, and percentage of traumatic brain injury[a]

Center	Patients		Bolt use (%)	Depth of introduction (mm)	Right frontal position (%)	Traumatic brain injury (%)
	No.	%				
Monza	28	28.3%	0	39.2 ± 8	24 (86%)	23 (82%)
Uppsala	25	25.3%	0	28.1 ± 1.3	20 (80%)	19 (76%)
Barcelona	23	23.2%	16 (76%)	46.8 ± 8	18 (78%)	19 (82%)
Vilnius	14	14.1%	0	20.7 ± 2	12 (85%)	14 (100%)
Newcastle	5	5.1%	5 (24%)	54 ± 1.1	5 (100%)	0
Heidelberg	4	4.0%	0	37.5 ± 1.6	2 (50%)	3 (75%)
Total cases	99	100%	21 (21%)	36.9 ± 1.3	81 (81%)	78 (78%)
P value			≤0.0001	≤0.0001	NS	≤0.0001

[a] NS, not significant.

RESULTS

Clinical Results

Population

Ninety-nine catheters were placed in patients, with a variable distribution between centers ranging from 4 to 28 cases/center (Table 1). Two catheters were not implanted because of technical problems (2 sensors were damaged by the surgeon during the procedure).

The main pathology was traumatic brain injury (78 patients, 78.8%), followed by miscellaneous pathologies (12 patients, 12.1%), subarachnoid hemorrhage (5 patients, 5%), and hydrocephalus (4 patients, 4%). The fixation bolt was used in 21% of the cases, with significant differences between centers. In 81% of the patients, the sensor was introduced in the right frontal lobe. The mean depth of placement into the parenchyma was 36.9 ± 13.6 mm, with significant intercenter differences. The mean duration of monitoring was 138.7 ± 118 hours (25th percentile, 50 hours; 75th percentile, 192 hours).

Preinsertion Zero-drift

Data were available from 76 catheters. The distribution of the values is presented in Figure 1. The mean recorded value before the probe insertion was 0.17 ± 1.1 mm Hg (median, 0 mm Hg; 25th and 75th percentile, 0 mm Hg).

Readings outside the range −1 to +1 mm Hg were recorded in only 3 centers on a total of 15 catheters (2 in Newcastle upon Tyne, 10 in Vilnius, and 3 in Uppsala; analysis of variance, not significant).

Complications at Insertion and during Use

Some centers pointed out difficulties in using the fixation probe at insertion and/or removal. Most of these incidents were recorded in the early patients: 1 probe was damaged by the surgeon before insertion, 1 defective cable was suspected, 3 probes were difficult to remove, 3 probes provided unreliable

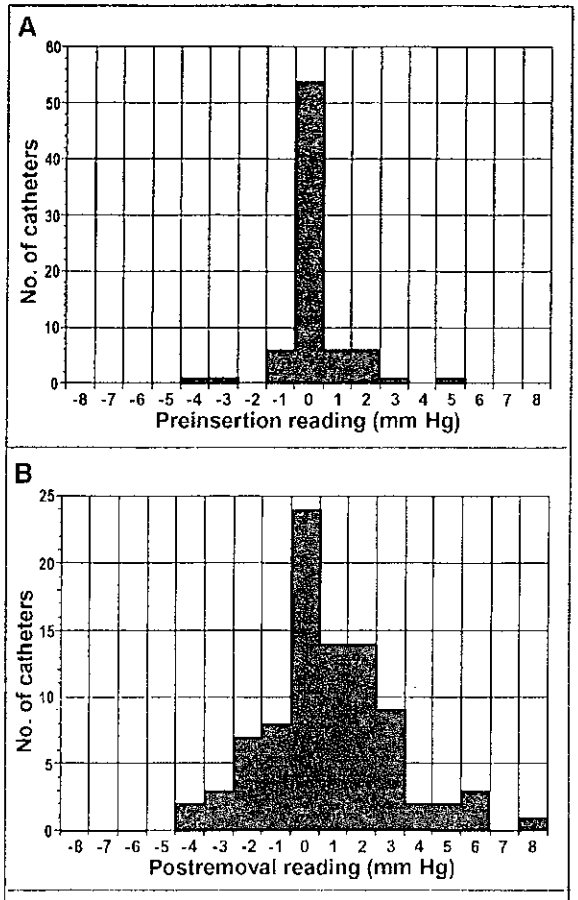

FIGURE 1. A, *graph showing distribution of the preinsertion values.* B, *graph showing distribution of the values at removal.*

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readings (checked with other systems), 5 probes had problems with the bolt, 2 probes were defective, 0 probes broke, 4 probes were dislocated (2 during surgery, 1 during nursing, 1 during radiology), 0 patients had central nervous system infection, and 2 patients had Grade I hematomas.

Postremoval Zero-drift

Data were available for 89 catheters, mainly because of damage during the removal phase that prevented the adequate recording of the postremoval zero reading. Distribution of the values is presented in Figure 1. The mean recorded value at removal was 0.8 ± 2.2 mm Hg (median, 1 mm Hg; range, −4 to 8 mm Hg; 25th percentile, 0 mm Hg; 75th percentile, 2 mm Hg). Statistically, but not clinically, significant differences were recorded between centers: Barcelona, 0.7 ± 1.7 mm Hg; Heidelberg, 2 ± 0 mm Hg; Monza, 0.7 ± 2.2 mm Hg; Newcastle upon Tyne, 1.2 ± 3.9 mm Hg; Uppsala, 1.7 ± 2.6 mm Hg; Vilnius, −0.3 ± 1.2 mmHg (analysis of variance, $P = 0.006$). Failures, defined as a recorded zero-drift of ±3 mm Hg or more, were identified in 22 cases. No relationship between failure and length of monitoring was identified (Fig. 2).

Bench Test Results

Continuous Readings at 0 to 20 mm Hg

Testing the recorded value after the application of a variable pressure, ranging from 0 to 20 mm Hg, the probability of a system failure, defined as a drift of more than 3 mm Hg, was estimated to range between 12 and 17% (Table 2).

Differences between Observed and Applied Hydrostatic Pressure

The box-and-whisker plot (Fig. 3) demonstrates the distribution of the differences between the observed and applied pressures at each of the applied pressure values and illustrates the

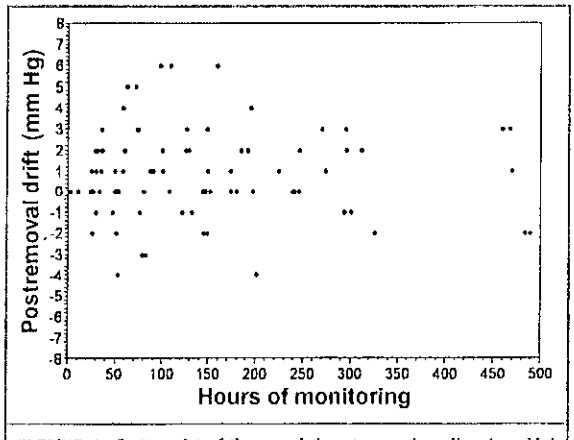

FIGURE 2. *Scatter plot of the recorded postremoval reading (mm Hg) and duration of monitoring (h).*

many observations of more than 3 mm Hg (i.e., 2 standard deviations) from the applied pressure. To confirm whether this was because of a consistent drift across the applied pressure values in individual catheters, e.g., whether a catheter consistently recorded a value 4 mm Hg above the applied level, we investigated the difference between the observed readings of individual catheters at an applied pressure of 5 mm Hg and an applied pressure of 0 mm Hg, and so on. For each individual catheter, we would expect the difference in observed pressures to remain at 5 for each 5-mm Hg increase in pressure. Table 3 shows that this was not the case; for instance, a catheter might have an observed pressure of 11 mm Hg when the applied pressure was 10 mm Hg and an observed pressure of 19 mm Hg when the applied pressure was 15 mm Hg.

DISCUSSION

The accuracy and reliability of different methods of measurement for ICP remains a critical problem during management of acutely brain-injured patients, particularly of patients with severe head injuries in whom ICP monitoring is an accepted standard of care.

To guide therapy decisions, accurate measurement of ICP is essential. As the treatment threshold for increased ICP is low (20 mm Hg), relative to the physiological range of pressure that can be monitored with this technology (typically, 100 mm Hg), a measurement accuracy of 1 to 2% is required (16). For this reason, we predefined a failure as a reading of more than ±3 mm Hg. Use of systems with poor accuracy or unacceptably high zero-drift could lead to inappropriate treatment or, worse still, failure to treat when treatment is warranted.

The gold standard for ICP measurement remains the fluid-coupled ventricular catheter attached to an external pressure transducer. The advantage of this approach is that by using an externally mounted transducer, zero-drift and calibration can be checked and corrected, if necessary. This approach, however, is not without difficulties, especially in comatose head-injured patients, in whom the ventricle can be difficult to puncture; an additional risk of infection is reported with this type of catheter. For these reasons, catheter tip-mounted pressure sensor technology offers advantages. With this technology, pressure is measured at the tip of the probe, and consequently, ICP is measured directly in the parenchyma. Furthermore, this technology allows monitoring of patients in whom it is difficult to puncture the cerebral ventricles, and it avoids the problem of hydrostatic pressure differences. The main disadvantage of such catheter tip technology is that once placed into the patient, any zero-drift cannot be checked for or corrected. For this reason, it is critical that catheter tip devices are stable and robust and that their zero-drift characteristics remain within the known manufacturer's specifications.

The catheter tip systems most frequently used in the management of head-injured patients (Camino and Codman) do not allow pressure calibration to be performed in vivo, and so they cannot be corrected for inherent zero-drift after catheter placement. One of the potential advantages of the system we

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TABLE 2. Pressure recorded during the bench test after the application of a variable pressure ranging from 0 to 20 mm Hg and estimate of the probability of a system failure[a]

Pressure (mm Hg)	Mean	SD	U	Min	Max	Percentile 25	Percentile Med	Percentile 75	Drift	Probability of system failure[b]
0	0.55	2.33	± 4.7	−7	6	0.0	1.0	2.0	0.55 ± 2.3	13%
5	4.83	2.44	± 4.9	−4	9	4.0	5.0	6.0	−0.17 ± 2.4	12%
10	10.04	2.56	± 5.1	1	15	9.0	11.0	12.0	0.04 ± 2.6	13%
15	15.07	2.65	± 5.3	6	19	14.0	16.0	17.0	0.07 ± 2.6	13%
20	20.28	2.94	± 5.9	7	25	20.0	21.0	22.0	0.28 ± 2.9	17%

[a] SD, standard deviation; U, uncertainty; Min, minimum value; Max, maximum value; Med, median.
[b] System failure is defined as a drift of more than 3 mm Hg.

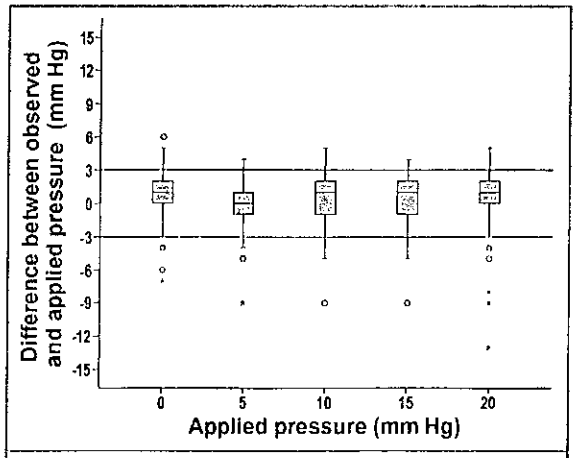

FIGURE 3. *Box-and-whisker plot (representing the 25th and 75th percentiles) showing the distribution of the differences between the observed and applied pressures at each of the applied pressure values, and the number of observations more than 3 mm Hg from the applied pressure.*

tested is the incorporation of a full Wheatstone bridge into the catheter tip electronics. This technological improvement should enhance the zero-drift characteristics by reducing temperature sensitivity and the effects of non-pressure-related external strains. Until recently, this approach was only possible in the physically much larger external strain gauge systems. Through advances in miniaturization technology, it is now feasible to incorporate this technology into small catheter tip systems. Despite our promising bench test study results, further work was required to determine the performance of this measurement device in the clinical environment.

After these bench tests were performed, the next and most critical step was to conduct a trial of this technology in the more demanding clinical environment. The BrainIT group, as a multicenter collaborative group of neurointensive care scientists and clinicians, were well placed to design and conduct such a trial. All participating centers had great clinical experience with various ICP monitoring devices.

TABLE 3. Bias data at different levels of pressure[a]

Difference (mm Hg)	Mean ± SD (mm Hg)	No. >8 or <2
0–5	4.28 ± 1.63	6
5–10	5.20 ± 0.68	0
10–15	5.04 ± 1.18	3
15–20	5.20 ± 1.12	3

[a] SD, standard deviation.

Issues Raised during the Multicenter Study

As in many multicenter trials, enrollment was slower than expected, and, because of local difficulties, some centers were not able to enroll the expected 15 cases. The cases are predominantly but not exclusively traumatic brain injuries, representing the use of ICP devices in other clinical conditions.

In this trial, there was no period of specific training or specific recommendations regarding insertion depth or whether to use the bolt or not. This could have an important influence on some of the problems detected in this study. In fact, a wide intercenter variability in the depth of probe placement was recorded across centers, ranging from 20 to 54 mm, with an average of 37 mm. These depths refer to distance from the end of the bolt or from the inner cranium. One of the helpful features of the Neurovent-P catheter is that number markings are recorded on its surface, thus making it easier to verify the actual placement depth. Unlike some bolts that have a physical stop, limiting depth of placement, this is not the case with the Raumedic bolt. It is surprising to find such a large intercenter variation, and perhaps this is in part a result of a lack of consensus or manufacturer guidelines for the depth of placement.

There were more technical complications reported than expected, with nearly 10% attributable to difficulties with the bolt fixation either on placement or removal. The bolt was difficult to remove in a number of patients, which could be an important problem in clinical use in countries where this is the preferred method of placement. However, bolts are not required by this device, and it can be easily implanted with a twist drill and safely tunneled.

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Adverse events were rare, with no infections and only 2 clinically nonrelevant hematomas. A higher-than-expected postremoval zero-drift was recorded and confirmed by postremoval bench test results. The probability of a catheter exhibiting a zero-drift rate of greater than ±3 mm Hg (failure) was pressure-dependent, with a 13% probability for low-pressure testing, which increased to 17% at a test pressure of 20 mm Hg. We consider this to be unacceptably high. We are unsure as to the root cause of the drift values outside this range, as they did not appear to be related to the center, physiological monitor, or any visible defect. A much larger study would be required to explore this aspect.

In general, the result of ICP measurement is only an approximation of the ICP value, and thus the ICP measurement result is complete only when accompanied by a quantitative statement of its uncertainty (6, 7, 12). We found that the postremoval uncertainty of the Neurovent-P catheter (Table 2) was within the limits ±4.7 to ±5.9 mm Hg (95% confidence interval). That uncertainty propagates to the uncertainty of clinical treatment decisions and to the uncertainty of the conclusions of ICP pathophysiology scientific studies. The challenge for ICP sensor manufacturers is to decrease that absolute ICP value measurement uncertainty to the clinically acceptable level of ±3.0 mm Hg or less.

CONCLUSIONS

The Raumedic Neurovent-P catheter performed well in clinical use in terms of robustness, with only a 2% complete catheter failure rate. The majority of other technical complications were associated with the bolt fixation technology. Adverse events in terms of infection or hematoma were rare and clinically nonsignificant.

At 13%, zero-drift rates of failure (defined as > 3 mm Hg drift) remain unacceptably high for this catheter. This is a particular issue with the Neurovent-P catheter, which provides no electrical means for adjusting any zero-drift identified before or during use. Despite the earlier reported excellent bench test zero-drift rates, under the more demanding clinical conditions, the zero-drift rate remains a concern with catheter tip strain gauge technology.

This performance is similar, but not superior, to that previously described in other articles on the clinical use of other solid-state and fiberoptic ICP devices (9, 11, 13, 15, 18–21). Nevertheless, in our opinion, this sensor has some clinical advantages over existing ones: its robustness is superior to traditional fiberoptic sensors, and it can be attached to any bedside monitor in the intensive care unit with a very simple interface.

APPENDIX

Investigators and Participating Centers

Barcelona, Spain: Juan Sahuquillo, M.D., Jorge Alberto de los Rios, M.D.; Heidelberg, Germany: Karl Keining, M.D., Janet Mattern, M.D.; Monza, Italy: Giuseppe Citerio, M.D., Davide Galli, M.D.; Newcastle upon Tyne, England: Iain R. Chambers, Ph.D.; Uppsala, Sweden: Per Enblad, M.D.; Vilnius, Lithuania: Saulius Ročka, M.D.

Disclosure

The BrainIT coordinating center (Southern General Hospital, Glasgow, Scotland) received a grant from Raumedic AG (Münchberg, Germany) to run the trial. Raumedic also donated all the disposables and catheters that were used in the study. None of the participants in the study received payment for the trial or for consultancy and/or advisory work, or honoraria for educational or other purposes, including for travel or other expenses. None of the participants hold stocks or shares in Raumedic.

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We thank all the staff at each of the participating centers for their time and help in collecting the data.

COMMENTS

Citerio et al. conducted careful postmarketing testing of the Raumedic Neurovent-P intracranial pressure (ICP) sensor. Novel design features had promised significant theoretical advantages of this technology, and laboratory testing had demonstrated lesser tendency toward zero-drift than other commonly used ICP devices. In practice, the device was quite robust, although superiority of performance could not be easily proven. With rigorous surveillance, problems were encountered in relation to bolt placement technique. And relevant zero-drift remained a frequent occurrence that was unrelated to duration of insertion. This affected the validity of ICP measurements in a significant fraction of cases.

Unfortunately, such careful studies are all too rarely undertaken after successful marketing of new devices, with diminished manufacturers' or champions' incentives to document real performance. And all too often, "equivalent performance" is sought "up front," which easily could reflect small sample size and type 2 error, whereas the advantages of new technology are accepted at face value on the basis of theoretical arguments. This study reminds me of Henri Poincaré's admonition in *La Science et l'Hypothèse*, more than 100 years ago, that "All generalization is a hypothesis. It ought always, as soon as possible, as often as possible, to be subjected to verification. If it does not stand this test, it ought to be abandoned without reserve. We do so with an ill humor. This ill humor is not justified" (1).

Issam A. Awad
Evanston, Illinois

1. Poincaré H: *Science and Hypothesis* [in French], 1906.

The authors have put together a very well-constructed, thorough, and transparent study of this promising ICP technology. Neurovent-P has the theoretical advantage of being a full Wheatstone bridge in the catheter tip, promising minimal to zero-drift, no adjustments after placement, ability to withstand a broad range of conditions, and thus improved accuracy for the patient and simplicity for the surgeons and nurses. In this study, the catheter seemed to be able to withstand the usually trying conditions of an ICU, provided real-time bedside recording, and demonstrated excellent preinsertion reliability. However, after removal, there were 22 cases in which the catheters displayed a 3 mm Hg or greater drift.

I am unclear on why there were significant differences in centers for the postremoval zero-drift measurement unless the bench test was flawed or the test was difficult to standardize owing to interobserver variability. There appeared to be few defects in the catheters. I agree with the authors, who stated that this technology is both accurate and robust, but, thus far, it is arguably no more reliable than our current fiberoptic standard. The aim should be to decrease the ICP measurement uncertainty below its current level.

Richard G. Ellenbogen
Seattle, Washington

This is an excellent contribution from the BrainIT group, a serious scientific multicenter neurointensive care study group from Europe that evaluated a commercial ICP monitor with due diligence. The authors found that the catheter performed well in clinical use with few adverse events, but zero-drift rate remained a concern. Overall, the authors felt that the performance was similar to that of other ICP monitors available. From the large number of detailed evaluations that were performed, we ought to be persuaded to believe them, although it is questionable whether we will switch from using current ICP monitoring devices, which are all fairly similar.

Neil Kitchen
London, England

The BrainIT group describes a well-conducted clinical evaluation of a new parenchymal ICP monitor. As one might perhaps expect, results during actual clinical testing were not as favorable as the previously reported results during bench testing. In particular, the zero-drift rate remains problematic. In future studies of this type, it might be interesting to compare different manufacturers' devices in a randomized (but, obviously, unblinded) fashion. Such a study design might allow determination of whether problems with a monitor are unique to that particular device, or whether all monitors at a particular institution have a high rate of problems (thus suggesting that difficulties are institution-specific). In the case of trials of ICP monitors, a comparison to ventriculostomy catheters should also be considered by study planners.

Alex B. Valadka
Houston, Texas

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APPENDIX 7

OPERATING MANUAL FOR THE LIQUOGUARD CSF DRAINAGE SYSTEM

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Software versions: 025.01.04 and 026.01.16

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US

Operating Manual

LiquoGuard® CSF

CE 1275

Möller Medical GmbH, Wasserkuppenstr. 29-31, D - 36043 Fulda

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The manufacturer reserves the right to make technical improvements.

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3 General Safety Instructions

3.1 Explanation of the safety symbols

Important information is marked in these operating instructions. This information is vital to exclude danger to patient and operating personnel, and to avoid damage or malfunction.

Achtung	Warning, important information
	Caution! Hazard to patient or operating personnel
i	Information or help
	Application part BF
CE 1275	Conformity to medical guideline 93/42 EEC
~	Identification symbol for electrical and electronic devices
	Alternating voltage
	Alarm signal deactivation switch AUDIO PAUSE
i	Consult instruction for use
SN	Serial number
	Manufacturer
REF	Catalogue number
LOT	Lot number
	Date of expiration
	Date of manufacture
	Application range

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General Safety Instructions

STERILE EO	Sterilized using ethylene oxide
	Do not use if packaging is damaged
	Do not reuse
	Do not resterilize
	Not for use in an MRI field
PHT DEHP	Contains or presence of phthalates
	Overall length

Each application of the unit is subject to precise knowledge of and compliance with these operating instructions. This operating manual does not replace the inservice of the user by the sales representative. The device must only be operated by qualified personnel or those with an equivalent level of knowledge and experience.

If components are used that do not correspond to the original parts of the manufacturer, the performance, safety and EMC behaviour may be impaired.

3.2 Manufacturer

The manufacturer can be regarded as being responsible for the safety, reliability and serviceability of the unit if:
assembly, upgrades, resettings, changes or repairs are only carried out by personnel who have been authorised to do so by the manufacturer. The electrical installation of the respective room complies to the appropriate requirements and the device is used according to the operating manual.

3.3 Precautionary duties of the operator

The operator is responsible for proper operation of this medical product.
Only qualified personnel may operate this unit. Operating instructions do not replace a proper inservice. Clinical application may only be performed by people who have been properly inserviced by qualified personnel.

The unit may not be operated if connected to power supplies whose soundness is doubtful. The supply voltage must match the details specified on the nameplate. Liquids must not penetrate parts of the device, which carry electrical voltage. Do not spray cleansing fluid into the memory card slot. Unplug the AC power cord prior to cleaning.

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3.4 Supplementary devices

Supplementary devices are not part of the unit's delivery scope:
Any additional equipment that is connected to the analogue and digital interfaces of the device must be proven to meet the requirements of the relevant EN specifications, (e.g. EN60601 for electrical medical devices). All device configurations must also satisfy the applicable version of the electrical system safety standard EN60601-1-1. Any operator connecting the additional devices is the system configurer and is therefore responsible for ensuring that the system safety standard EN60601-1-1 is upheld. In case of questions, please contact the manufacturer.

3.5 Single-use

Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilisation may compromise essential material and design characteristics leading to device failure.

3.6 Electro-magnetic emission

The ***LiquoGuard® CSF*** is suitable for operation in the stipulated electro-magnetic environment. The customer and/or operator of the ***LiquoGuard® CSF*** should ensure that it is used in one of the electro-magnetic environments described below.

Measurement of emitted interference	**Conformance**	**Guidelines for the electro-magnetic environment**
Emitted high-frequency interference acc. to CISPR 11	Group 1	
Emitted high-frequency interference acc. to CISPR 11	Class B	The ***LiquoGuard®*** uses HF energy exclusively for its own function. Its HF emittance is therefore very low and interference with neighbouring electronic devices is improbable.
Harmonic emittance acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuation/flicker emittance acc. to IEC 61000-3-3	Not applicable	

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3.7 Recommended safety distances

Recommended safety distances between portable and mobile HF telecommunication devices and *LiquoGuard®*

LiquoGuard® is intended for operation in an electro-magnetic environment, in which HF disturbances are controlled. The client or operator of ***LiquoGuard®*** can assist in avoiding electro-magnetic disturbances by keeping to the minimum distances between portable and mobile HF telecommunication devices (transmitters) and ***LiquoGuard®*** - depending on the output power of the communication device, as stipulated below.

Capacity transmitter power [W]	Safety distance dependent on transmission frequency [m]		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

3.8 Electro-magnetic resistance

Resistance test	IEC 60601 - testing level	Conformance level	Electro-magnetic. Environment / Guidelines
Discharge of electro-static electricity (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should consist of wood or concrete or tiles. If the floor is covered with synthetic material, relative humidity should be at least 30 %.
Rapid transient electrical disturbances/ bursts IEC 61000-4-4	±2 kV for power lines ±1 kV for input and outtput lines	±2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Surge voltages Surges IEC 61000-4-5	±1 kV Normal mode voltage ±2 kV Common mode voltage	±1 kV Normal mode voltage ±2 kV Common mode voltage	The quality of the supply voltage should correspond with that of a typical business or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage IEC 61000-4-11	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	< 5 % U_T (> 95 % intrusion of U_T) for 1/2 period 40 % U_T (60 % intrusion of U_T) for 5 periods 70 % U_T (30% U_T intrusion) for 25 periods < 5 % U_T (> 95 % U_T intrusion) for 5 seconds	The quality of the supply voltage should correspond with that of a typical business or hospital environment. If the operator of the product demands continued functions even during the occurrence of power supply interruptions, we recommend the use of an uninterrupted power supply or battery.
Magnetic field for supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields for the net frequency should correspond with typical values as found in business and hospital environments.

Note: U_T is the AC supply voltage prior to application of the testing level.

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3.9 Electro-magnetic resistance for non-life-supporting devices

Resistance tests/ Standard	IEC 60601-testing level	Conformance level	Electromagnetic environment / Guidelines
Conducted HF-resistance variable according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	Portable and mobile radio devices should not be used at a distance to the product, including lines, of less than the recommended safety distance, which is calculated according to the equation corresponding to the transmission frequency. **Recommended safety distance:** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{V_1}]\sqrt{P}$ for 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ for 800 MHz to 2.5 MHz with P as nominal transmitter power in Watt (W) acc. to transmitter manufacturer stipulations and d as recommended safety distance in meters (m). According to an on-site[a] examination, the field intensity of stationary radio transmitters ought to be lower than the correlation level[b]. Disturbances may occur in the environment of devices carrying the following symbol.
Radiated HF-resistance acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Notes:
NOTE 1 The higher frequency range applies to 80 MHz and 800 MHz.

NOTE 2 These guidelines may not be applicable in all cases. The diffusion of nominal electro-magnetic factors is influenced by absorption and reflection of buildings, objects and people.

[a] The field intensity of stationary transmitters, such as radio base stations and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and TV transmitters theoretically cannot be predetermined accurately. An examination of the site should be considered in order to determine the electro-magnetic environment of the stationary transmitter. If the measured field intensity at the site, at which the product is used, exceed the above mentioned conformance levels, the product should be observed to prove the intended function. Unusual performance characteristics may require additional measures, such as changes to the alignment or position of the product.

[b] The field intensity should be less than 3 V/m at 150 MHz to 80 MHz.

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4 Purpose

Möller Medical's ***LiquoGuard® CSF*** is a

- pressure controlled
- and / or volume controlled

tube pump for use in: monitored medical rooms in hospitals only.

The purpose of *LiquoGuard® CSF* with the tube set for *LiquoGuard®* REF.-No.: **92 007 836 (1500 mm/59.06 inch) or REF.-No.: 92 008 568 (2000 mm/78.74 inch) is the targeted pumping of CSF fluid.**

LiquoGuard® may not be used as an infiltration pump or infusion pump.

LiquoGuard® does not serve diagnostic purposes.

4.1 Indications for Use

The ***LiquoGuard® CSF*** system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The ***LiquoGuard® CSF*** system controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The ***LiquoGuard® CSF*** system also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

4.2 Contraindications

The contraindications do not apply to the use of a CSF draining system such as the ***LiquoGuard® CSF*** system, but to the application of intrathecal CSF drainage itself. As, however, CSF discharge is only applied in connection with CSF drainage, contraindications described below are in connection with the application of external CSF drainage only.

Absolute operative contraindications: Coagulopathy, thrombocythemia.

Relative operative contraindications: In superficial or deep infections of skin, bone, meninges or brain. Especially in infections of the brain, meninges or cerebral chambers (encephalitis, meningitis and ventriculitis) dysfunctional CSF resorption indicates relief, as does simultaneous intake of intrathecal antibiotics in the case of ventriculitis.

Indication for permanent CSF drainage: If permanent CSF drainage is indicated (e.g. in normal-pressure hydrocephalus), a temporary CSF drainage would be indicated for diagnostic purposes only (e.g. b-wave diagnostics), but not for continuous therapy. This would indicate a CSF shunt system, usually a ventriculoperitoneal shunt or a ventriculo-atrial shunt.

4.3 Combination with other products

LiquoGuard® CSF may only be used in connection with Möller Medical's tube set for ***LiquoGuard®*** **REF.-No.: 92 007 836 (1500 mm/59.06 inch)** or **REF.-Nr.: 92 008 568 (2000 mm/78.74 inch)** , the tube set may only be used in connection with the ***LiquoGuard®***.

The tube set for ***LiquoGuard®*** REF.-No.: 92 007 836 or. REF-No.: 92

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008 568 is connected to a surgically implanted CSF draining catheter and does not come into contact with the body.
The tube set for ***LiquoGuard®*** REF.-No.: 92 007 836 or. REF-No.: 92 008 568 may only be connected to ventricular drainage catheters with an internal diameter of >= 1 mm (0.039 inch) and with lengths of <= 350 mm (13.78 inch) or lumbar drainage catheters with an internal diameter of >= 0.7 mm (0.028 inch) and a length of <= 800 mm (31.5 inch).

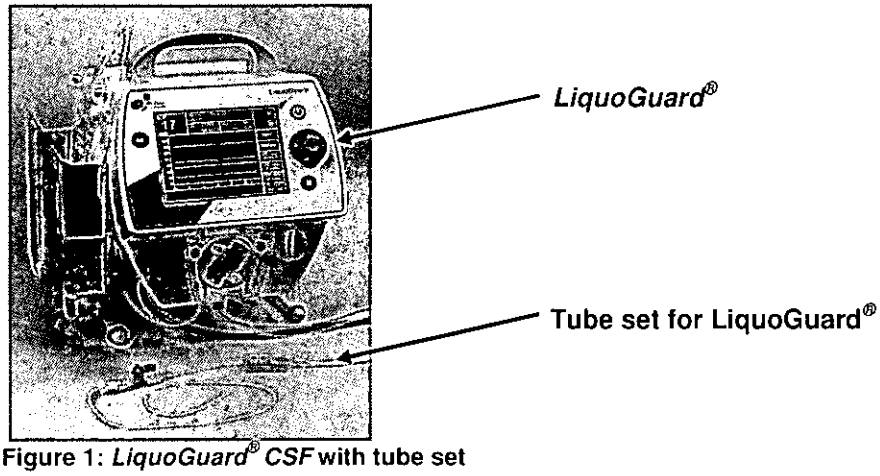

Figure 1: *LiquoGuard® CSF* with tube set

4.4 Patient population

The application may be considered for neonatal to geriatric patients.

4.5 Remaining risk

LiquoGuard® CSF is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error. The remaining risk for the patient exists mainly in the selection of parameters unsuitable for the patient or other application errors. The operator must be aware of this risk.
LiquoGuard® CSF does not serve diagnostic purposes.
For application during computer tomography (CT), the tube set may remain attached to the patient. ***LiquoGuard® CSF*** must be disconnected.

Application during Magnetic Resonance Tomography (MRT) or near an MRT device is prohibited.

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5 Set-Up and Installation

Ensure that the package has been delivered to you without damage. Please inform your sales representative immediately of any transport damage.

5.1 Unpacking the Device and Checking for Contents

Delivery of ***LiquoGuard®*** always consists of one carton. When unpacking ***LiquoGuard®***, ensure that no parts remain in the package and that all parts are present.

The delivery scope consists of (1 item each):

- ***LiquoGuard® CSF***
- AC power cord
- Operating manual

Every manipulation of ***LiquoGuard®*** requires exact knowledge and observance of these operating instructions. These instructions do not replace proper user training. Only qualified personnel may operate this unit. ***LiquoGuard®*** must be prepared according to cleaning guidelines prior to first application. For cleaning, use a mild detergent or disinfectant (e.g.: 70 % alcohol).

We suggest that packaging is retained for further use.
LiquoGuard® may only be shipped in the original packaging.

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5.2 Installation

Remove ***LiquoGuard® CSF*** from its packaging and place it on a suitable, steady surface.

LiquoGuard® CSF can be:

- safely positioned in a suitable, stable location.
- suspended on a 25 mm (0.98 inch) x 10 mm (0.39 inch) wall rail.
- or attached to an IV pole with a diameter of 25 mm (0.98 inch).
- or universally attached to various IV poles or the patient's bed with the attachment pole (accessory).

Observe the maximum tube length of 1.5 m/59.06 inch (REF.-No.: 92 007 836) or 2 m/78.74 inch (REF.-No.: 92 008 568) between catheter and ***LiquoGuard®***.

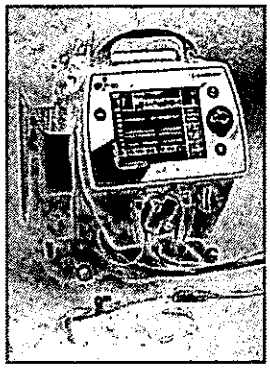

Figure 2: *LiquoGuard®* standing on base feet

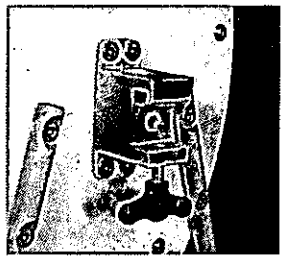

Figure 3: *LiquoGuard®* - view from behind
Attachment system for wall rail 25 mm (0.98 inch) x 10 mm (0.39 inch)

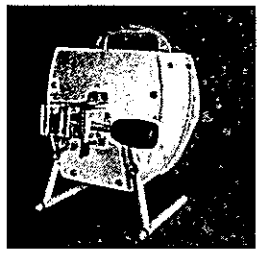

Figure 4: *LiquoGuard®* - view from behind
Pole clamp

Insert the AC power chord into ***LiquoGuard® CSF*** at the lower side of the casing side and into a plug with connected protective earth conductors. Please observe the stipulated voltage values on the type plate.

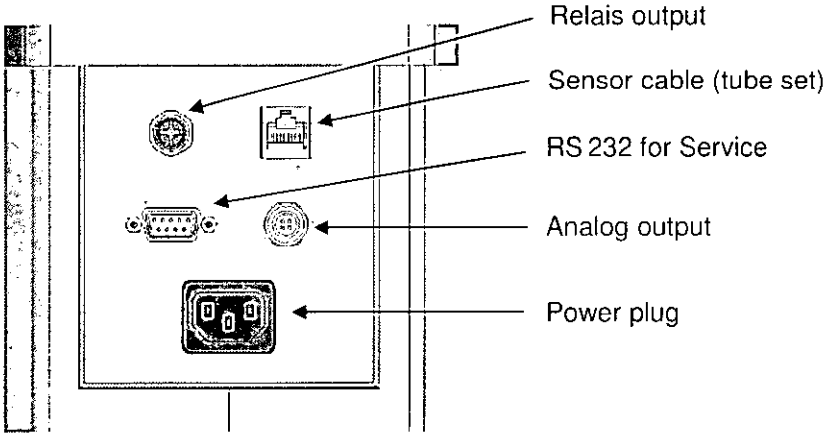

Figure 5: *LiquoGuard®* - View from below - Connections

The relay output can be used for an alarm connection to the device call system (frequently also known as the diagnostics call or nurse call). The function of this connection must be

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checked and validated in individual cases (Please Observe the prerequisites for Supplementary devices in Chapter 3.4 on Page 7).
This further alarm routing does not eliminate the need to control the patients. The alert notices from the ***LiquoGuard® CSF*** must be controlled in every case.

Connecting the AC power cord to ***LiquoGuard®*** puts the device into standby mode.

Further startup requires a tube set for ***LiquoGuard®*** by Möller Medical, **REF.-No.: 92 007 836** or **REF-No.: 92 008 568.**

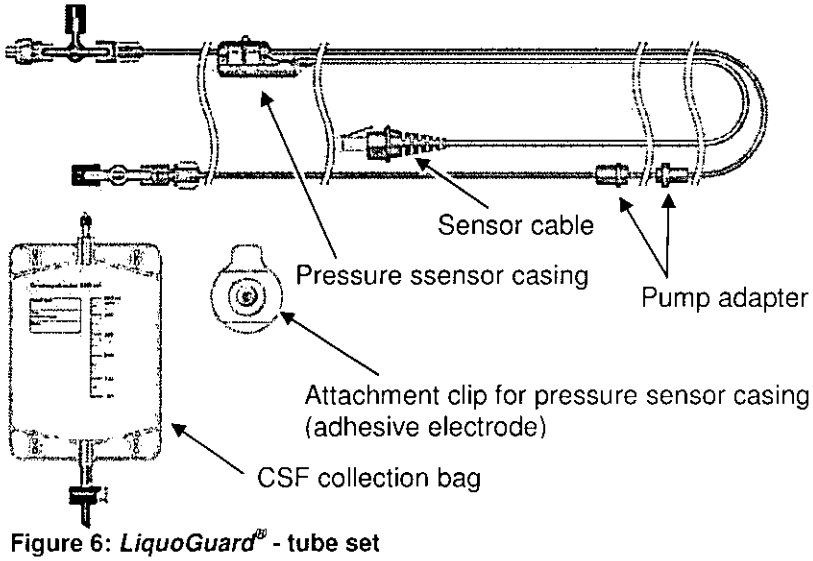

Figure 6: *LiquoGuard®* - tube set

To avoid false alarms, you should familiarise yourself with the alarm concept of ***LiquoGuard® CSF*** (see Page 15).

Please continue reading starting at page 30 for information on Application and operation.

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6 Alarm concept

The ***LiquoGuard® CSF*** alarm concept is designed in such a way that during correct operation the operator is always notified of alarm conditions by visible and audible alarms (i.e. an operator must always be within earshot and visibility range). ***LiquoGuard® CSF*** is equipped with a physiological and technical alarm condition. Alarm condition priority is stipulated with "HIGH Priority" for all alarm conditions. ***LiquoGuard® CSF*** creates visible and audible alarm signals. The alarm system is designed without self-regulating alarm signals.

6.1 Alarm system description

Terms and definitions

Terms	Definitions	Application for *LiquoGuard®*	Explanation
Alarm condition	Condition of the alarm system once it has determined a possible or real threat.	Excess of upper or lower alarm limit	
Alarm condition delay	Time between occurrence of an alarm condition either on the patient side (PHYSIOLOGICAL ALARM CONDITION), or on the device side (TECHNICAL ALARM CONDITION), up to system determination of an existing threat.	See chapter 6.2	
Alarm limit	Limit value used by an alarm system to determine an alarm condition.	See chapter 6.2	Control panel
Alarm OFF	Condition of indefinite duration, in which an alarm system or a part thereof does not issue alarm signals	The user can set certain alarm conditions to OFF If these are not useful due to the condition of the patient. It is the responsibility of the user to set these consciously to OFF.	
Alarm paused	Condition of limited duration, in which an alarm system or a part thereof does not issue alarm signals	No possible setting	
Alarm presetting	Set of saved configuration parameters, including the selection of algorithms and initial values for the use of algorithms, which influence or change the effect of the alarm system.	N/A	
Alarm reset	Action performed by operator to cancel an alarm signal, for which there is no currently associated alarm condition.	N/A	

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Alarm concept

Terms	Definitions	Application for LiquoGuard®	Explanation
Alarm settings	Alarm system configuration including but not limited to: - Alarm limits - Properties of all conditions of alarm activation and - The values of parameter variables, which determine the function of the alarm system.	In some cases adjustable by user (see chapter 6.2)	
Alarm signal	Signal type created by the alarm system to display the existence (or the occurrence) of an alarm condition.	- Visible alarm signal - Audible alarm signal The audible alarm signal has an audio pressure level of 55dBA at a 1-metre distance	Visible impulse signal via red LED light in service screen. On-board sound emitter
Delay in alarm signal emittance	Time from start of alarm condition to emittance of alarm signal.	Depending on alarm condition, see chapter 6.2	
Audio OFF	Condition of unlimited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	settable	refers to all alarm conditions active at the time of key activation
Audio paused	Condition of limited duration, in which an alarm system or a part thereof does not issue an audible alarm signal.	Settable to a maximum of 180 minutes.	refers to all alarm conditions active at the time of key activation
De-escalation	Process which the alarm system uses to lower the priority of an alarm condition or the urgency of an alarm signal.	No application	
Escalation	Process which the alarm system uses to raise the priority of an alarm condition or the urgency of an alarm signal.	No application	
False negative alarm conditions	Missing alarm condition, if a valid triggering occurrence in the patient, in the device or in the alarm system has occurred.	Dual safety-Probability very low	
False positive alarm conditions	Existing alarm condition, if no valid triggering occurrence in the patient, in the device or in the alarm system has occurred.		
Information signal	Every signal, which is not an alarm or reminder signal.	Applies.	
Self-retaining alarm signal	Alarm signal which continues to emit after its triggering occurrence has been eliminated, until it is stopped with a deliberate operator action.	Does not apply.	
Non-self-retaining alarm signal	Alarm signal, which automatically stops if the associated triggering occurrence has been eliminated.	Applies.	
Physiological alarm condition	Alarm condition originating from a monitored, patient-related variable.	Applies.	
Technical alarm condition	Alarm condition originating from a monitored, device or alarm system-related variable.	Applies.	

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6.2 Alarm system overview

Alarm conditions	Pulsation frequency not correct	Lower pressure limit value undercut	Upper pressure limit value exceeded
Physiological alarm condition	Pulsation frequency too small (limit value)/ too large (limit value)	Measured pressure too low	Measured pressure too high
Technical alarm condition	n.a.	n.a.	n.a.
Alarm limit	Pulsations frequency (<=30) or (>= 180)	Lower pressure limit value (P-min) Adjustable by operator	Upper pressure limit value (P-max) Adjustable by operator
Alarm condition delay	Averaged value in 12 sec.	Filtered measurement value	Filtered measurement value
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	Not adjustable by operator Specified to 20 sec	Not adjustable by operator Specified to 20 sec
Alarm signal	Audible / Visible	Audible / Visible	Audible / Visible
Alarm signal description in display	Pulsation alarm!	Measured pressure too low	Measured pressure too high
Audio paused or Audio off	YES	YES	YES

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Alarm concept

Alarm condition	**Pressure constant**	**Sensor defective or disconnected**
Physiological alarm condition	Measured pressure too constant	n.a.
Technical alarm condition	n.a.	a) „Sensor defective": Difference between the two sensors is too high b) „Disconnection": cable can't be detected anymore
Alarm limit	standard 0.2 mmHg; adjustable by operator OFF or 0.1-2 mmHg	a) „Sensor defective": Difference between the two sensors is > 4 mmHg b) [illegible]
Alarm condition delay	12 seconds	a) „Sensor defective": n.a. b) „Disconnection": 3 Seconds
Delay in alarm signal emittance	Not adjustable by operator Specified to 20 sec	a) „Sensor defective": specified to 20 Seconds b) „Disconnection": n.a.
Alarm signal	Audible / Visible	Audible / Visible
Alarm signal description in display	Pressure too constant	Sensor defective or disconnected!
Audio pausedor Audio off	yes	no

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Alarm concept

Alarm condition	Physiological alarm condition	Technical alarm condition	Alarm limit	Alarm condition delay	Delay in alarm signal emittance	Alarm signal	Alarm signal description in display	Audio paused or Audio off
Battery empty	n.a.	Voltage of battery too low	Internal device specification	n.a.	Not adjustable by operator Specified to 20 sec	Audible / Visible	Battery empty, connect to AC	YES
Internal safety measures from hardware and software tests -dual safety- **These alarm condition or alarm signal descriptions are not displayed. In the case of such alarm conditions, *LiquoGuard®* must be checked by Service.**	n.a.	Internal device assessments	Internal device specification	n.a.	Not adjustable by operator Specified to 20 sec	Audible / Visible	Device error x	YES

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6.3 Inspection of alarm functions

Connecting the AC power chord to ***LiquoGuard® CSF*** results in a short peep tone and the two inner red diodes light up. This is a test for the emergency alarm (audible and visible).
A function test is also performed when ***LiquoGuard® CSF*** is activated. An audible information signal is created and the two external red diodes, as well as the central blue diode light up. The motor also starts up and the current software versions as well as the bus address are displayed for a short while.

6.4 Alarm system, dual safety

The path from pressure measurement by ***LiquoGuard® CSF*** to the alarm was designed according to dual safety aspects. This entails 2 sensors in the tube set, dual measurement value recording and processing, as well as various means of alarm emittance.
The two outer red LEDs are activated by ***LiquoGuard®***s main controls. Alarm signals here (rapid flashing) are supported by displayed information. The audible signal in the main control is a trumpet call.
The two adjacent red LEDs are controlled by the monitoring system. They usually flash slightly delayed from the other LEDs at a slower rhythm.
If the monitoring system determines an error at the main controls, which does not issue an audible alarm, the monitoring system will issue an audible alarm in the form of a rhythmic beep with a fixed frequency. This condition is termed an emergency alarm. It can be cancelled by pressing the standby button three times. If the device returns to this condition repeatedly, the device should be checked by Service.
If a technical fault occurs during battery operation, the device may issue a continuous high-pitched tone. This is also an alarm signal. It can only be cancelled by reconnecting the device to the AC power. There is no other way to cancel this supply alarm.

Important:
The alarm system only refers to ***LiquoGuard® CSF*** itself. Possible signals from an external connected system do not release the operator from his duty to promptly and appropriately react to alarm situations signaled by ***LiquoGuard® CSF*** even if an external system should not display this alarm condition.

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7 Product description

7.1 *LiquoGuard® CSF* design

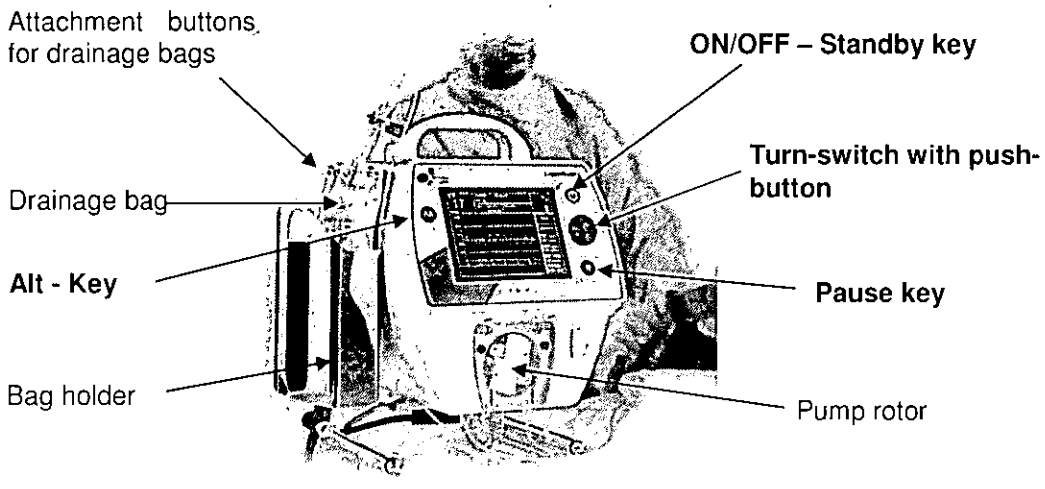

Figure 7: *LiquoGuard® CSF* - design

LiquoGuard® CSF is switched on and off with the **ON/OFF - Standby key**. All functions of the display control panel are set with the **turn-switch**.
You can change between pause mode and active mode of ***LiquoGuard®*** using the **pause switch**. The pump is switched off in pause mode. The **Standby-key** returns you to the next higher menu level from all sublevels. Pressing the **Alt-key** changes the menu items on the right display edge (see „Second selection menu", page 25).

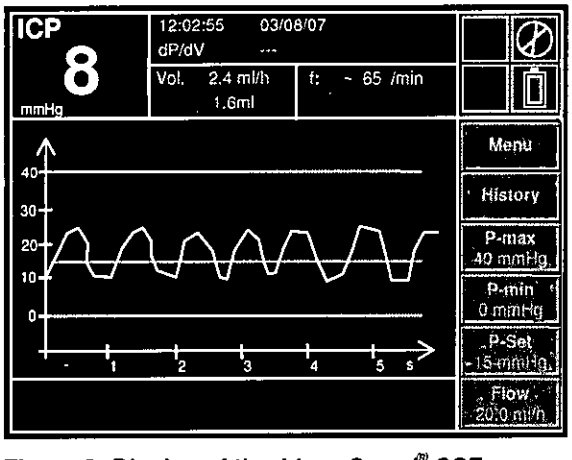

Figure 8: Display of the *LiquoGuard® CSF*

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7.2 Display fields

The monitor design of ***LiquoGuard® CSF*** is divided into display fields and display operating fields.
The **display fields** provide you with the following information:

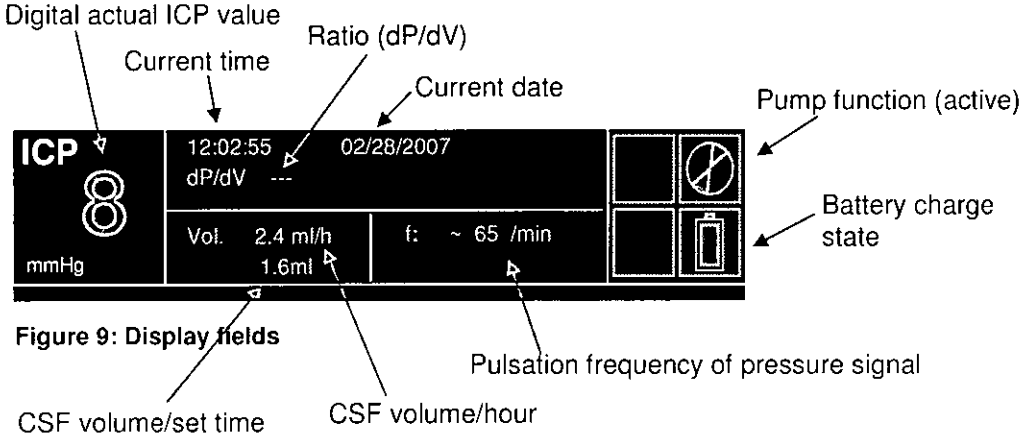

Figure 9: Display fields

7.2.1 Digital actual ICP value or actual P_{CSF} value [mmHg]

The digital actual ICP value/actual P_{CSF} value [mmHg] is the filtered pressure value [mmHg], measured by the pressure sensors. ICP: IntraCranial Pressure [mmHg]; P_{CSF}: Pressure of **C**erebro**S**pinal **F**luid [mmHg]

7.2.2 Ratio dP/dV [mmHg/ml]

Ratio of pressure to volume (Volume elasticity co-efficient, Compliance). This can only be displayed when at least 0.5 ml were pumped between pump start and pump stop and if this created a pressure difference of at least 2 mmHg.
Permanent compliance measurement requires hysteresis set to 1.5 mmHg (under: Sub-menu Extended application; (1) Hysteresis controller [mmHg]).
Note: Accuracy is not better than 20-30%.

7.2.3 Date/Time

These two fields automatically display the current date and current time. The current settings can be changed in the menu.
The date can be displayed in three formats:
DD.MM.YYYY, MM/DD/YYYY, YYYY-MM-DD, e.g.: 28.02.2007; 02/28/2007; 2007-02-28
Note: If the date/time was changed during an application, data (Date/Time) may appear twice or display gaps.

7.2.4 Pulsation frequency of pressure signal (f: ~ ---/min)

This displays the pulsation of the CSF recognised by the device. This recorded pulsation and the alarm conditions are integrated into the alarm concept of the ***LiquoGuard®***. The alarm limits are:

- Upper alarm limit → f >= 180/min
- Lower alarm limit → f <= 30/min

With sufficiently large fluid pulsation the pulsation frequency complies approximately with the pulse of the patient. In the ventricular mode, pulsation alarm is on by default and is an additional monitoring function to increase patient safety.

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It can however be de-activated if required, e.g.: in case of craniectomy/operative decompression: First press the alt key and the right display will appear with a menu containing 5 to 6 sub items (see page 25: "Second selection menu"), Then select "pulse" and set to "NO". The pulsation alarm remains de-activated until this is explicitly changed or a new application is started.
Pulsation recognition is not reliable for permanent lumbar drainage and is therefore not displayed. In this case alarms due to pulsation are not triggered.

7.2.5 CSF volume/hour (Vol. 0.0 ml/h)

This field displays the CSF volume per hour that has been pumped off. The value is always averaged to 15 minutes (adjustable in the system menu) and is updated every minute.

7.2.6 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h)

This field displays the CSF volume per "x" hours that has been pumped off. Variable „x" can take values between 2 and 24 (steps of 2; see page 45 Duration of volume balance [h]) The value always displays the actual volume in this period. It is updated on an hourly basis. As long as the set balance time (e.g. 24 hours) has not been reached, the actually conveyed volume is displayed in ml. If this function is set to "OFF" in the system menu, the volume measuring function is active, i.e. balancing no longer takes place, and only the conveyed volume is displayed. This counter can always be reset to zero using the alt key and "Reset volume" (see page 25: "Second selection menu").
Note: In the event that the tubing is changed more frequently for one individual patient without turning off the device, the entire balance will be continued until the end of its use so that the total quantity drained can be read at the end.

7.2.7 Battery charge state

LiquoGuard® CSF was designed for battery supplied operation for a maximum of 3 hours. A progressive decrease of battery capacity is an indication for a damaged battery (contact service). The display field Battery SOC indicates the current battery charge state during battery operation. During mains operation, a filling symbol indicates charging. A full symbol indicates a full battery. During battery operation the battery symbol is red and the blue LED flashes to show the operator that it is not connected to AC power.

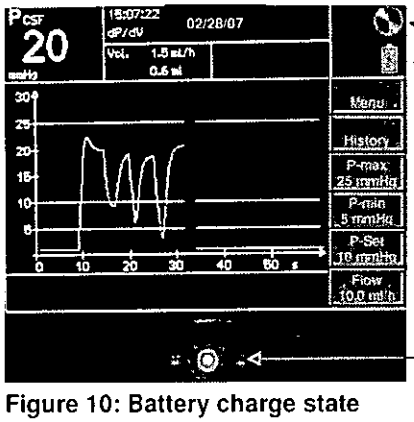

Figure 10: Battery charge state

Before the battery is entirely depleted it will sound an alarm and display: "Battery empty, connect to AC!" The device must then be connected to AC power immediately. If this does not occur, the display will turn black after approx. 5-10 minutes and the alarm continues to sound for a few more minutes. The device will then deactivate until it is reconnected to AC power. Discharging the battery completely can cause permanent damage and thus should be avoided. Complete charging of an empty battery requires approximately 8 hours.

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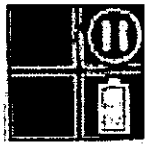
7.2.8 Pump function



If pump mode is set to "Pause", the pump will not work. To access the pump function you have to press the "Pause"-key.

Figure 11: Pump function - Pause

7.2.9 Graphic display of patient parameters

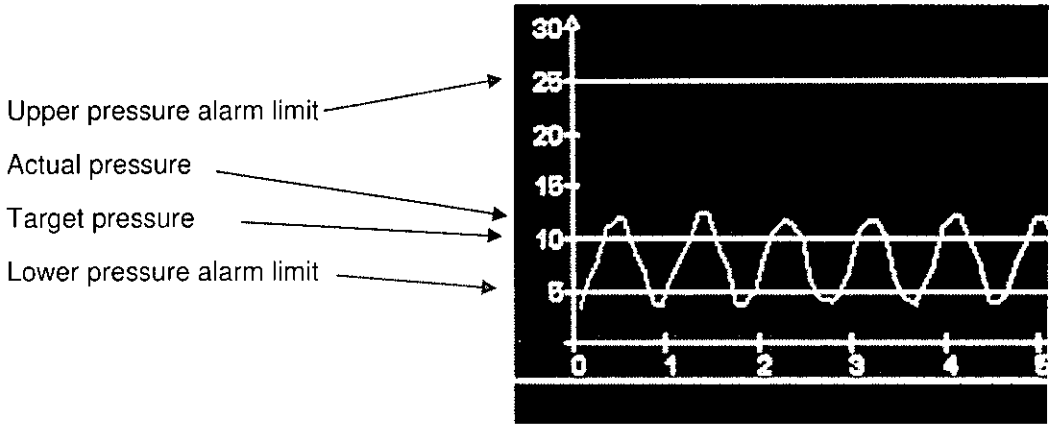


Figure 12: Display of pressure values

The upper pressure alarm limit (P-max) is the upper adjusted alarm limit for the alarm condition. The lower pressure alarm limit (P-min) is the lower adjusted alarm limit for the alarm condition.

7.3 Display operating fields

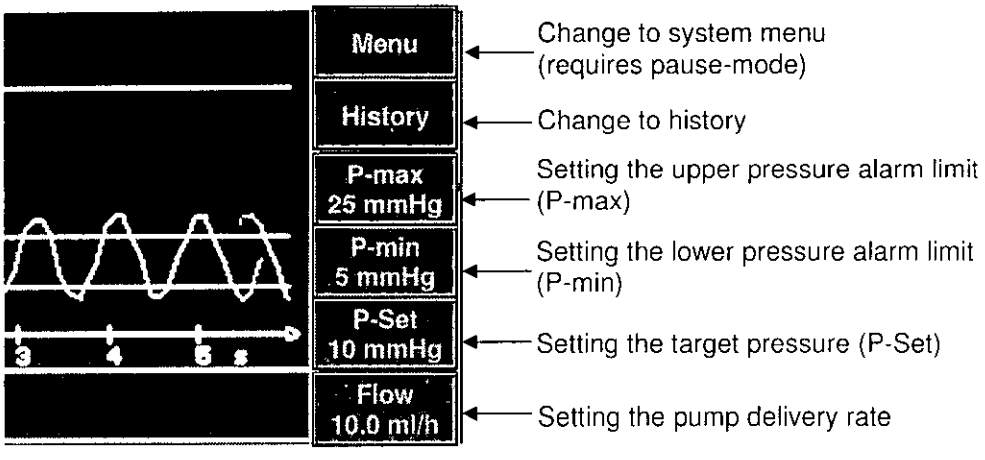


Figure 13: Display operating fields

The display control fields are selected via the turn-switch of ***LiquoGuard® CSF*** whereby the display control fields change their background color. The respective activated field is highlighted in light blue. Pressing the turn switch activates the selected display operating field and highlights it dark blue. By turning the turn switch changes can now be made in

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this field. Further depression of the push button activates the changes. (A text will appear in the display as a reminder: "Confirm changes with the wheel".) If the desired function is not confirmed within a preset time by pressing the turn switch, a timeout will occur. A negative confirmation tone is created (400 msec deep tone). In this case the originally set value is kept.

7.3.1 Quick reference guide - Setting/Changing of values:

1. Press the blue turn-switch. The "menu" field will now be highlighted.
2. By turning the switch you can move the illumination to the desired field.
3. By pressing the switch again, the highlighted field turns dark.
4. Now you can set the desired value. Important: You have to confirm this value by pressing the turn-switch again. If you forget to confirm, the new value will not be maintained and after a short interval the device will go back to the old value (operation timeout).
5. After confirmation of the new set value the field is highlighted again.
6. By turning the switch you can move the illumination again to another field.

Notes:

- If the switch is not touched for a short interval, there will be an operation timeout (no field is highlighted anymore) and you have to start at the beginning.
- By each short pressing of the Standby key you can go one step back.

To adjust the patient parameters please also read starting at Page 33.

7.3.2 Second selection menu

Pressing the Alt-key changes the menu items on the right display edge:

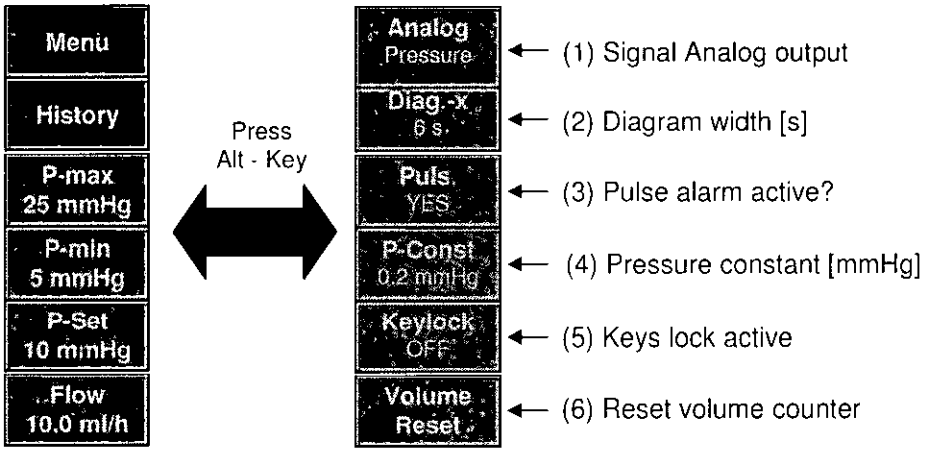

Figure 14: Second selection menu

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After the timeout period, which also applies for the system menu, you are returned to the standard key allocation as this contains the most information for the application.
Note:
If an audible alarm is active, pressing the Alt key will take you to the alarm pause selection (see page 38 Audio paused or Audio off). Therefore the Alt key has 3 levels, whereby only 2 are used without an alarm.

(1) Signal analog output

Meaning: Selection of the value to be issued via the analog output.

Possible parameter settings: Zero, Pressure, Flow

Note: The "Zero" setting serves offset correction purposes. The Pressure setting issues a value for pressure analog to the CSF-pressure measured by ***LiquoGuard® CSF.***
The same scale (20 ml/h correspond with 20 mmHg) can also be used to issue the pump flow corresponding to the history view.
This may be expedient as pressure regulation is active and if the pressure is consistent. Subsequently the quantitative size is the volume flow.

(2) Diagram width [s]

Meaning: The spread of the X-axis in the display diagram (Display) is stipulated by the Diagram Width (s).

Default value: 6 seconds (ventricular), 60 seconds (lumbar)
Minimum value: 6 seconds
Maximum value: 10 minutes

(3) Pulsation alarm active?

Meaning: Pulse recognition can be de-activated in the system menu, if patient conditions do not permit accurate measurement.

Possible settings: YES, NO (Default value: YES)

Notes:
- This parameter can only be set for ventricular application. The pulsation alarm is always de-activated for lumbar applications.

Attention: There is no reliable alarm function for catheter occlusions, catheter disconnections, or collapsed ventricles if the pulsation alarm is deactivated.

(4) Pressure constant [mmHg]

Meaning: A value of 0.2 [mmHg] means that the minimum pressure and the maximum pressure during the past 12 seconds (120 measured values) must differ by more or equal to 0.2 mmHg, so that no alarm is issued for "Pressure too constant". The alarm delay time of 20 seconds applies here, too.
The purpose of this function is to recognize a torn off/occluded catheter. The function is available for ventricular and lumbar drainage but not for the infusion test.

Default value: 0.2 mmHg
Minimum value: 0.1 mmHg (resp. OFF)
Maximum value: 2.0

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(5) Keys lock active [min]

Meaning: To prevent unintentional chages to the operating field parameters, "Keylock" can be set, so that ***LiquoGuard® CSF*** creates a keys lock after a certain inactive period. By default this function is set to OFF.

Default value: OFF
Minimum value: OFF (keys lock inactivated)
Maximum value: 60 minutes

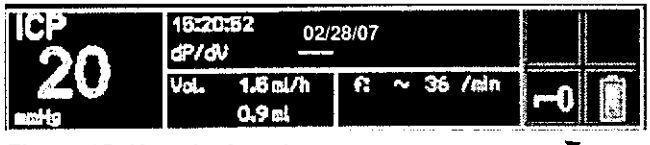

Figure 15: Keys lock active

Symbol for active keys lock

If the keys lock is active, a key will appear in the display and no further settings can be performed via the operating field. The key lock is deactivated by pressing and holding the "**Alt key**" for 2 seconds. The lock is automatically re-activated if the preset time has lapsed without key activation.
Note: the keys lock is automatically de-activated every time an audible alarm signal is sounded. This also applies for the opening of the lid, if the question appears: "Interrupt application?".

(6) Reset volume counter
The volume counter is reset to zero when confirming "Volume reset".

Note: The key "Volume reset" is only active if "Duration volume balance" is set to "OFF" in the system menu.

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7.4 Technical Data

Order number:	**00 002 563**
LiquoGuard® dimensions:	Length x Width x Height: 280 mm x 210 mm x 315 mm (11.02 inch x 8.27 inch x 12.4 inch)
Weight:	approx. 4.8 kg (10.58 lb)
Electrical supply: Voltage 100 – 240 VAC (alternating voltage)	
Frequency	50 – 60 Hz
Current consumption	0.5 – 0.2 A
General characteristics:	
Operating conditions: Temperature Humidity	 +10 °C to +40 °C (+50 °F to +104 °F) 30 to 75 % rel. humidity
Transport - storage conditions Temperature Humidity	 -10 °C to +50 °C (+14 °F to +122 °F) less than 90 % rel. humidity
Protection category	IP 20 - ***LiquoGuard® CSF*** IP 20 - Tube set for ***LiquoGuard®***
Pump rate	1 ml/h to 120 ml/h (variably adjustable)
Flow rate accuracy	± 15 %
Pressure range	-15 mmHg to +75 mmHg
Accuracy of pressure sensors (according to data sheet)	± 0.5 mmHg
Display accuracy of system	± 2 mmHg
Application temperature range	+10 °C to +40 °C (+50 °F to +104 °F)
Relay output:	pure switch output for extra-low voltages of 25V AC / 60V DC, Current limitations: 3 A
Output signal of analog interface: Direct connection	 5.9 mV/mmHg (Tolerance: ± 12 mV or ± 10 % *)
With TruWave adapter cable	33 µV/mmHg (Tolerance: ± 66 µV or ± 10 % *) *The highest value is valid respectively.

<u>Attention</u>: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

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7.5 Recurring inspections

LiquoGuard® CSF must be subjected to safety inspections at least every 12 months. Documents on safety inspections can be requested from the manufacturer.

In addition to the safety inspections, further maintenance of the *LiquoGuard® CSF* is required in order to verify measures for the dual safety of the device.

Maintenance must be conducted by a maintenance center approved by the manufacturer. Information on maintenance can be requested from the manufacturer's service division (see page 52). Enter safety inspections into the equipment log book and document inspection results. If the device is not fully functional or safe to operate, it must be repaired immediately by device service personnel. The safety inspections and technical measurement checks can be performed by the Service department of Möller Medical service@moeller-medical.com.

7.6 Dimensions, weight and transport information

LiquoGuard® CSF dimensions with packaging:	Length x Width x Height: 580 mm x 430 mm x 415 mm (22.83 inch x 16.93 inch x 16.34 inch)
Weight:	approx. 8 kg (17.64 lb)
Transport and storage conditions	
Temperature:	-10 °C to +50 °C (+14 °F to +122 °F)
Humidity:	less than 90 % rel. humidity

When transporting, do not stack more than 3 cartons above one another.

The external packaging is a folding corrugated cardboard box. The internal packaging is made from polyethylene foam rubber.

The packaging material is highly flammable and represents a fire hazard. Keep away from naked flames and do not smoke!

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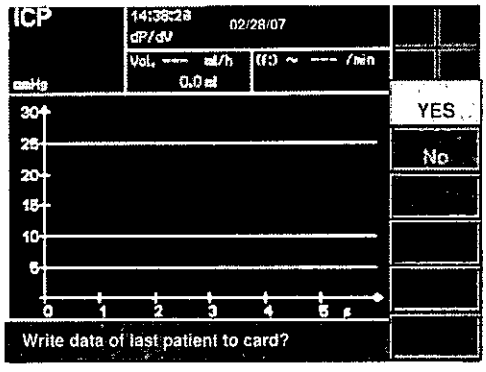
8 Application and operation

LiquoGuard® CSF may only be switched on if power supply is conveyed via power input. The ***LiquoGuard®*** is ready for operation once the **ON/OFF – Standby – button** is activated. ***LiquoGuard®*** starts with a recognition signal and the current software versions as well as the Bus address are displayed for a short while.
Note: The emergency alarm is tested when ***LiquoGuard®*** is plugged in. This means you will have to hear a short beep. A function test is also performed when ***LiquoGuard®*** is activated (see page 20 "Inspection of alarm functions").

As a first step the subsequent display screen will appear.



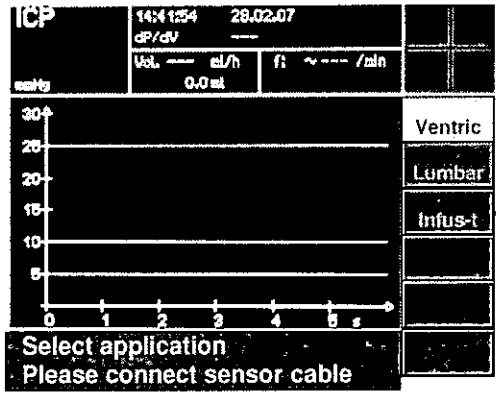
Should you not have written the data from the last patient to the memory card, this procedure can be carried out now (confirmation with the turn switch). All existing data is fully deleted once a new tube set is connected.
(This step can be skipped by activating the alt key or the standby key.)

Figure 16: Write data to memory card?

Select the desired application in the next step:

- **Ventricular drainage (Ventric)**
- **Lumbar drainage (Lumbar)**
- **Lumbar infusion test (Infus-t)**

Please read page 36 (Ventricular drainage) or page 37 (Lumbar drainage) or as of Page 54 (Option: Lumbar Infusion Test).



Turn the turn-switch to move the highlight to the desired field. Press the turn-switch to confirm the desired application.
(By pressing the "Alt" key or the "Standby" key the device is switched off.)

Figure 17: Select application

The following steps apply only to the following applications: Ventricular drainage or lumbar drainage. An additional software upgrade is required to run the device application option

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of "lumbar infusion test". This special application is described in detail in Chapter 12 (Option: Lumbar Infusion Test) as of Page 54.

8.1 Connection of the tube set

Please be sure to see that the following procedures are carried out:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.
2. Connect the tube set to the drainage bag and fasten the drainage bag to the holder provided

Note: Insert the drainage bag into the top of the bag holder at the ***LiquoGuard®*** (see Page 21, Figure 7).The drainage bag is freely suspended by the upper attachment buttons at the bag holder.

3. Insert the tube set into the pump: Ensure that the connecting pieces are correctly seated in the guides. Turn the pump rotor counter-clockwise by three rotations. Check whether the pump tube was correctly threaded.

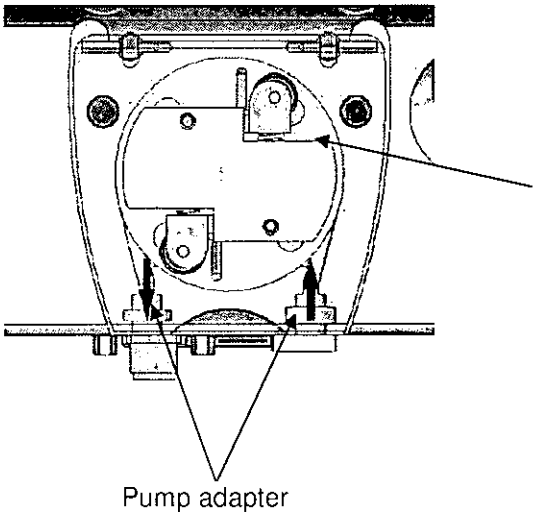

Figure 18: Pump rotor

As a first step you open the front cover of the pump and insert the tube set with the pump adapters into the pump receptacles.

Then thread in the pump tube by manually rotating the pump rotor to the left, threading via this rotor edge.

Manually turning the pump rotor counterclockwise for at least three rotations ensures that the tube is not jammed anywhere.

Then close the front cover.

4. Turn the stop cock of the 4-way manifold by 180° flow direction from the pump to the catheter... and remove the protective cap on the catheter side.

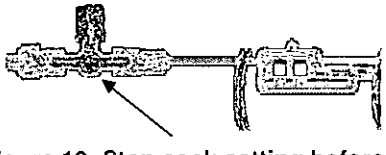

Figure 19: Stop cock setting before the application

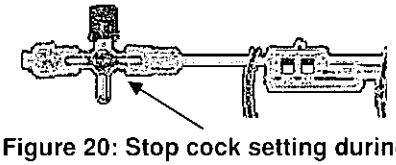

Figure 20: Stop cock setting during the application

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5. If you haven't done it yet: Connect the sensor cable to the ***LiquoGuard®*** (connection under the device).

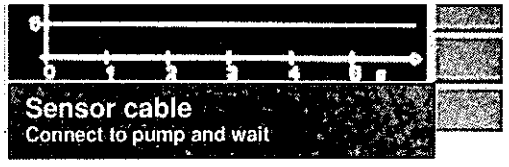

Figure 21: Connect sensor cable to pump

Notes:

- In the event that a tube set had previously been attached, the point concerning "connect the sensor cable to the pump and wait" will be skipped, since the device will automatically recognize the tube set.
- Should you select a tube set that is unsuitable or which has already been used, the following message will appear: "wrong tube set for this application" and/or "please change the tube set". In this case, disconnect the tube set from the device. The following message will then reappear: "Sensor cable - connect to the pump and wait". Either connect a tube set which is suitable for the selected application or go back a step using the ESC key, in order to select an application for which the tube set is suitable.

6. Connect the catheter to the tube set (Please observe page 10 "Combination with other products").

7. Use the adhesive electrode (attachment area depends on application, see Pages 36/37) to attach the pressure sensor housing to the patient. Follow the display to do so:

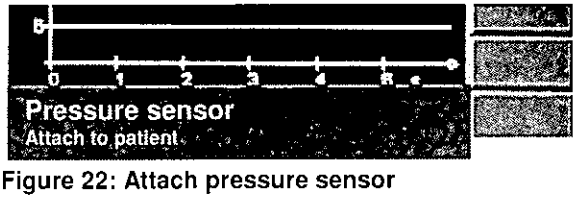

Figure 22: Attach pressure sensor

Until this point in time, the tube set can still be disconnected, use the "Esc" key to return to the beginning step-by-step. The tube set is not yet marked as being used.
As soon as the catheter and the pressure sensor are connected to the patient and this is verified by activating "Okay", the tube set is marked as used and can no longer be employed for a new application. A brief notice appears stating, "Connect sensor cable to the pump and wait", whereby the device checks to see whether the sensor cable is actually connected. At this point the alarm function will activate and the device is put into normal operating mode.

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Notes:

- ▶ During all steps observe also the instructions displayed on the ***LiquoGuard®*** and always adhere to the prescribed sequence of steps.
- ▶ After you have connected the tube set to the catheter, attached the pressure sensor housing to the patient and confirmed with "OK", ***LiquoGuard®*** electronically marks the tube set as used and it cannot be used again.

ATTENTION:

To avoid possible CSF reflux, always close the 4-way stop cock between the tube set and the catheter before removing or replacing the tube set.

The tube set must be replaced after a maximum of 120 continuous operating hours.

Attention: During patient bed bathing please ensure that no liquid penetrates the pressure sensor housing of the tube set for *LiquoGuard®*.

Patient showering is not permitted.

8.2 Setting of patient parameters

Setting of patient parameter target values is carried out via the display control fields, as described as of page 24. For LiquoGuard there are 2 target value settings for application as well as 2 safety settings for the alarm limits:

Setting the patient parameters may only be carried out by qualified personnel.

8.2.1 P-max:

P-max (mmHg) is used to set the upper alarm limit for **LiquoGuard®** alarm conditions. If the filtered actual ICP value is higher than the upper pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 25 mmHg
Minimum value: limited by P-Set
Maximum value: 75 mmHg

8.2.2 P-min:

P-min (mmHg) is used to set the lower alarm limit for ***LiquoGuard®*** alarm conditions. If the filtered actual ICP value is smaller than the lower pressure limit value (alarm limit), ***LiquoGuard®*** creates an alarm condition and issues an optical (red flashing LED) as well as an audible alarm signal. The alarm signal has been set to a time delay of 20 seconds. The color of the digital actual ICP value also changes from green to red.

Default value: 0 mmHg
Minimum value: -15 mmHg
Maximum value: limited by P-Set

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8.2.3 P-Set or P-Stop

During ventricular application **P-Set** (mmHg) is used to set the target value for pressure regulation. If the filtered actual ICP value (mmHg) reaches a pressure higher than **P-Set**, the ***LiquoGuard®*** pump is activated and pumps off the CSF. Pumping continues until the filtered actual ICP value reaches a pressure value lower than **P-Set**. The symmetrical hysteresis value (standard 0.5 mmHg) of this regulation is adjustable in the menu.
During lumbar application **P-Stop** (mmHg) is used to specify the value under which the pump no longer conveys.

Default value:	15 mmHg
Minimum value:	2 mmHg or limited by P-min
Maximum value:	limited by P-max

8.2.4 Flow

Flow sets the pre-selected flow rate of the ***LiquoGuard®*** pump (ml/h). Therefore pumping of the CSF can be influenced by time.

Default value:	20 ml/h
Minimum value:	1 ml/h
Maximum value:	50 ml/h (ventricular application)
	20 ml/h (lumbar application)

Notes:

- When starting a new application (by switching on the device), the parameters are always automatically reset to the standard values.
- In the event that an application is interrupted or when a tube set is renewed (without turning off the device), the parameter values last used will remain set.

Default values:

- ▶ **P-max: 25 mmHg**
- ▶ **P-min: 0 mmHg**
- ▶ **P-Set: 15 mmHg**
- ▶ **Flow: 20 ml/h**
- ▶ **Pulse alarm: "ON"; coupled to: Filter time Control 1.0**
- ▶ **Pressure constant : 0.2 mmHg**

ATTENTION:

An adjustment of the standard values may only be carried out by specialists.
Before every use, the user should check to see whether the momentary settings are suitable for the patient!

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8.3 Short checklist

After attaching the tube set and setting all patient parameters, ***LiquoGuard® CSF*** works independently. Before letting the system work independently you should review the following short checklist:

- **Is the tube set correctly inserted in *LiquoGuard®*?**
- **Are the catheter and drainage bag connected correctly?**
- **Are the stop cocks of the tube set in the correct position for the application?**
- **Are the set patient parameters correct?:**
  - **P-Set or P-Stop - *Pressure setting parameters***
  - **Flow - *Pump delivery rate settings***
- **Are the set alarm limit values correct for the following alarm conditions:**
  - **P-max - *upper alarm limit value for the alarm condition***
  - **P-min - *lower alarm limit value for the alarm condition***
- **Is the pulsation alarm activated?**
- **Is the "Pressure constant" alarm activated and properly set?**

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8.4 Ventricular drainage

During ventricular drainage, ***LiquoGuard® CSF*** functions as a pressure controlled tube pump. Adjustment specification here is **P-Set.** The pressure housing must be attached at the height of the Foramen Monro. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore the position of the sensor at the head must be considered when evaluating pressure values.

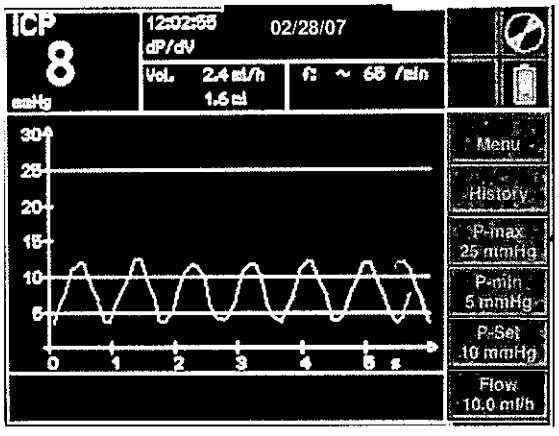

Figure 23: Display setup during ventricular drainage

There are 4 physiological alarm limits during ventricular drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)
- **Measured pulse frequency invalid** (f <= 30/min - fixed limit value)
- **Measured pulse frequency invalid** (f 180/min- fixed limit value)

ATTENTION:
In both important cases of catheter blockage and collapsed ventricles it is usually the case that the pulse can no longer be measured, which triggers an alarm - if activated!

By default, pulsation alarm is set to on. It is an additional monitoring function to increase patient safety (see page 22: Pulsation frequency of pressure signal (f: ~ ---/min)).

It would be expedient to deactivate pulse recognition in the system menu, if patient conditions do not permit accurate measurement. As an indication to the operator that pulse recognition is deactivated, the system displays "(f:)" instead of "f:".

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8.5 Lumbar drainage

During lumbar drainage, ***LiquoGuard® CSF*** functions as a volume controlled tube pump. The specified setting here is the pump flow rate (**Flow**). During lumbar drainage, pulse recognition is deactivated, the time axis is set to 60 seconds by default and P-Set becomes P-Stop (see page 34, P-Set or P-Stop).
The pressure sensor housing should always be on or slightly below the level of the catheter end in the spine. Ask the patient about his sleeping behaviour. Patients sleeping on their sides should have the pressure sensor housing attached to their backs. Patients sleeping on their backs should have the pressure sensor housing attached to their sides. A safety cushion (available as an accessory) can be applied to avoid pressure pains. If the patient moves his head, the measured pressure values may deviate depending on head movements. Therefore avoid that the patient lies on the side, at which the sensor is attached.

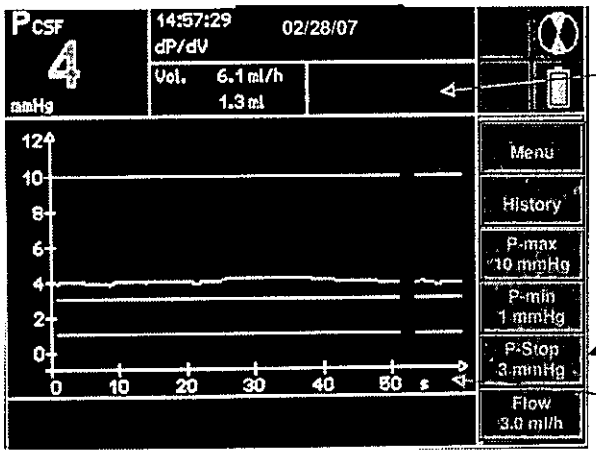

Figure 24: Display setup during lumbar drainage

There are 2 physiological alarm limits during lumbar drainage, which the ***LiquoGuard® CSF*** displays during an alarm condition.

- **Measured pressure too low** (P-min - alarm limit can be set by operator)
- **Measured pressure too high** (P-max - alarm limit can be set by operator)

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8.6 Audio paused or Audio off

In case of an alarm condition, the alarm signals are created with a 20 second delay. The alarm condition is also displayed. In case of multiple alarm condition these are displayed alternatively. (In the example contained in Figure 25 "Measured pulse frequency invalid!" alternates with "Measured pressure too low!".)
Additionally a key menu with 4 options appears on the right hand side of the display: Audio Pause 20 min (duration settable in system menu), Audio Pause 60 min, Audio Pause 180 min and Audio off.

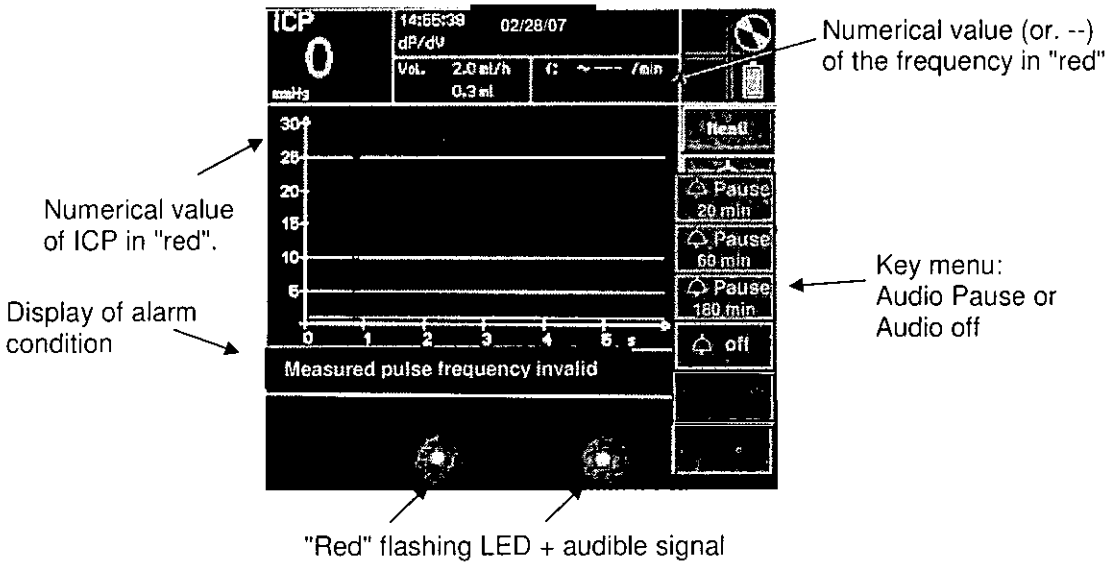
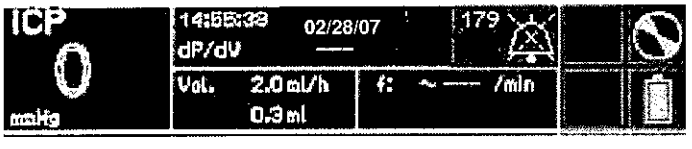


Figure 25: *LiquoGuard® CSF* in alarm mode

The *LiquoGuard® CSF* alarm system cannot be deactivated. The function "Audio paused" or "Audio off" can create a condition in which no audible alarm signal is emitted.



Use the turn switch to select the desired bell (Audio Pause 20 min, Audio Pause 60 min, Audio Pause 180 min or Audio off) and press the turn switch to confirm the function "Audio paused" or "Audio off". This condition is displayed by a crossed out red bell. The remaining duration in minutes is displayed on the left hand side (see Figure 26). In the case of "Audio off" it displays "OFF".

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"Audio paused" and "Audio off" refer to all alarm conditions active at the time of key activation.
In the case of the 3 audio pause time, the cancellation of the alarm condition does **not** lead to the cancellation of "Audio paused". In the case of "Audio off" the cancellation of the alarm condition does lead to the cancellation of the condition "Audio off".

Example:
- Alarm due to low pressure and pulse
- Audio Pause 20 min was pressed
- Both alarm conditions are cancelled and return (within 20 minutes) → Audio Pause remains constant
- Pressure rises to overpressure alarm: An audible alarm is sounded
- Renewed activation of Audio Pause 20 min
- The old alarm pause is deleted, the new pause now applies for 20 minutes for overpressure only!

Notes:

- The delay time of 20 seconds applies for each individual alarm condition.
- In the case of alarm conditions "Sensor defective or disconnected" and "Device error" the pump is stopped, irrespective of further conditions. This is marked by the display of a red pump symbol.
- If an alarm is created and if alarm paused is not pressed for 1 hour, the pump is stopped (this does not apply for exceeding P-max). This is also displayed by a red pump symbol. If alarm pause is pressed, the pump restarts immediately if the alarm condition permits this.
- Aside from the alarm condition (displayed in red), possible reasons for the alarm condition may also occur (e.g. "frequent causes: Catheter occluded/disconnected, ventricles collapsed, ...). These should provide an indication for the possible reason for this alarm condition, although it is the responsibility of the medical personnel/the physician to determine the actual reason for this alarm condition.
- Should "Audio pause" or "Audio off" be activated, this setting can be cancelled by activating the "Audio on" button (through "Audio on" an audible (acoustic) alarm signal will be reactivated). The "Audio on" field can be reached by pressing the alt key twice.

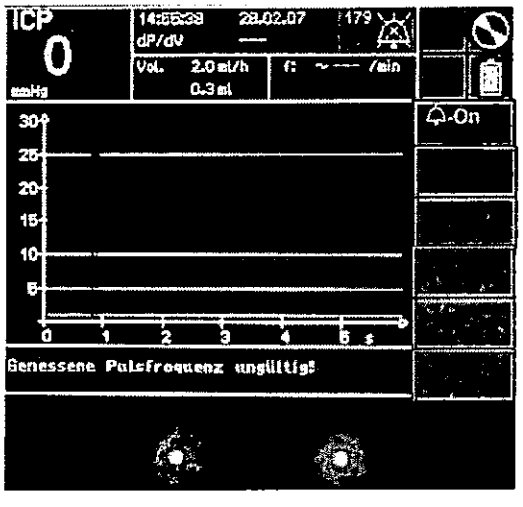

Figure 27: ***LiquoGuard® CSF*** **– „Audio On"-key**

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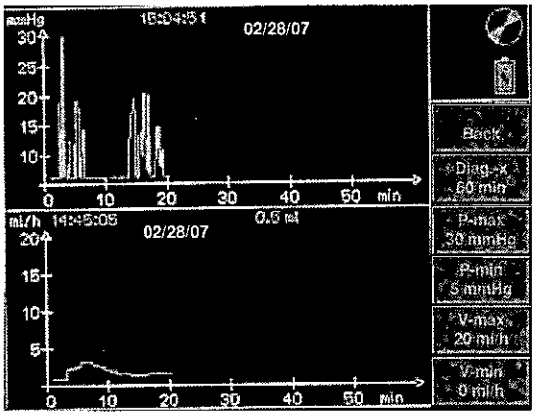
8.7 History

You can move to the "History" function via the display control field key "**History**". You can leave the "History" function via the Standby key, as well as via the Back button or the Alt key.
In the "History" function 2 diagram fields are displayed:

The upper diagram displays the pressure value [mmHg] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].



Display operating keys

Figure 28: History frame

The lower diagram displays the pumped-off CSF volume [ml/h] (y-axis) via the lapsed time [preset time spread of x-axis / Seconds – Minutes – Hours].

Display control keys:

- **Diag.-x**
  This key is used to set the time spread of the axis (x-axis) from:
  - 10 seconds to 120 seconds in increments of 10 seconds,
  - 3 minutes to 120 minutes in increments of 1 minute,
  - 3 hours to 72 hours in increments of 1 hour,

  The setting is the same for both diagrams.
- **P-max / P-min**:
  You can use these two keys to set the spread of the pressure values (y-axis) in the upper diagram (adjustable from -50 mmHg to 99 mmHg).
- **V-max/V-min** :
  You can use these two keys to set the spread of the volume values (y-axis) in the lower diagram (adjustable from 0 ml/h to 130 ml/h).

You can view the long-term process of the two diagrams in time frames using the turn-switch.
The two blue digital displays in the lower diagram will show you the time frame for time and date of the y-axis position. The volume value on the right indicates how much CSF (ml) was conveyed in that precise time period (whereby the balance is determined from the displayed measurement values).

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8.8 Output of memory data

The internal memory of ***LiquoGuard®*** provides space for 150.000 data sets.
In the following table you can see the relation between sampling interval and memory storage time:

Sampling interval	Memory storage time
6.0 s	10d 09h 39m
5.0 s	8d 16h 03m
4.0 s	6d 22h 26m
3.0 s	5d 04h 49m
2.5 s	4d 08h 01m
2.0 s	3d 11h 13m
1.5 s	2d 14h 24m
1.0 s	1d 17h 36m
0.5 s	20h 48m
0.2 s	8h 19m
0.1 s	4h 09m

Please remember: The smaller the sampling interval, the more frequently the data will have to be stored on a card, since the data will otherwise be overwritten.

The following data is stored in the internal memory of ***LiquoGuard® CSF.***

- Date
- Time
- Pressure
- Flow
- Compliance
- P-Set
- Flow-Set
- Pause: 1 if pause, otherwise 0
- Pumping: 1, is pump is activated, otherwise 0
- Marker: at the moment always 0
- Statuscode

Table headlines:

Date	Time	Pressure	Flow	Compliance	P-Set	Flow-Set	Pause	Pumping	Marker	Statuscode

An MMC or SD memory card (format: FAT 16) can be used to read out data created by ***LiquoGuard® CSF***. Insert the memory card into the slot next to the pump, whereby the contacts must point towards the pump head. ***LiquoGuard® CSF*** will ask whether the data must be written to the card. Confirmation with "Yes" will immediately start the copying process. The card symbol will change its color to orange; the inside of the symbol will display the percentage of the already copied data. After copying is completed, the symbol changes back to blue and the card can be removed.

Display for memory card

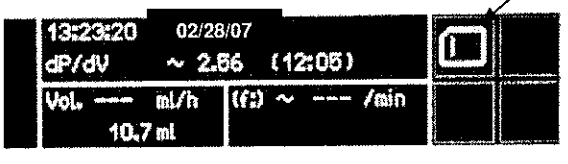

Figure 29: Symbol for memory card

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During writing the software checks whether a memory card is full. The writing procedure becomes irregular towards the end and if there is insufficient space, the error message "Error while writing to card!" will be displayed. The started file is subsequently deleted and the card symbol will display "Err", until the card has been removed.
In this case ensure that there is sufficient memory on your card and then resave. (A full internal memory requires approx. 4 - 5 MB memory capacity).

ATTENTION: The card must not be removed during the copying process!
All data on the memory card may be irretrievably lost!

8.9 Replacement of tube set

After 5 days, ***LiquoGuard® CSF*** displays two round flashing red arrows in the info field of the keys lock (see page 26) together with the red text "Please change tube set!". This indication is not an alarm. If keys lock is active, the tube set symbol alternates with the key symbol. After 7 days, ***LiquoGuard® CSF*** emits the same message as an alarm. The alarm pauses can be used here, but the alarm does not disappear during this application.
In order to perform a proper change of the tube set, the application has to be interrupted with "Set change" (see 8.10).

Figure 30: Symbol for tube set replacement

8.10 Interruption of an application

There are 2 ways to interrupt an application:

1) Press and hold the **"ON/OFF – Standby – key"** for at least 2 seconds
2) Open the front cover of the pump of the ***LiquoGuard® CSF***

Both of these ways cause a new selection menu to appear on the right side of the display showing 4 different points to be selected (Interrupt, END, Change set, Esc)

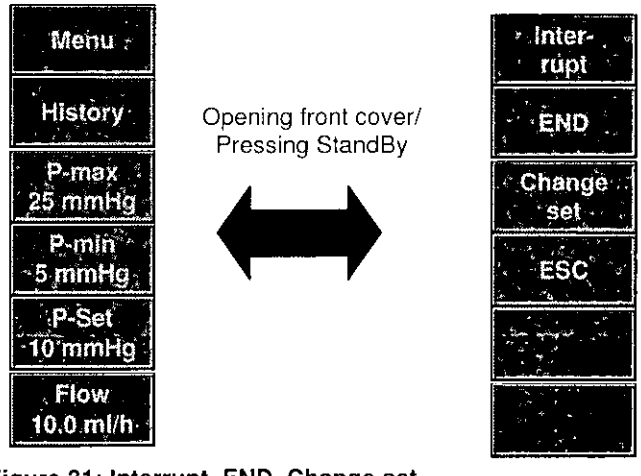

Figure 31: Interrupt, END, Change set

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Should you wish to change the tube set, select "Change set". If you want to interrupt the application (e.g. to perform a CT), select "Interrupt". In both cases, the next question to appear will be, "Interrupt application?". By selecting "Yes", the question, "valve to catheter closed?", will appear.
Be sure to see that the shut-off valve to the catheter is closed, then verify this with "Okay". The tube can now be removed (and reconnected later) or the tube set can be renewed.
When the tube set is reattached, one should not forget to open the shut-off valve to the catheter once again.

Notes:

- If the sensor cable is disconnected, the notice "Interruption, connect tube set" will appear and the symbol for a circulating pump will be displayed in red. The measuring value will be displayed as -- . In the data record you can recognize this condition as measuring values < - 90 mmHg
- Pulling the plug from the tube set without following the instructions described above will always lead to the alarm condition of "Sensor defective or disconnected". Should this occur, reattach the plug. Should you wish to end or interrupt the application, or to change the tube set, please follow the instructions described above.
- When the alarm condition "Sensor defective or disconnected" appears, it is impossible to activate "Audio pause" or "Audio off". An intentional removal of the tube set must be performed using the 4 keys on the right edge of the display (Interrupt, End, Change set, Esc; see Figure 31) (as described above, these 4 keys can be activated using the Standby key or by opening the cover). The device will recognize any other procedure as being faulty.
- With "Esc" you will always be able to return to the normal control display.

8.11 Exiting the application

Press and hold the ON/OFF - Standby key for at least two seconds. As described under 8.10, a selection menu with 4 points will appear. Select "End". The question "Sure to turn off the device?" will appear and the total volume of the application will be displayed. If confirmed with "Yes", ***LiquoGuard® CSF*** will exit the application and switch off.

Please observe that you cannot start a new application with the used tube set.

Should you have forgotten to read out the data via the memory card, you can restart ***LiquoGuard® CSF*** and read out the data one last time. The connection of a new tube set deletes all existing data.

In Standby mode (***LiquoGuard® CSF*** - is connected to AC power) the blue LED flashes and the battery is charged.

If the AC power chord is disconnected, ***LiquoGuard® CSF*** is switched off.

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8.12 Demonstration mode

The device has a demonstration mode ("Demo mode"), which may only be used for the purpose of performing demonstrations and for teaching! The Demo mode can be recognized through the red flashing "Demo" indicator to the upper left of the display (to the right and beside ICP/P_{CSF}).
One automatically comes to the Demo mode when a special, unsterile demonstration tube set is connected.
Note: In the Demo mode, the device will turn off automatically after a certain period of time without previous warning! The Demo mode should NEVER be used on a patient!

8.13 System menu

Use the display control field key "Menu" to access the "System menu". However, access to the system menu is only possible if ***LiquoGuard® CSF*** is in "Pause mode". The selection bar is moved with the turn-switch. The corresponding sub-menu is selected by pressing the turn-switch. The submenus consist of several parameters that are displayed in sequence. A further parameter is always reached by pressing the turn-switch. You can now change the preset value by turning the turn-switch. A value being edited is displayed as orange during this time. If you want to accept the changed value, press the turn-switch. A text will appear in the display as a reminder: "Confirm changes with the wheel".

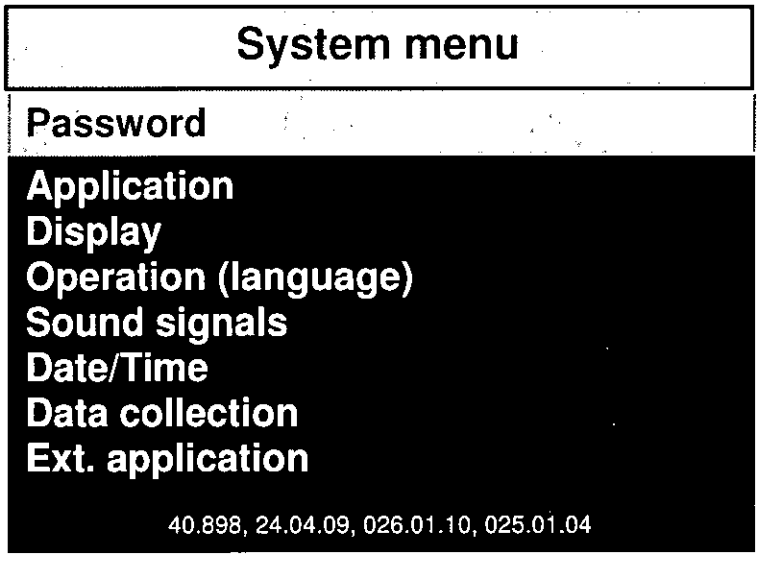

Figure 32: System menu

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Input of figures in the system menu is also possible in numbers. To activate this function during number input in the system menu, press the Alt key. A numeric keyboard appears in which you can enter values using the wheel. Press "END" to accept the values. Values which are too large are automatically limited by the maximum value. The Alt key therefore no longer serves as Esc at this point.

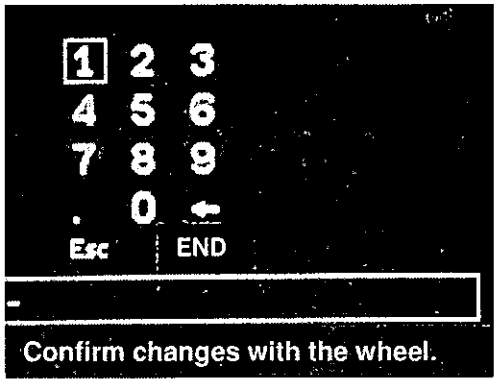

Figure 33: Numerical input

If the value is not to be adopted, leave the level with the Standby key or wait until the system menu is automatically exited - a negative confirmation tone is then sounded. You can set the time for automatic exiting (Standard 60 seconds).

8.13.1 Sub-menu Password

This point currently has no function for the operator. All menu items remain visible for the operator.

8.13.2 Sub-menu Application

The settings for the application are made in the Application sub-menu.

(1) Sampling rate memory [s]

Meaning: Time step in which a measured value is saved to memory.

Default value: 6.0 seconds
Minimum value: 0.1 seconds
Maximum value: 600 seconds

(2) Duration of volume balance [h]

Meaning: Time step for calculating the volume balance – also see page 23 Volume balance: CSF volume/set time (Vol. 0.0 ml/x h).

Default value: 24 hours
Minimum value: OFF (set values: OFF, 2 h ... 24 h, steps of 2)
Maximum value: 24 hours

(3) Flow increment

Meaning: This setting changes the increment for the operating field "Flow" (ml/h).

Default value: 1.0
Minimum value: 0.1
Maximum value: 10.0

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(4) Pressure increment

Meaning: This setting is used to change the time step for the operating fields "P-max / P-min / P-Set" (mmHg).

Default value: 1.0
Minimum value: 1.0
Maximum value: 10

(5) Duration Audio pause

Meaning: This setting sets the time for the shortest possible duration of "Audio paused".

Default value: 20 minutes
Minimum value: 1 Minute
Maximum value: 20 minutes

(6) Define application

Meaning: This can be used to reset the type of application during an application.

Possible parameter settings: lumbar, ventricular
(No default value, setting remains after reset)

8.13.3 Sub-menu Display

The settings for the display are made in the "Display" sub-menu.

(7) Range diagram

Meaning: The pressure axis in measuring mode is automatically scaled according to the alarm limits. In order to display a larger range, 20 % more than the upper alarm limit and 20 % less than the lower alarm limit are shown. The percentage is always related to the upper alarm value.

Default value: 20 %
Minimum value: 0 %
Maximum value: 100 %

Example: P-min = 5 mmHg, P-max = 25 mmHg, the diagram ranges from 0 mmHg (5-5) to 30 mmHg (25+5).

(8) Timeout backlight [s]

Meaning: In order to save power or to have a darker screen during night operation, the background lighting automatically switches into the darkest setting after an adjustable time (seconds). If this function is not wanted, the parameter can be set to OFF. During battery operation, the display is always darkened after 5 seconds.

Default value: OFF
Minimum value: OFF
Maximum value: 600 seconds

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(9) Brightness Display

Meaning: The brightness of the background lighting of the display is preset here. The value directly affects the display as it is changed so that the user can find the correct setting more easily. Setting is made in 4 steps.

Default value: 4
Minimum value: 1
Maximum value: 4

(10) Colour mode

Meaning: You can select a colour mode setting between 1 and 0.

"1" " means "dark" display background colour
"0" " means "light" display background colour
(Default value: "dark" display background colour)

8.13.4 Sub-menu Operation (language)

The "Operation" sub-menu contains functions that relate to the behavior of the unit with respect to the user.

(1) Language (language)

Meaning: The display language can be set here, and further languages can be stored.

Default value: ENGLISH
Value (depending on configuration): DEUTSCH, ENGLISH, Français, Svenska

(2) Operation Timeout [s]

Meaning: Settings or key activations are exited after a set time in seconds, independent of the level or in which parameters the input is carried out. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the input can only be exited by pressing the service screen "Standby" or "Alt". This time does not apply to the system menu.

Default value: 10 seconds
Minimum value: 1 second
Maximum value: 120 seconds

(3) Timeout menu [s]

Meaning: The system menu is closed after the preset time in seconds, independent of the level or the parameter currently being entered. A parameter which has not yet been accepted with "OK" (pressing of the turn-switch), is discarded. If the parameter is set to "OFF", the system menu can only be exited by pressing the service screen "Standby" or "Alt".

Default value: 60 seconds
Minimum value: OFF
Maximum value: 600 seconds

8.13.5 Sub-menu Sound signals

The operator cannot change the volume of the activation signal.

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8.13.6 Sub-menu Date/Time

The system clock of ***LiquoGuard®*** can be set or changed respectively in this sub-menu.

(1) Date format

Meaning: Setting the date format

Default value: DD.MM.YYYY
Possible parameter settings: DD.MM.YYYY; MM/DD/YYYY; YYYY-MM-DD

(2) Clock: Year

Meaning: Setting of the current year

Minimum value: 2001
Maximum value: 2099

(3) Clock: Month

Meaning: Setting of the current month

Minimum value: 1
Maximum value: 12

(4) Clock: Day

Meaning: Setting of the current day

Minimum value: 1
Maximum value: 31, depending on the set month

(5) Clock: Hour

Meaning: Setting of the current hour

Minimum value: 0
Maximum value: 23

(6) Clock: Minute

Meaning: Setting of the current minute

Minimum value: 0
Maximum value: 59

(7) Clock: Second

Meaning: Setting of the current second

Minimum value: 0
Maximum value: 59

8.13.7 Sub-menu Data collection

(1) Decimal point

Meaning: Decimal markers in figure display on memory card. This setting is required for various countries.

Default value: Comma
Possible parameter settings: Comma, full stop

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(2) Data format MMC

Meaning: Setting the data format output depending on evaluation software

Default value: ASCII
Possible parameter settings: ASCII, LABpilot

8.13.8 Sub-menu Extended application

(1) Hysteresis controller [mmHg]

Meaning: This setting pre-selects a defined hysteresis for the pressure controller (target pressure curve). The hysteresis is symmetric to the target value, i.e. a target value of 12 mmHg and a hysteresis of 0.5 mmHg starts the pump at a pressure higher than 12.5 mmHg and will pump until the pressure is lower than 11.5 mmHg.

Default value: 0.5 mmHg
Minimum value: 0.5 mmHg
Maximum value: 1.5 mmHg

(2) Filter time control [s]

Meaning: The measured value for display of the digital pressure value can be filtered to avoid too high pressure changes of the digital pressure value as well as a continuous on and off of the pump. In order to filter out the pulse beat, the value must be set to at least 1.0 seconds. The set value displays after which time period 63% of the new value was reached after a step.

Note: This value is coupled to the pulsation alarm during ventricular drainage. If the pulsation alarm is ON, it is activated, the value is automatically set to 1.0; if pulsation alarm is OFF, it is set to 0.0 (in order to achieve a more rapid reaction time for the pump). This can be set manually by way of the system menu, but will once again be returned to the standard values when an adjustment is made for the pulsation alarm.

Default value: 1.0 (lumbar drainage, lumbar infusion test and ventricular drainage if pulsation alarm ON); 0.0 (ventricular drainage if pulsation alarm OFF)
Minimum value: 0.0
Maximum value: 60.0

(3) Filter time display or filter time display lumb. [s]

Meaning: The measured value for display in the diagram can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. If a clearly higher value is selected instead of a time resolution of 6 seconds, we recommend setting a longer filter time to enable the display of an averaged value. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 0.0 ventricular drainage; 0.5 lumbar drainage / lumbar infusion test
Minimum value: 0.0
Maximum value: 60.0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(4) Filter time history [s]

Meaning: The measured value to store the data for the history function and the memory card can be filtered. Should the pulsation be recognizable by the heart beat, the value must be 0.1. But then the scan time for the memory must obviously be set to 0.1 seconds. For a storage time of 1 second or more you should also select a filter constant of 1 second or more, so that averaged values can be stored. The set value displays after which time period 63% of the new value was reached after a step.

Default value: 1.0
Minimum value: 0.0
Maximum value: 60.0

(5) Average value volume [min]

Meaning: Period for the calculation of the average volume flow

Default value: 15
Minimum value: 15
Maximum value: 60

(6) System information

Meaning: The setting "Yes" is used to display system information serving Möller Medical service staff for remote diagnosis.

(7) Reset System menu

Meaning: With the setting or changing of Reset System menu to "Yes", all changed setting parameters in the system menu are reset to standard values stipulated by the manufacturer. If confirmed with "No", all settings changed by the operator will be retained.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Troubleshooting

***LiquoGuard®* CSF may not be opened by the operator!**

This chapter describes some problems which may occur in connection with ***LiquoGuard® CSF*** Several possible solutions are listed for each problem. The first proposed solution is generally the most suitable. If the problem is not resolved, work through the proposed solutions in the order listed until the fault is rectified. ***LiquoGuard® CSF*** must always be switched off during connection or disconnection of connectors, with the exception of the tube set. If this does not remove the error, please contact the Möller Medical service division: service@moeller-medical.com.

Problem	Solution
Not functional, the display is switched off. Or ***LiquoGuard® CSF*** cannot be activated.	***LiquoGuard® CSF*** is not correctly connected to the AC power supply. Check power supply, switch on any multiple sockets, and check feed line. If these possibilities can be excluded, the error must be corrected by the service centre.
Pump does not rotate.	Pump is in "PAUSE" mode
Moistness penetrated the connectors	Pull AC power chord. Allow connectors to dry.
The device issues a rhythmic beep	Indicates an alarm. Press the Standby key 3 times in succession. If the device returns to this condition repeatedly, the device should be checked by Service.

If these measures do not eliminate the problem, the device should be inspected by Möller Medical service personnel.

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10 Service

If the solution to a problem cannot be found, please contact the responsible service centre of Möller Medical.

Each return delivery of ***LiquoGuard® CSF*** must exclude risk of infection by a previously conducted disinfection procedure. The disinfectant may not be sprayed into the memory card slots.

Consumable materials should be disposed of in accordance with hospital guidelines.

Service Information

Never open the device if it is connected to the power supply. Attention - even then internal unit parts can still be voltaged.

Möller Medical service centre:

Möller Medical GmbH
Wasserkuppenstrasse 29-31
D – 36043 Fulda
Phone: +49 (0) 661 / 94 19 5 - 0
Fax. +49 (0) 661 / 94 19 5 - 90
http://www.moeller-medical.com
E-mail:info@moeller-medical.com

Service
Phone: +49 (0) 661 / 94 19 5 - 48
Fax. +49 (0) 661 / 94 19 5 – 92
E-mail:**service@moeller-medical.com**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11 Accessories

The products described here represent only a small selection of the equipment available for ***LiquoGuard® CSF***. The currently valid list of equipment (including the prices) can be requested from Möller Medical on a separate Order form (neurochirurgie-vertrieb@moeller-medical.com; +49-(0)661-94195-85).

11.1 Tube set for LiquoGuard®

REF.-No.: 92 007 836 (1500 mm/59.06 inch)
1 cmpl packed Article No.: **00 002 650**

REF.-No.: 92 008 568 (2000 mm/78.74 inch)
1 cmpl packed Article No.: **00 002 911**

11.2 *LiquoGuard®* Software: Lumbar Infusion Test

Additional option for ***LiquoGuard®*** Article No.: **00 003 165**

11.3 Tube Set for the Lumbar Infusion Test *LiquoGuard®*

REF. No.: 92 008 646 (1500 mm)
1 cmpl packed Article No.: **00 002 962**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12 Option: Lumbar Infusion Test (Not available in the US)

Unlike in CSF drainage, this application consists of infusing artificial cerebrospinal fluid (CSF) into the spinal canal.

ATTENTION: A prerequisite for the lumbar infusion test is that the operator is familiar with the regular use of ***LiquoGuard®***, that she/he has received extensive training on the device and has read and understood the instruction manual in its entirety.

12.1 General Description

The lumbar infusion test is an established clinical method for indirect measurement of the CSF absorption capability of patients with normal pressure hydrocephalus (NPH). Following the puncture of the intrathecal space, a suitable infusion system with combined pressure measurement is connected, fluid is pumped into the subarachnoid space of the patient at a defined flow rate, and the cerebrospinal pressure is measured simultaneously. The user determines the flow rate and detects the initial and final fluid pressure values.
In the lumbar infusion test with ***LiquoGuard®***, artificial CSF ("infusion solution" - saline solution or CSF substitute) is infused into the patient at a defined flow rate (volume flow rate "Flow"). The pressure value prior to infusion (P-Start) and the stabilized pressure value during infusion (Plateau) are required to compute the ROF (Resistance to OutFlow). The ROF is computed as follows:
(Plateau [mmHg] – P-Start [mmHg]) / Flow [ml/min].
This value is indicated on the ***LiquoGuard®*** display. The ROF dimension is [mmHg / (ml/min)]. The display indicates this in the same manner, although "Flow" is adjusted in [ml/h].
The patient must lie down for the duration of the application to avoid excess pressure.
Qualified personnel must be present for the duration of the application. The measured value depends directly on the initial pressure and the plateau pressure set by the physician. The physician is therefore directly responsible for the measurement results.

Attention:
Reaching a plateau level is dependent on the health of the patient. The physician must monitor the patient constantly and must interrupt or discontinue the test using the Pause key in cases where the patient is observed to demonstrate dangerous pressure levels. The evaluation of these pressure levels is alone the responsibility of the physician; the ***LiquoGuard®*** serves merely as an aid to make this work easier.

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Option: Lumbar Infusion Test (Not available in the US)

12.2 Purpose

The option "lumbar infusion test" of the ***LiquoGuard®*** may only be used in conjunction with the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646**. This tube set also contains the spinal cannula (touhy needle) which is needed for the infusion test.

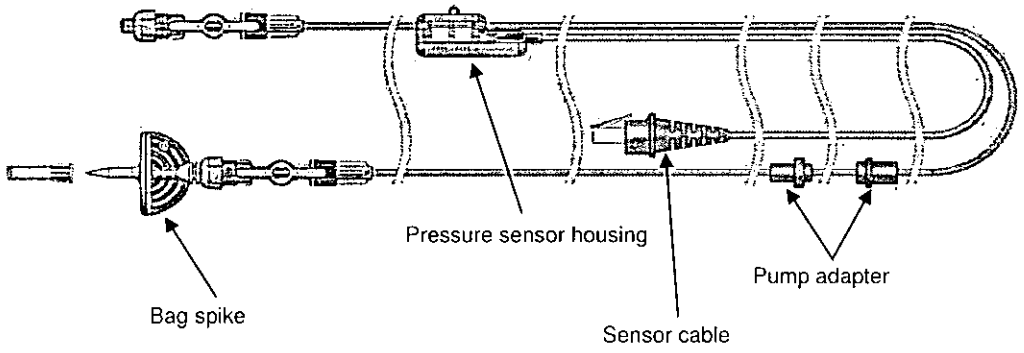

Figure 34: Tube set for lumbar infusion test (spinal cannula and adhesive electrode not displayed)

The purpose of the tube set "tube set for lumbar infusion test ***LiquoGuard®***" is to convey at constant flow rate up to 100 ml infusion solution (physiological saline solution or CSF substitute) through the spinal canal with simultaneous pressure measurement. The purpose of the device in conjunction with the tube set is: "to carry out the lumbar infusion test".
The appropriate location for its application includes monitored medical hospital rooms or neurosurgical practices. Qualified personnel must stay with the device/patient for the entire duration of the application.
The application time is limited to one hour.

The tube set for the lumbar infusion test is intended for use in combination with ***LiquoGuard®*** and must therefore be connected to this system, i.e. the set alone cannot fulfill the intended purpose of the system. It has been designed exclusively for the infusion of CSF-like fluid into the subarachnoid space and must not be used for the infusion of drug solutions or other constituents. The lumbar infusion test only serves for NPH diagnosis by means of the evaluation method referred to as "lumbar infusion test" in the related literature. The withdrawal of CSF or the connection to other body systems (e.g. blood system) are incompatible with its intended use.

For this special application ***LiquoGuard®*** may be used for the infusion of fluid (saline solution or CSF substitute) into the spinal canal.
It is, however, not an infusion pump because the lumbar infusion test serves diagnostic purposes and is continuously monitored by the operator.

ATTENTION: The lumbar infusion test must not be the only means of diagnosis resulting in measures taken on the patient.

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Option: Lumbar Infusion Test (Not available in the US)

12.3 Indications

Diagnostic indications for lumbar infusion test

The nervous system (brain, spinal cord) is surrounded by cerebrospinal fluid (CSF). The production and absorption of CSF are in a stable balance. Normal pressure hydrocephalus (hereinafter abbreviated as NPH) is a disease that involves an imbalance between the production and absorption of CSF. Patients with this clinical picture can show numerous different symptoms such as gait disorders (magnetic gait), memory disturbances and micturition problems (incontinence). These symptoms are typical of NPH, but can also be diagnosed in individuals with other cerebral disorders (such as Alzheimer's disease or other dementia problems). The treatment of NPH involves the continuous drainage of CSF from the ventricles of the brain into another body cavity, usually intraperitoneal (ventriculoperitoneal shunt = VP shunt) or into the blood system (usually into the atrium, i.e. ventriculo-atrial shunt = VA shunt). In order to determine whether and how a shunt system can contribute towards successful therapy, meticulous diagnosis must be performed in order to ascertain whether a patient actually suffers from NPH. Besides the determination of clinical symptoms, imaging diagnosis is required in order to check for typical NPH symptoms (extension / disproportion of ventricles, effacement of the cerebral sulci, etc). Since, however, the combination of clinical and imaging exams is not sufficient for safe diagnosis, further examination methods must be applied. Besides continuous lumbar drainage, the lumbar infusion test represents an additional method for NPH diagnosis verification.

12.4 Execution of the lumbar infusion test

The puncture of the intrathecal space is a prerequisite for the lumbar infusion test. The patient is usually placed in the lateral position, the skin in the centreline of the lumbar spine is disinfected, and under sterile conditions the subarachnoid space is punctured using a suitably dimensioned spinal cannula. As soon as the proper CSF flow is ensured, a tube system is connected to the positioned needle. This tube system is connected to a pressure measuring device. Using an infusion pump, sterile, CSF-like fluid can be infused via the tube system. Prior to starting the infusion, the initial pressure must be measured. Afterwards, the fluid is infused at a defined rate (in most cases 1 to 2 ml/min) while continuously measuring the pressure until a specific plateau pressure has been reached, or until a critical pressure value forces the attending physician to abort the test. To calculate the ROF ratio (resistance to outflow, indicated in mmHg/ml/min), the pressure difference determined (plateau pressure – initial pressure) is divided by the flow rate (ml/min). A ratio higher than the critical value (in most cases 12-18 mmHg/ml/min) is an essential criterion for the diagnosis of an NPH. However, expert literature does not describe the lumbar infusion test as a single method for NPH diagnosis, and this method is not suitable for this purpose.

Puncture of the subarachnoid space

The subarachnoid space is punctured by means of a spinal cannula (usually a Touhy needle).

Intrathecal CSF drainage

The withdrawal of CSF requires the surgical installation of an approved cannula into the intrathecal space. This surgical intervention is indicated in case of suspicion of NPH.

12.5 Contraindications

The contraindications determined for any other puncture of the subarachnoid space also apply in this context:

Absolute contraindications: Blood coagulation disorders, thrombocythemia, superficial or deep infections of the skin, bone, meninges or brain. Especially in case of cerebral,

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meningeal or intraventricular infections (encephalitis, meningitis and ventriculitis), increased intracranial pressure, CSF passage dysfunctions and expansive spinal column or cord processes

12.6 Use in Conjunction with other Products

The option "lumbar infusion test" of the ***LiquoGuard®*** may only be used in conjunction with the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646** by Möller Medical. Accordingly, the "tube set for the lumbar infusion test ***LiquoGuard®***", **REF. No.: 92 008 646** may only be used with the option "lumbar infusion test" of the ***LiquoGuard®***.

12.7 Patient Population

This application may only be used on patients with suspected normal pressure hydrocephalus (age group: usually middle-aged to elderly).

12.8 Remaining Risks

The use of ***LiquoGuard®*** with the "lumbar infusion test" option poses the following risks when carrying out the lumbar infusion test: increased CSF pressure, fluid infusion outside the subarachnoid space in the event of malpositioning of spinal cannula, cerebrospinal fluid infection.

12.9 Application and Operation

The lumbar infusion test is incorporated as option and can be selected via the menu prompt at the beginning (see Page 30). If the option is available, "*Infusion test*" is displayed on the screen when the device is switched on (when software version is displayed).
As the lumbar infusion test is a diagnostic procedure during which small pressure differences are decisive, qualified personnel must stay with the patient throughout the entire process and attend the application. This is important as changes in the position of the patient would more significantly affect the measurement than the additional infiltration.
The operator must manually start and finish the procedure as the automatic mode is risky for the same reasons. In this way the operator specifies the initial pressure as well as the changed final pressure.

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Option: Lumbar Infusion Test (Not available in the US)

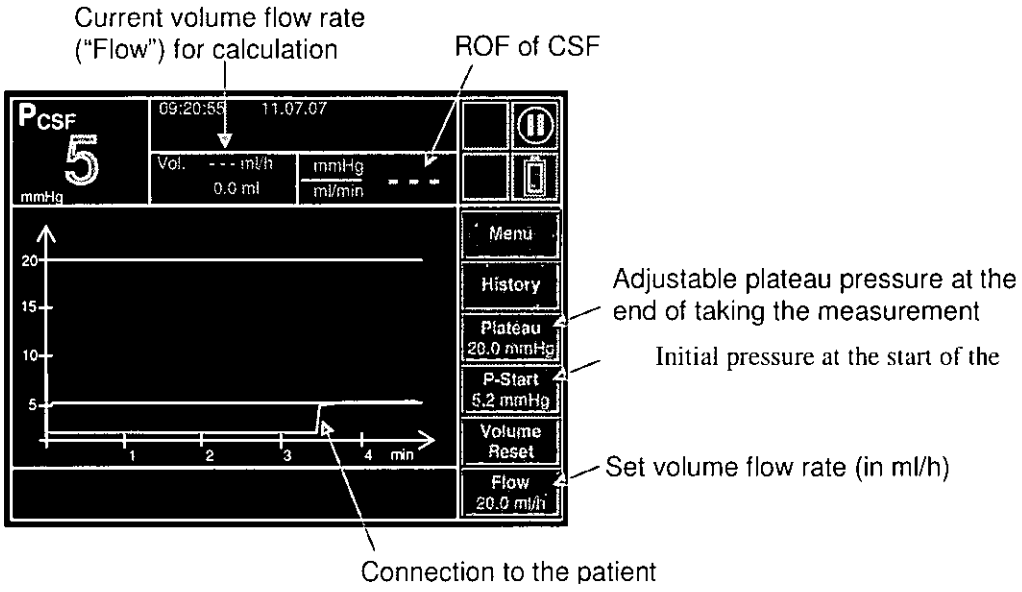

Figure 35: Display setup for option "lumbar infusion test"

Notes:

- The filtered pressure values only are displayed.
- Two horizontal gray curves are displayed rather than the alarm limits. The operator sets one curve to the initial pressure value. The second curve can then be set to the final pressure value.
- The pressure axis scaling is based on these two curves; however, they can be moved directly on the screen prior to accepting the values. The display is rescaled by accepting the values.
- These two cursor values and the set volume flow rate are always used to compute the CSF flow resistance. The physician has to make the moment he accepts this value as the actual measured value dependent on the current pressure signal; meaning the moment when the measured pressure has actually reached the upper plateau.
- The motor no longer stops during pumping when the pressure has dropped below the lower alarm pressure, but rather when the upper alarm limit is exceeded.
- There is no "Pressure too constant" alarm for the infusion test. This parameter is also skipped in the menu.
- The "History" function is also available for the infusion test. A wider pressure range can be viewed here when taking the measurement.
- Data storage and data transfer to a memory card work in the same way as in the Drainage Mode.

12.9.1 Preparation

For the first steps please see at page 30.
→ „Select application": For the lumbar infusion test select "Infus-T".

Afterward, please carry out the following procedures:

1. Remove a tube set for the selected application from the sterile package and clip the adhesive electrode to the pressure sensor housing.

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Option: Lumbar Infusion Test (Not available in the US)

2. Insert the tube set into the pump (see page 31).

3. "Sensor cable - connect to pump and wait."
→ If you haven't done it yet: Connect the sensor cable to the pump (see page 32). The next step is indicated automatically.

4. "Bag with infusion solution - connect to tube set and confirm."
→ Remove the protective cap from the spike and use it to prick the container with the CSF substitute.
As soon as you have verified with "Okay", the pump will begin running with a maximum velocity.
Note: By pressing ESC, you will be returned to "Connect the sensor cable to the pump and wait". If the sensor cable is still connected, the device will automatically continue to the next step ("... container with the infusion solution..."). Should you wish to interrupt this process, you must first disconnect the sensor cable from the device and then press Esc. Hereby, you will return to "Connect sensor cable to the pump and wait", where you can now press Esc once again in order to return to the site where a particular application can be selected.

5. "Fill tube – Press END once tube is filled."
→ Remove the protective cap from the one way stop cock and fill (aerate) the tube set.
Wait until fluid starts dripping from the tube set, then press "END".
Note: If air still remains in the tube set, the measurement may be inaccurate and air may be pumped into the patient.

6. Remove the additionally wrapped spinal cannula (Touhy needle) from the packaging and puncture the patient. Wait until the cannula is filled with CSF.

7. Connect the cannula with the tube set.

8. "Pressure sensor - Attach to patient."
→ Attach the pressure sensor to the patient to avoid inaccurate measurements. After you have pressed "Okay", the current pressure will be applied as "P-Start" (initial pressure). This is typically the correct pressure for starting the application. The operator, however, can still change this value at a later stage.

Note: Until this point in time, the tube set can still be removed by pressing "Esc" and returning step-by-step in order to start at the beginning. The tube set is not yet marked as being used.
As soon as you have connected the catheter and the pressure sensor to the patient, and have verified this with "Okay", the tube set is marked as used and can no longer be used elsewhere. Once again, the message "Connect sensor cable to the pump and wait" appears briefly, whereby the device controls whether or not a sensor cable has actually been connected.
As of this point in time, the alarm function is also activated and the device is in normal operation.

12.9.2 Taking the Measurement

At the end of the menu prompts the ***LiquoGuard®*** is in Pause mode, i.e. the pump is inactive. Now check whether the current pressure is relatively constant and whether it complies with the automatically set start curve ("P-Start"). If the start curve does not comply with the constant pressure, adjust the start curve using "P-Start".
If the pressure is not constant, please check whether the sensor was attached correctly. The patient must remain still, otherwise fluctuations in pressure may occur.

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Option: Lumbar Infusion Test (Not available in the US)

Once the pressure is stable (constant) and the start curve is correctly set, press the "Pause" key to start the pump.

Notes:

- If the current pressure and the start curve are identical, only the start curve will be visible.
- The display runs from the right-hand to the left-hand side. The current values are always indicated on the right-hand side (unlike the Drainage Modes).
- No value is displayed as long as the pump is in Pause mode because there is no volume flow rate ("Flow").
- When the pump mode of the device is activated, the pump is always active for 8 seconds, after which pumping is interrupted for 2 seconds in order to measure the pressure until pumping once again resumes, a procedure which continues repeatedly.

12.9.3 Infiltration

The pressure increases after the pump is activated until a new stable pressure plateau has been reached. This constant pressure that corresponds to the set flow of the pump is required to compute the "ROF of CSF". The operator must set the reached plateau pressure via "Plateau", whereby she/he must ensure that this plateau value is actually stable and does not rise further.
"ROF of CSF" is always computed with the currently applicable settings/values, so that the operator has an idea what the probable result may be at the end of taking the measurement.
If "Flow" is changed during the application, the operator will have to wait for a stable plateau pressure again.

Note:

- The start curve (P-Start) can be adjusted throughout the application.
- In practice it is often difficult to reach a stable plateau value. The final value is subject to strong variation. In this case, it must be ensured that the pressure does not increase any further. The attending physician is responsible for setting the correct plateau pressure value.

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Option: Lumbar Infusion Test (Not available in the US)

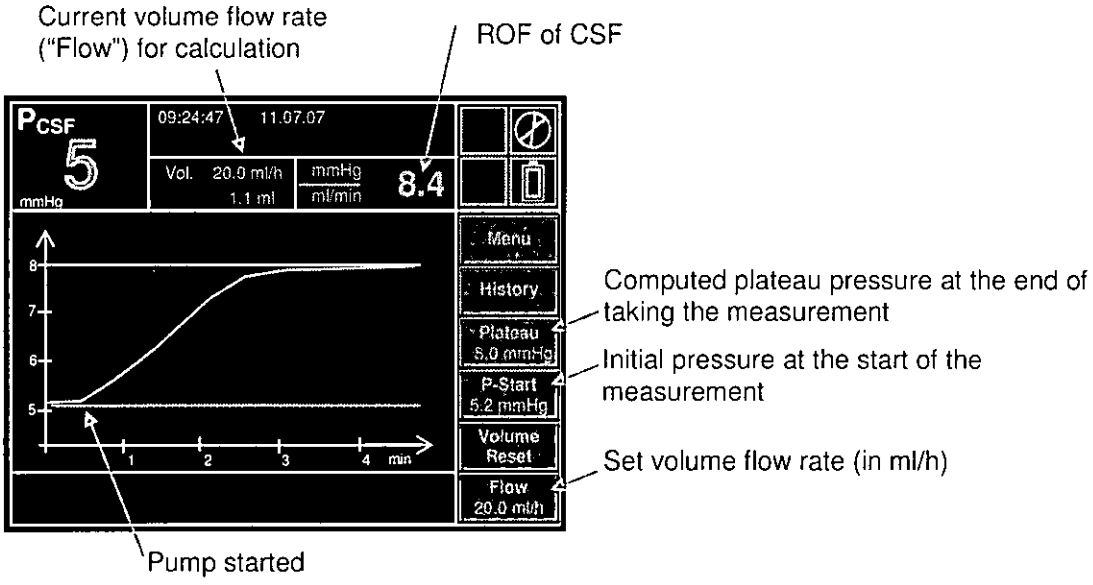

Figure 36: Display setup for option "lumbar infusion test" during the application

Setting options:

- **Plateau**: P-Start to 75 mmHg, default value: 40 mmHg
- **P-Start**: -15 mmHg to Plateau, default value: 0 mmHg
- **Flow**: 1 - 120 ml/h, default value: 20 ml/h

12.9.4 Alarms

Alarms can occur for "Pressure too high" (upper alarm limit exceeded) and "Pressure too low" (dropping below lower alarm limit) throughout the infusion test. These alarms can be set to "Audio paused" or "Audio off" analog to the drainage mode (see also Page 38). Press the "Alt" key (also see Page 25) to call up a second menu selection. Here you can adjust the alarm limits.

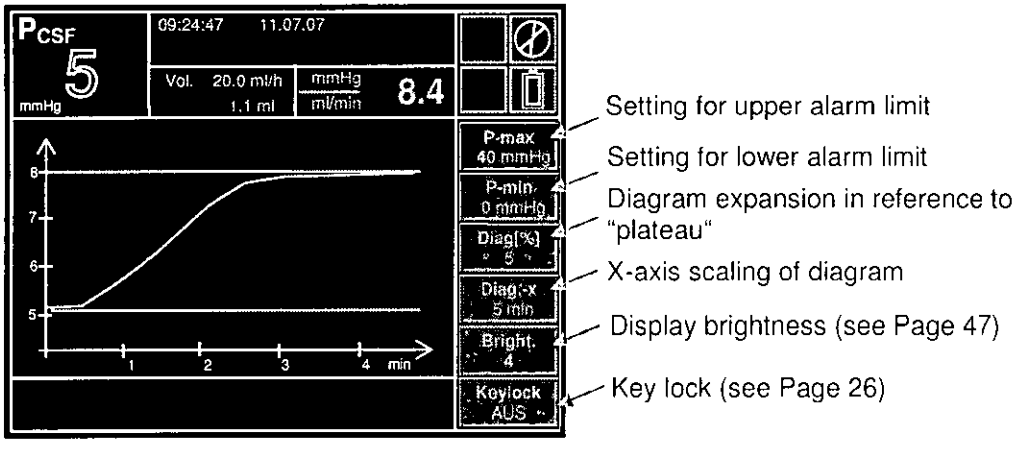

Figure 37: Display setup for option "lumbar infusion test", 2nd selection menu

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Option: Lumbar Infusion Test (Not available in the US)

Setting options:

- **P-max**: P-min to 75 mmHg, default value: 40 mmHg
- **P-min**: -15 mmHg to P-max, default value: 0 mmHg
- **Diag [%]**: 0-50, default value: 0
- **Diag. x**: 60 seconds to 20 minutes, default value: 5 minutes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 8

LABELS FOR THE LIQUOGUARD CSF

Back to **List of Appendices**
Back to **Chapter 13. Proposed Labeling**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIQUOGUARD CSF – DEVICE LABELING

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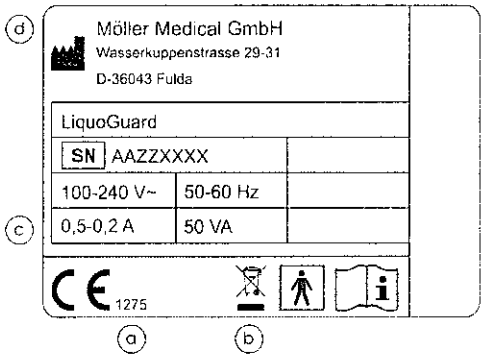

Aufschlüsselung der Seriennummer:

AA = Herstelljahr d.h.: Für Herstelljahr 2004 ist AA = 04
ZZ = Herstellmonat d.h.: Für Monat November ist ZZ = 11
XXXX = fortlaufende Gerätenummer mit 0001 beginnend
unabhängig von Herstelljahr und Herstellmonat.

Schrift: Schwarz

MöllerMedical Wasserkuppenstrasse 29-31 • 36043 Fulda Tel.: +49 (0) 661-94195-0 • Web: www.moeller-medical.com					Art.-Nr. 20 007 982		Allgemeintol. DIN ISO 2768 m	Maßstab 1:1
								Werkstoff: gef. aus: 30 000 146
								Halbzeug:
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					Bearb.	16.03.06	DE	
					Gepr.	25.02.10		LiquoGuard
e	Symbole geä.	KO3262	25.02.10	Mü-De	Norm			
d	Hersteller	KO 3014	08.10.08	AH				
c	geändert	KO 2488	07.09.06	LW				
b	hinzu	KO 2455	19.07.06	DE				
a	geändert	KO 2443	19.07.06	DE				
Zust.	Änderung	KO-Nr.	Datum	Name				

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Werkstoff-Nr.:

LDP001-001 01 01-00 e-4

Blatt 1 von 1

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LIQUOGUARD CSF – PACKAGING LABELING

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149,5 (e)

100 (e)

(b)

Möller Medical GmbH
Wasserkuppenstrasse 29-31
D-36043 Fulda

LiquoGuard, REF 00002563

SN AAZZXXXX		
100-240 V~	50-60 Hz	
0,5-0,2 A	50 VA	

CE 1275

(a)

Aufschlüsselung der Seriennummer :

AA = Herstelljahr d.h.: Für Herstelljahr 2006 ist AA = 06
ZZ = Herstellmonat d.h.: Für Monat Februar ist ZZ = 02
XXXX = fortlaufende Gerätenummer mit 0001 beginnend unabhängig von Herstelljahr und Herstellmonat.

Schrift : Schwarz

MöllerMedical Wasserkuppenstrasse 29-31 · 36043 Fulda Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com					Art.-Nr. 20 007 865	Allgemeintol. DIN ISO 2768 C	Maßstab 1:1	Gewicht:	Volumen:
							Werkstoff: gef. aus : 30 004 755 (e)		Werkstoff-Nr.:
							Halbzeug:		
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					Bearb.	17.03.06	DE		
					Gepr.	09.08.10		LiquoGuard	
e	hinzu/geändert	KO3380	09.08.10	MÜ-De	zul. gespeichert von:	sdehler	17.01.2011 13:24:48		
d	Symbole geö. & hinzu	KO3262	01.03.10	MÜ-De	Vertraulich/Confidential				
c	überarbeitet	KO3044	11.12.08	MÜ-De	Weitergabe sowie Vervielfältigung dieser Unterlage, Verwertung und Mitteilung ihres Inhalts nicht gestattet soweit nicht ausdrücklich zugestanden. Zuwiderhandlungen verpflichten zu Schadensersatz. Alle Rechte für den Fall der Patenterteilung oder Gebrauchsmuster-Eintragung vorbehalten			LDP001-001 00 01-00 e-4	Blatt 1 von 1
b	geändert	KO 2488	07.09.06	LW					
a	geändert	KO2443	14.07.06	DE					
Zust.	Änderung	KB-Nr.	Datum	Name	Dateiname: LDP001-001 00 01-00 e-4			Ers. für: LDP001-001 00 01-00 d-4	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

APPENDIX 9

LABELS FOR THE LIQUOGUARD CSF TUBING SET, 1500MM

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Back to Chapter 13. Proposed Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIQUOGUARD CSF TUBING SET, 1500MM – PACKAGING LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tube set for - CSF drainage pump
LiquoGuard®

LOT

Art.-Nr. 00 002 650

REF.: 92 007 836

1500 mm

+40°C (104°F)
+10°C (+50°F)

STERILE EO

MRI

PHT DEHP

MöllerMedical

Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda, Germany

CE 1275

20008691 - 2010-03

(b)

(b) Achtung! Originalablage des PDF's für Fertigung: Dokumentenablage_Gültig

MöllerMedical
Wasserkuppenstrasse 29-31 · 36043 Fulda
Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com

Art.-Nr.: 20 008 690

Allgemeintol.

Maßstab 1:1 | Gewicht: | Volumen:

Werkstoff: bez.: Druckerei Mergard | Werkstoff-Nr.: 14,8 cm x 10,5 cm
Halbzeug: JAC script weiß, Klebstoff D131 80g/m²

Zust.	Änderung	KO-Nr.	Datum	Kürzel
f	kpl. überarbeitet	KO3262	02.03.10	MÜ-De
e	Logo + Anschrift	KO 3010	29.09.08	AH
d	neues Logo	KO 2981	03.07.06	AH
c	Text überarbeitet	KO 2835	17.03.08	LW
b	hinzu	KO 2801	15.01.08	LW
a	Art.-Nr. hinzu	KO 2735	04.12.07	LW

	Datum	Name
Bearb.	29.03.07	LW
Gepr.	02.03.10	
Norm		
zul. gespeichert von:	sdehler	02.03.2010 09:26:00

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Dateiname: LDP 002-001 00 11-00 f-4

Ers. für: LDP 002-001 00 11-00 e-3

Verpackungsaufkleber
Schlauchset "LiquoGuard" 1500 mm

LDP 002-001 00 11-00 f-4

Blatt 1 von 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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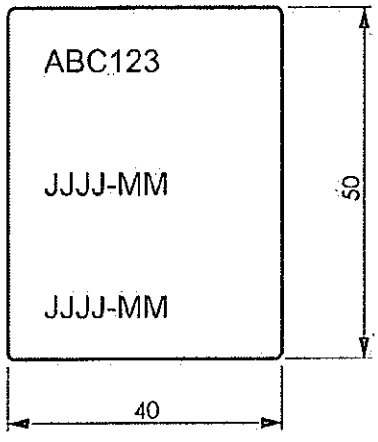
LIQUOGUARD CSF TUBING SET, 1500MM – PACKAGING LABELING: VARIABLE DATA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA request 2015-10257; Released by CDRH on 07/08/2016

LDP002-001 00 09-00 b-4

(a) Chargenbezeichnung (FKLeitz des Fertigproduktes)	ABC123
Herstelldatum	JJJJ-MM
Verwendbar bis	JJJJ-MM



Hinweis : - JJJJ - MM Jahr - Monat

(b) - Haltbarkeit des Produktes 2 Jahre 11 Monate

MöllerMedical
Wasserkuppenstrasse 29-31 · 36043 Fulda
Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com

Art.-Nr.	Allgemeintol. DIN ISO 2768 m	Maßstab 1:1	Gewicht:	Volumen:
20 008 687		Werkstoff: gef. aus: Art.-Nr. 30 002 734	Werkstoff-Nr.:	
		Halbzeug: Rollen - Haftetiketten 50 x 40 mm		

	Datum	Name
Bearb.	28.03.07	LW
Gepr.	15.03.12	
zA gespeichert von: ohorwat	15.03.2012 11:05:01	

Aufkleber

für Schlauchset "LiquoGuard"

Vertraulich/Confidential

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Zust.	Änderung	Kü-Nr.	Datum	Name
b	Haltbarkeit	KO3769	15.03.12	HOR
a	Chargenbez. geä	KO 467	07.02.11	MÜ-Do

Dateiname: LDP002-001 00 09-00 b - 4

Ers. für: LDP002-001 00 09-00 a-4

LDP002-001 00 09-00 b-4

Blatt 1 von 1

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245

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LIQUOGUARD CSF TUBING SET, 1500MM – PATIENTS STICKER

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LDP002-001 00 12-00 d-4

LiquoGuard® Drainageset 2007-05 **Art.No. 00 002 650** REF.: 92 007 836 LOT L010489A/1/2 1500 mm Möller Medical GmbH · 36043 Fulda, Germany	***LiquoGuard®*** ***Drainageset***
LiquoGuard® Drainageset 2007-05 **Art.No. 00 002 650** REF.: 92 007 836 LOT L010489A/1/2 1500 mm Möller Medical GmbH · 36043 Fulda, Germany	
LiquoGuard® Drainageset 2007-05 **Art.No. 00 002 650** REF.: 92 007 836 LOT L010489A/1/2 1500 mm Möller Medical GmbH · 36043 Fulda, Germany	MöllerMedical Möller Medical GmbH Wasserkuppenstraße 29-31 36043 Fulda, Germany
LiquoGuard® Drainageset 2007-05 **Art.No. 00 002 650** REF.: 92 007 836 LOT L010489A/1/2 1500 mm Möller Medical GmbH · 36043 Fulda, Germany	30004037 – 2009-03

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2. "Chargenbezeichnung" und "Verwendbar bis" werden chargenspezifisch angepasst!!!

MöllerMedical
Wasserkuppenstrasse 29-31 · 36043 Fulda
Tel.: +49 (0) 661-94195-0 · Web: www.moeller-medical.com

Art.-Nr.	Allgemeintol.	Maßstab 1:1	Gewicht:	Volumen:
30 004 037		Werkstoff: bez.: Druckerei Mergard	Werkstoff-Nr.: © 6,8 cm x 8,5 cm	
		Halbzeug:		

	Datum	Name
Bearb.	29.01.08	LW
Gepr.	16.03.09	
Norm		

Patientenaufkleber

Schlauchset "LiquoGuard" 1500 mm

Zust.	Änderung	KB-Nr.	Datum	Name
d	Größe Ref.-Nr., Art.-Nr. Datum geändert	KO 3105	16.03.09	HOR
c	Größe, 4 Aufkleber	KO 3058	07.01.09	HOR
b	Logo + Anschrift	KO 3010	29.09.08	AH
a	neues Logo	KO 2981	03.07.08	AH

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Dateiname: LDP002-001 00 12-000 - 4

Ers. für: LDP002-001 00 12-00 c-4

LDP002-001 00 12-00 d-4

Blatt 1 von 1

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 03, 2012

MOLLER MEDICAL GMBH
C/O G.E.O. INC.
1612 JENKS DRIVE
CORONA, CALIFORNIA 92880
ATTN: GRANT GECKELER

510k Number: K121248

Product: LIQUOGUARD CSF LIQUOGUARD CSF

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NE/DONED K121248/S(

Möller Medical GmbH

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Tel.: +49 (0) 661-94195-0 · Fax: +49 (0) 661-94195-850
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MöllerMedical

Möller Medical GmbH · Wasserkuppenstr. 29-31 · D-36043 Fulda

FDA CDRH DMC
JUL 2012
Received K34

27 June, 2012

Food and Drug Administration
Center for Devices and Radiological Health
LCDR Andrew Yang, BE, ME, EIT
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
OCT - 3 2012
Received

Traditional 510(k) Premarket Notification for LiquoGuard CSF System
Additional Information Submittal

Dear Mr. Yang:

Möller Medical submits this revised Traditional 510(k) Premarket Notification, for the new medical device **LiquoGuard CSF System**. Changes have been effected pursuant to our previous communications with your office. Please incorporate our previous submission of April 2012 by reference. This submittal includes the secondary predicate device "intracranial pressure monitor (ICP)".

In the event your office needs to contact Möller Medical during the review of this information, please contact the undersigned at (714) 312-6863, by fax at (714) 637-2460, by email at ggeckeler@geoinc.org or by mail delivered to 1612 Jenks Drive, Corona, CA 92880.

Sincerely,

Grant Geckeler
US-Agent of Möller Medical GmbH

Enclosure: One paper copy and one electronic copy (CD-ROM)

FB_002_004
MM 2012-06_Cover_Letter
GWG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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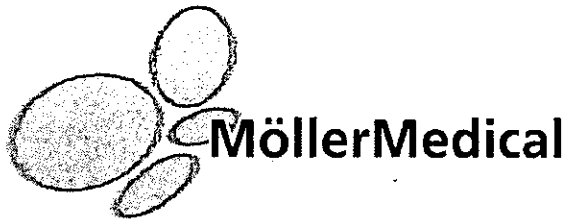
FDA CDRH DMC
JUL 19 2012
Received



TRADITIONAL PREMARKET NOTIFICATION [510(K)] SUBMISSION

LIQUOGUARD CSF SYSTEM

Legal Manufacturer:
Möller Medical GmbH
Wasserkuppenstraße 29-31
36043 Fulda
GERMANY

Contact:
Grant Geckeler
Email: ggeckeler@geoinc.org
Phone: +1 714 283 1683
Fax: +1 714 637 2460

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of revision

Revision	Description	Date
000	Issue of the 510(k)	2012-04
001	Including "Table of revision". Including secondary predicate device "Intracranial pressure monitor (ICP)".	2012-06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix	Description
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Medical Device User Fee Cover Sheet (From FDA 3601)

The MDUFMA Cover Sheet is provided in front of the 510(k).

2. CDRH Premarket Review Submission Voluntary Cover Sheet

The CDRH Premarket Review Submission Cover Sheet is provided in front of the 510(k).

3. 510(k) Cover Letter

The 510(k) Cover Letter is provided in front of the 510(k).

4. Indication for Use Statement

The Indication for Use Statement is provided **Appendix 1**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. 510(k) Summary

Submitter Information: Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

Establishment Registration Number: 3006611221

Contact Person: Grant Geckeler
Free lance consultant
1612 Jenks Drive
Corona, CA 92880
Phone: +1 714 283 1683
Fax: +1 714 637 2460
E-mail: ggeckeler@geoinc.org

Name of Device:

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF System pump and LiquoGuard CSF System tube set

Classification: Shunt, Central Nervous System and Components, Class II, 21 CFR § 82.5550

Product Code: JXG

Substantial Equivalence:

The Möller Medical LiquoGuard CSF System is substantially equivalent to the CSF drainage systems listed below with regard to intended use, design, operating principles, and materials.

Integra NeuroSciences Corporation	K030289, K032817
Codman & Shurtleff, Inc.	K061568

The Möller Medical LiquoGuard CSF System shares features with, and is substantially equivalent with regard to these features, to the intracranial pressure monitor listed below (the shared features include CSF pressure monitoring, semiconductor sensor principle, display, alarm functions and data recording).

Camino NeuroCare.™ Inc.	K962928

Device Description:

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during

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vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Intended Use:

The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The device also monitors intracranial pressure and cerebrospinal fluid flow during CSF drainage, and provides alarm functions similar to those of intracranial pressure monitors.

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6. Truthful and Accuracy Statement

The Truthful and Accuracy Statement is provided in **Appendix 2**.

7. Class III Summary and Certification

Not Applicable.

8. Financial Certification or Disclosure Statement

Not Applicable (clinical study is conducted in Europe with a CE marked device).

9. Declarations of Conformity and Summary Reports

Not Applicable.

10. Executive Summary

10.1 Registration History

The LiquoGuard CSF System is CE marked since 2006. All over 200 devices are successfully placed on the European market, in South America, Russia, etc. without any incident.

The FDA registration process started in 2007 after major software improvements. This is the third attempt at a 510(k). This time the submission includes significant amount at clinical data to show safety and efficacy of the device (see **Section 10.7**) and was extended by a secondary predicate device, the ICP monitor, to establish the substantial equivalence with regard to some of the technologies used (display, semiconductor sensor, alarm functions).

10.2 Indications for use

The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (primary predicate devices).

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The LiquoGuard CSF System also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions similar to those offered by intracranial pressure monitors (secondary predicate device).

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

10.3 Device description

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

10.4 Predicate devices with same indication

The Möller Medical LiquoGuard CSF System and the Integra LifeSciences (K030289, K032817) and Codman & Shrutleff (K061568) "primary" predicate devices listed in this application have the same indication.

10.5 Predicate device with same technological characteristics

The Möller Medical LiquoGuard CSF System and the Multi-Parameter Monitor (K962928) "secondary" predicate device listed in this application have the same technological characteristics.

10.6 Summary of substantial equivalence discussion

The LiquoGuard CSF System is a tube system with integrated redundantly designed pressure sensors, as well as a rotor pump device, into which a part of the tube system is inserted in order to perform pressure and volume-controlled CSF drainage. The intrathecal CSF drain is used independent of the LiquoGuard CSF System, and the products approved for intrathecal CSF drainage can be connected to the LiquoGuard CSF System (but are not

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part of the system). The indication for insertion of intrathecal drainage will not be affected by using the LiquoGuard CSF System.

The control parameters for the CSF drainage (target pressure, CSF volume) are equal between the existing dripping chamber systems and the LiquoGuard CSF System. The effective mechanism and the function of the CSF extraction by means of a target value-controlled rotor pump in the LiquoGuard CSF System is comparable to the CSF extraction that is realized after the target pressure is reached by means of an overflow. Therefore, the LiquoGuard CSF System offers comparable effectiveness to existing CSF drainage systems.

The measuring sensors are comparable to the ones used in ICP monitors (Multi Parameter Monitor), as well as many functions (ICP value display, trend analysis, etc.), alarm settings (e.g. high pressure) and components (e.g. battery, display, microcontroller, etc.).

10.7 Performance Testing - Clinical

On April 8, 2009 representatives of Möller Medical and of the FDA met in Rockville to discuss the need of clinical data and the realization of a clinical trial.

After consulting the FDA the following points were defined as guideline for the planed clinical trial:

- The clinical question is one of safety – efficacy is assumed based on the fact that the CSF draining is already a gold standard in trauma and neurosurgery.
- Clinical data is requested to answer the issue of whether or not the action of the LiquoGuard CSF System pump results in a significant increase in adverse events compared to the drip chamber (predicate device).
- The clinical trial can be done by an observational study, as a control group historical data can be used.
- No scientific study will be necessary. To avoid any bias, it is sufficient to include all patients treated with the LiquoGuard CSF System in a facility over some period of time the data collection.
- The data can be collected in Europe.

On the basis of this guideline Möller Medical defined a study protocol and started the clinical trial in 2009 (please refer to **Section 20** for detailed information).

11. Device Description

11.1 Definition of drainage system

Cerebrospinal fluid (CSF) is drained from a patient using (i) a catheter placed in the third or lateral ventricle or lumbar subarachnoidal space, and (ii) a "drainage system" that removes any excessive CSF coming out of the catheter, and disposes of the fluid into a collection

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bag. Conventionally, the drainage system is a dripping chamber which works like a siphon or spill: any excessive CSF pressure leads to dripping inside the dripping chamber.

11.2 Product idea of the LiquoGuard CSF System

The key disadvantages of the conventional drainage systems are that they have no integrated alarm functions, that they are error-prone and they cannot measure ICP and drain at the same time with only one access to the patent. A wrong cock position or a clogged/disconnected catheter can lead to under- or overdrainage. This problem is solved by the LiquoGuard CSF System that replaces the drainage systems above. It consists of (a) a tube set that is connected to the catheter just like the conventional dripping chamber. The tube set contains a dual pressure sensor measuring the pressure inside the tube at the end of the catheter. The other component (b) is an electronically controlled pump removing CSF as long as the measured pressure is excessive. The LiquoGuard CSF System detects many typically occurring and dangerous situations not caught by dripping chambers and / or ICP monitors, e.g. a sudden pressure drop by an accidentally extracted catheter, or a pressure staying constant for an extended period of time (which is unphysiological and may indicate a clogged/disconnected catheter or an accidentally opened 4-way stop cock).

11.3 Components of the LiquoGuard CSF System

The LiquoGuard CSF System consists of the LiquoGuard CSF System pump and the LiquoGuard CSF System tube set.

11.3.1 LiquoGuard CSF System pump

The LiquoGuard CSF System main (see **Figure 1**) unit contains a peristaltic pump in which the tube set is inserted and connected for operation. It has a blue turning knob and three touch keys for user operation, a card slot to insert a memory card and a display to show pressure and flow values as well as a pressure and flow history. There are 5 light emitting diodes and a speaker for the audible alarms.

The main unit is software operated by a micro controller and energy supplied by mains or battery.

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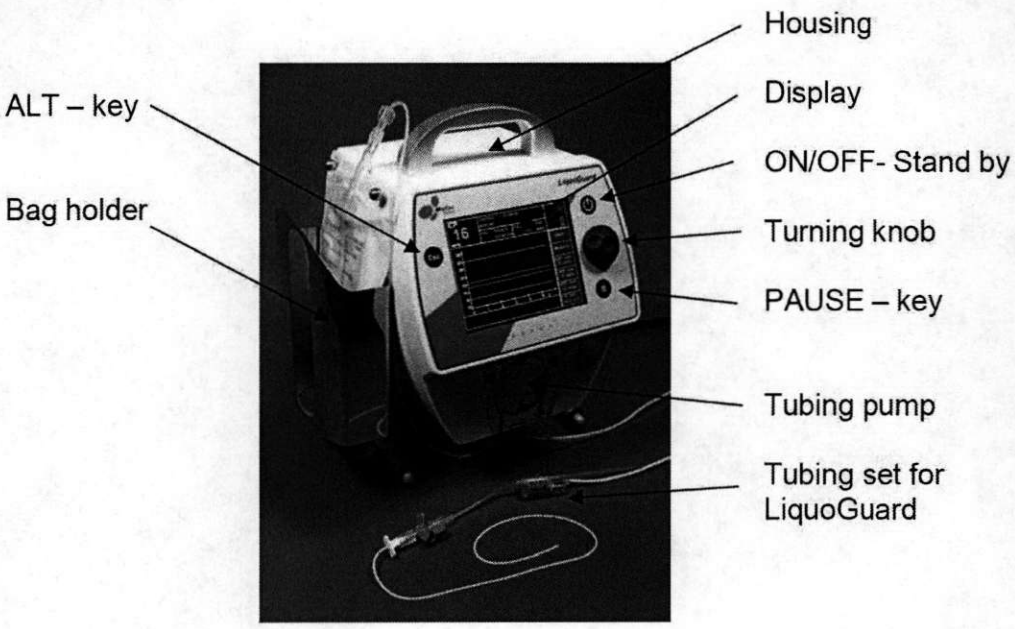

Figure 1: Front view of LiquoGuard CSF System

11.3.2 LiquoGuard CSF System tube set (disposable)

The LiquoGuard CSF System tube set consists of a polyvinyl chloride (PVC) tubing, luer locks, stop cocks, a drainage bag with a reflux valve, specially shaped plastic pieces to ensure correct insertion into the pump, and a pressure sensor housing with two piezo-resistant pressure transducers, a cable for connection to the pump and a sticker to attach the sensor housing to the patient's skin. The tube set is only for use with the LiquoGuard CSF System. Please refer to **Appendix 3** for the product materials and **Appendix 4** the packing contents.

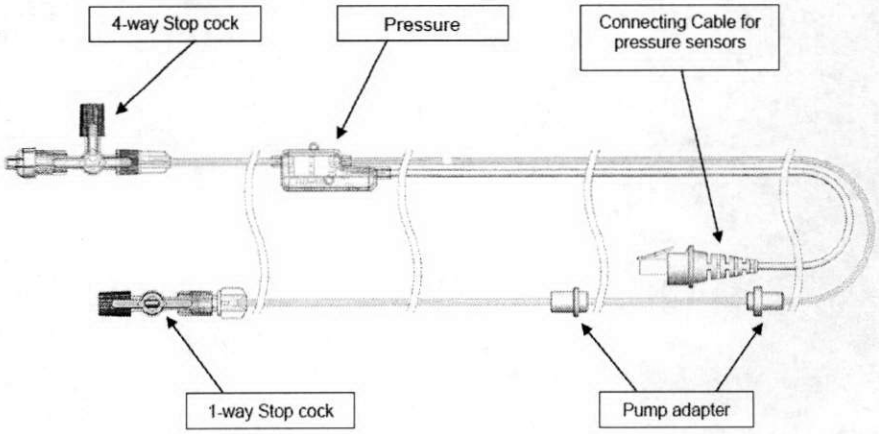

Figure 2: LiquoGuard CSF System tube set as schematic picture with its individual parts

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The tube set exists in two variants which only differ in the length of the PVC tubing (1500mm and 2000mm). All components are exactly the same. The tube set is supplied as disposable sterile product.

11.4 Principle of the LiquoGuard CSF System

The normal operation of the pump works as follows:

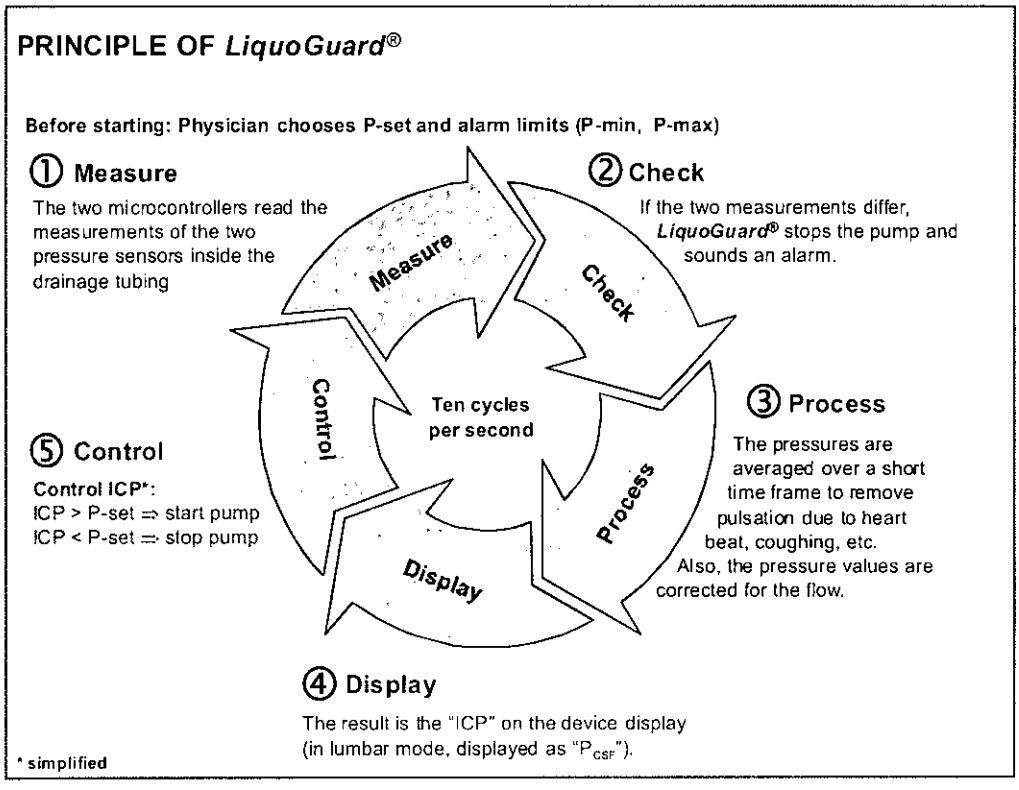

Figure 3: Principle of LiquoGuard CSF System

- Every 0.1s, read the measurements of two pressure transducers inside the tubing.
- Compare the two pressure values using the two microcontrollers of the LiquoGuard CSF System. If the resulting values differ by more than the combined tolerance of both sensors, assume that at least one of the sensors is malfunctioning: in this case, ignore all settings and all measured values, stop the pump, and sound an alarm.
- Otherwise, average the measured pressure value over the two pressure transducers and over a short time frame (configurable, standard setting 1s). The result is the CSF pressure shown on the device display – we call it simply ICP (intracranial pressure) in the following. The goal of this averaging is to remove the physiological pressure pulsations caused indirectly by the heart beat from the measurement.
- If ICP is higher than P-set (desired pressure, ordered by physician) by some small margin, operate the pump.
- If ICP is lower than P-set by some small margin, stop the pump.

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- Independently from P-set: if the measured pressure value (before averaging) is lower than the lower alarm limit, stop the pump.
- Independently from all settings: If measured pressure value (inside the tubing) is lower than 2 mmHg, stop the pump.

11.5 Details regarding the principle

11.5.1 Two microcontrollers

There are two microcontrollers. Each one has an analogue to digital converter and calculates the actual pressure inside the tube system. These values are communicated between the two controllers.

The system always displays the arithmetic average of the two measured values (the diagram shows the master controller's pressure signal). If both values differ by more than 4 mmHg, an alarm is generated, as the system can't determine which value is the correct one. If the two values are within the valid range the average of the two sensors is used to control the pump.

A comment on the "small margin" mentioned above: this is needed to prevent the pump from starting/stopping too frequently. This small margin is called the "hysteresis"; it is a standard tool in all regulating devices that use only "on" and "off"-states, like switching a pump on or off. In the case of LiquoGuard CSF System, the hysteresis value is configurable and defaults to 0.5 mmHg.

A comment on the "lower alarm limit" mentioned above: The default value of the lower alarm setting is 0 mmHg. This setting can be changed by an order of a physician, however the allowed values are restricted to be above or equal to a minimum of -15 mmHg, which is a small negative value, far too small to tear off and aspirate brain tissue. To put this into perspective, note that negative ICPs of -50 mmHg and more occur physiologically in a healthy human being.

Detailing the difference between ICP and pressure in the drainage tubing: The pressure inside the tubing is equal to the ICP by the laws of hydrostatics, if there is a non-occluded liquid column between the ventricle and the pressure sensors. As this normally is the case the measured pressure is displayed as "ICP" on the devices display. However, in the cases of catheter occlusion or collapsed ventricles (=closing of the catheter holes by brain tissue), the ICP can rise above the pressure inside the tubing. A drip chamber, working on hydrostatics alone, drains CSF depending on the pressure inside the tubing. The LiquoGuard CSF System does the same – it requires an excess pressure inside the tubing for pump operation. In the case of collapsed ventricles, the ICP may be high and yet no drainage will occur with both the drip chamber and the LiquoGuard CSF System. The effects of the two systems are thus substantially equivalent.

11.5.2 LiquoGuard CSF System alarm system

The main safety advantage of the LiquoGuard CSF System over the passive dripping chambers and solely pressure measuring ICP monitors is the combination of both systems in one device and the sophisticated alarm system: there are many potentially hazardous

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situations in which LiquoGuard CSF System will call a nurse or doctor by audible and visible alarm signals. The following is a summary of all alarms offered:

Pulsation alarm:

- LiquoGuard CSF System continuously monitors the physiological pressure pulsations caused by the heartbeat.
- LiquoGuard CSF System will sound an alarm if this pulsation is not present.
- This is a check if the liquid column between the ventricle and the pressure sensors is present.
- Possible reasons for this include catheter occlusion and collapsed ventricles (catheter holes covered by brain tissue).

Pressure alarms:

- LiquoGuard CSF System will sound an alarm if the pressure is higher or lower than the respective pre-selected alarm limits
- LiquoGuard CSF System will sound an alarm if the pressure remains constant for an extended period of time (Possible reasons include catheter problems with lumbar drainage)

Sensor cross-checking:

- LiquoGuard CSF System dual pressure sensor technology measures the pressure inside the tube with two completely independent transducers.
- Even the cables are duplicate.
- If there is any discrepancy between the two sensor readings, LiquoGuard CSF System will sound an alarm and shut the pump off as security measure.

Watchdog functionality:

- The sensor information is processed by two completely independent microcontrollers (that have been programmed by two different software engineers).
- These controllers read out the two pressure sensors and exchange their results via interprocessor communication.
- LiquoGuard CSF System will sound an audible and visible alarm and shut the pump off as security measure if there is any significant discrepancy of the data, or failure of the other controller to answer. The alarms are independent as well (different speakers and LEDs for each microcontroller).
- This technology is similar to the safety concepts of avionics in airplanes or the redundancy of powerplants.

Battery alarm:

- In mobile application, LiquoGuard CSF System monitors the remaining battery time.
- LiquoGuard CSF System will sound an alarm if the battery is low.

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11.5.3 Battery back-up

A rechargeable lead-gel battery is used as backup to ensure the system functionality for up to 3 hours while there is no mains power. The device has a charging symbol which goes down as the battery discharges. Before the battery is entirely depleted, an alarm will sound and the display will read "Battery empty, connect to AC". After the battery alarm sounds, there is still 5-10 minutes of battery power remaining until the display goes off, at which time the alarm continues to sound for a few more minutes until the device deactivates.

Complete charging of an empty battery is approximately 8 hours.

Discharging time is getting shorter. For security reasons the rechargeable battery is replaced once a year during security checks. The device has to go into service every 12 months for checks on the security system, dual processor system, communication with pressure sensors, and battery.

11.6 Key Questions & Answers of previous 510(k) application

11.6.1 Over-drainage

In patients with elevated ICP but small/slit-like ventricles, the active removal of CSF may lead to further ventricular collapse and catheter occlusion with brain tissue or debris, necessitating catheter removal/revision with significant potential morbidity/mortality.

"The LiquoGuard CSF System does not work by "active removal of CSF"; over-drainage/aspiration is not possible. In contrast, this danger is present with the predicate device (drip chamber).

To clarify the principle of LiquoGuard CSF System: Although LiquoGuard CSF System is an "active" (electrical) device, it does not "aspirate", meaning it never generates negative pressure. The pump only operates if the pressure inside the tube is excessive, i.e. necessarily positive (no "suction" or "aspiration"). This is equivalent to the drip chamber which drains only when the pressure inside the tube suffices to drive CSF up to the height of the drip chamber. Therefore, LiquoGuard CSF System drains CSF exactly when the properly adjusted drip chamber would, and LiquoGuard CSF System does not remove CSF under the types of conditions that a properly adjusted drip chamber would not. An "active" aspiration of tissue or debris is not possible by design, because the preset target pressure is always positive.

In contrast to the LiquoGuard CSF System, a drip chamber can aspirate tissue and debris if it is adjusted at a level lower than the patient or if it falls to the ground. In these cases, the drip chamber can generate a negative pressure inside the catheter equal to the weight of the CSF column inside the tubing, reaching from the patient to the drip chamber. For example, with a CSF density of water (1 g/ml) and a drip chamber on the ground (1 m = 3 ft below the patient), this corresponds to a negative pressure of –10 kPa = –75 mmHg, clearly dangerous for the patient.

In practice, medical personnel can be very hesitant to report such incidents, but an example can be found in MAUDE report # 1221649-1996-00006. In the case cited there, the drip chamber fell to the floor, subarachnoidal bleeding and death of the patient followed. Another example is MAUDE report # 2648988-2003-00009, where a malfunctioning

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stopcock led to over-drainage of 200 cc. Many MAUDE reports mention leakages of drip chamber-based drainage sets, which may lead to accidental and unnoticed over-drainage.

With LiquoGuard CSF System, a leaking tube set, (or disconnected catheter, malfunctioning stop cock etc.) will be detected as soon as it lowers the patient's CSF pressure level below the pre-set alarm level. Please see **Section 18** test reports 41 and 52, where the reliability of pressure alarms and the detection of disconnections are confirmed.

In small/slit-like ventricles, the catheter holes may be covered by brain tissue which prevents drainage by any gravity-fed CSF drainage system. In this case, a drip chamber fails to drain and fails to notify medical personnel. LiquoGuard CSF System, lacking an excessive pressure in the tubing, fails to drain just like the predicate device. However, LiquoGuard CSF System will most likely either sound the "pulsation invalid" alarm or the "pressure too constant" alarm in this case. Please see **Section 18** test reports 42, 43 and 44, where we confirmed the reliability of these alarms as well as the alarm consequences of a catheter occlusion.

To explain the above mentioned alarms: Normally, the pressure pulsations caused by the heart beat are detected by LiquoGuard CSF System and can be seen on LiquoGuard's display, as long as the liquid column between ventricle and pressure sensor is complete. When the catheter holes are covered by brain tissue (or the catheter is occluded, etc.), this liquid column is interrupted and the measured pulsation is lost inside the tubing, where the sensors are positioned. As soon as LiquoGuard CSF System registers no pulsations, it sounds an alarm.

To summarize, LiquoGuard CSF System places no additional risks on a patient with small/slit-like ventricles. In contrast, drip chambers – when unattended – may well place such risks.

LiquoGuard CSF System does help to detect potentially deleterious situations because of its alarm features, whereas with a drip chamber, medical personnel are not alerted to potential problems by the device."

11.6.2 Under-drainage

Patients with elevated ICP may need 5-10 cc of CSF removal quickly to avert cerebral herniation, and a fixed setting of drainage may not allow this.

"We agree that there is a risk of under-drainage, but if this happens, it will not go unnoticed. As soon as the ICP (and with it the pressure inside the tubing) raises above the pre-set alarm level of LiquoGuard CSF System, the device will sound an alarm and thus call the attention of medical personnel to the patient's condition. (No such safety feature is present with the drip chambers.) Please see **Section 18** test report 41.

The drainage rate of LiquoGuard CSF System is pre-selected and can be set as high as 50 ml/h. It can be further adjusted up to 150 ml/h using a password-protected hidden menu. Should that not be sufficient – which can be noticed by a continued alarm – the three-way stopcock of the tubing set can be connected to another drainage bag to quickly allow removal of excessive fluid.

With drip chambers, a significant risk of accidental and unnoticed under-drainage exists; causes include catheter clogging, clogging of air vents, anti-reflux valves and other kinds of blockages. In this context, refer to MAUDE # 1226348-2007-00216 where a blocked anti-

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reflux-valve was followed by patient's death. An under-drainage situation cannot go unnoticed when using the LiquoGuard CSF System (see above)."

In patients requiring lumbar intrathecal catheterization for CSF diversion (which is usually performed to allow dural healing after surgery to prevent/fix CSF leak), under-drainage may prevent sufficient CSF removal that is needed for dural closure. This would put the patient at increased risk for wound infection/meningitis.

"Especially in the cases of CSF leaks after surgery, LiquoGuard CSF System allows a very smooth and continuous drainage as the flow rate can be set to a certain rate and the device will continuously drain with this rate as long as the pressure is above a certain pre-set level.

In contrast, lumbar drainage with the predicate devices (drip chambers) is done via a very thin catheter, that can easily be occluded or squeezed and therefore lead to unnoticed under-drainage or via a nurse opening and closing the stopcock in order to get out the right amount of fluid drainage – which is difficult to control and can lead to pressure fluctuations which often cause headaches, nausea and vomiting for the patients.

Once the need for drainage is addressed, LiquoGuard CSF System offers the possibility of slowly and precisely adjusting the flow rate. This is difficult (if not impossible) with the drip chambers.

An under-drainage situation cannot go unnoticed when using LiquoGuard CSF System. Should the pressure rise above the pre-set alarm limit, LiquoGuard CSF System will sound an alarm; personnel will become aware of the problem; and adjustments to the flow rate (flush the catheter, etc.) can be made accordingly. Please see test report 41.

12. Substantial Equivalence Discussion

Primary predicate device: Dripping chamber

The LiquoGuard CSF System shares indications and essential design principles with the following predicate devices, which have been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created and the LiquoGuard CSF System is substantially equivalent to the predicate devices. Please refer to **Appendix 5** for copies of the 510(k) summaries for these substantially equivalent devices and **Appendix 6** for the clinical evaluation according to MEDDEV 2.7.1.

Table 1: Substantial Equivalence Devices – Dripping Chamber

Trade Name	510(k) Submitter/Holder	510(k) Number
Hermetic Plus External CSF Drainage System External Drainage Set	Integra LifeSciences Corp	K030289, K032817
CODMAN EDS 3 CSF External Drainage System	Codman & Shrutleff, Inc.	K061568

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Secondary predicate device: Intracranial pressure monitor

The LiquoGuard CSF System shares some technological and functional aspects with the following predicate device, which has been determined by the FDA to be substantially equivalent to pre-amendment devices. Therefore, no new safety or efficacy issues are created and the LiquoGuard CSF System is substantially equivalent to the predicate device. Please refer to **Appendix 5** for copies of the 510(k) summaries for these substantially equivalent devices.

Table 2: Substantial Equivalence Devices – Intracranial pressure monitor

Trade Name	510(k) Submitter/Holder	510(k) Number
Multi-Parameter Monitor (MPM) Intracranial Pressure Monitoring System	Camino NeuroCara, ™ Inc.	K962928

12.1 Indications for use

The LiquoGuard CSF System is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF System controls CSF pressure, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices).

The LiquoGuard CSF System also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions similar to those offered by intracranial pressure monitors (secondary predicate device).

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

12.2 Device design and working principle

12.2.1 Primary predicate device: Dripping chamber

A dripping chamber is a gravity-driven siphoning device. It basically functions as a spill, disposing of all fluid that rises higher in the tubing than the nozzle inside the chamber. In CSF drainage, this principle is being used to maintain a desired target pressure in the patient. Referring to **Figure 4**, the desired target pressure is defined at the Foramen of Monro (marked as a white F inside a red circle). Aligning the dripping chamber at a height Δh relative to the patient's Foramen of Monro, the fluid column inside the tubing creates, by Pascal's law, a pressure of

(1) $P_{target} = \rho\, g\, \Delta h$

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at the Foramen of Monro. Here, ρ is the mass density of the fluid (CSF), and g is the gravitational acceleration (9.81 m/s^2). Equation (1) is a general law of fluid statics and correct unless the catheter or tubing is clogged or not completely filled between the ventricle and the dripping chamber.

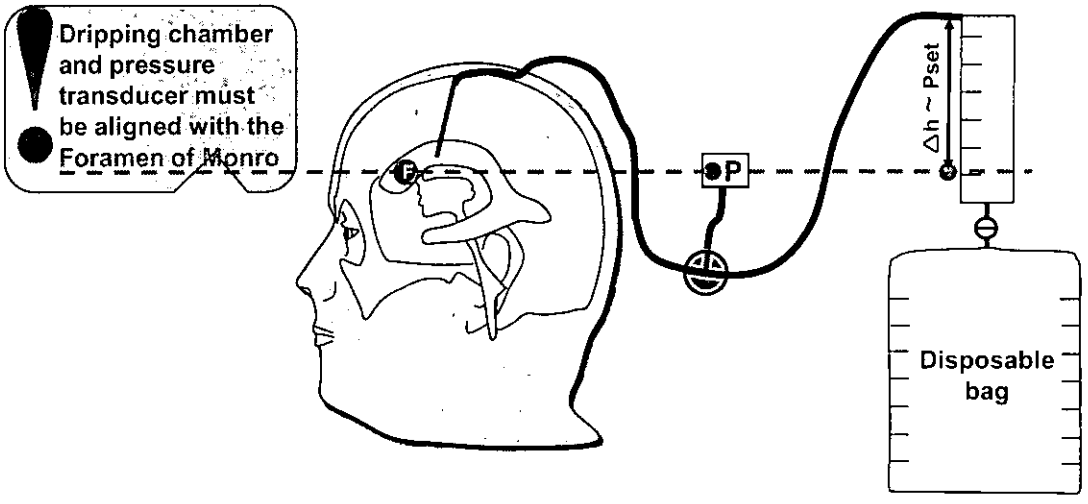

Figure 4: CSF drainage using predicate device (dripping chamber)

In the case of CSF drainage using the LiquoGuard CSF System (**Figure 5**), exactly the same Pascal's law states that the pressure at the Foramen of Monro must be *equal* to the pressure sensed by the dual electronic pressure sensors (box marked P in **Figure 5**) that are fixed outside on the patient's head at the height of the Foramen of Monro. This is again generally correct unless the catheter or tubing is clogged or not completely filled between the ventricle and the pressure sensors. LiquoGuard CSF System uses its tube pump to reduce excessive pressure sensed at the pressure sensors, using the algorithm

If sensed pressure > P_{target}, then switch pump ON.

If sensed pressure < P_{target}, then switch pump OFF.

(slightly simplified).

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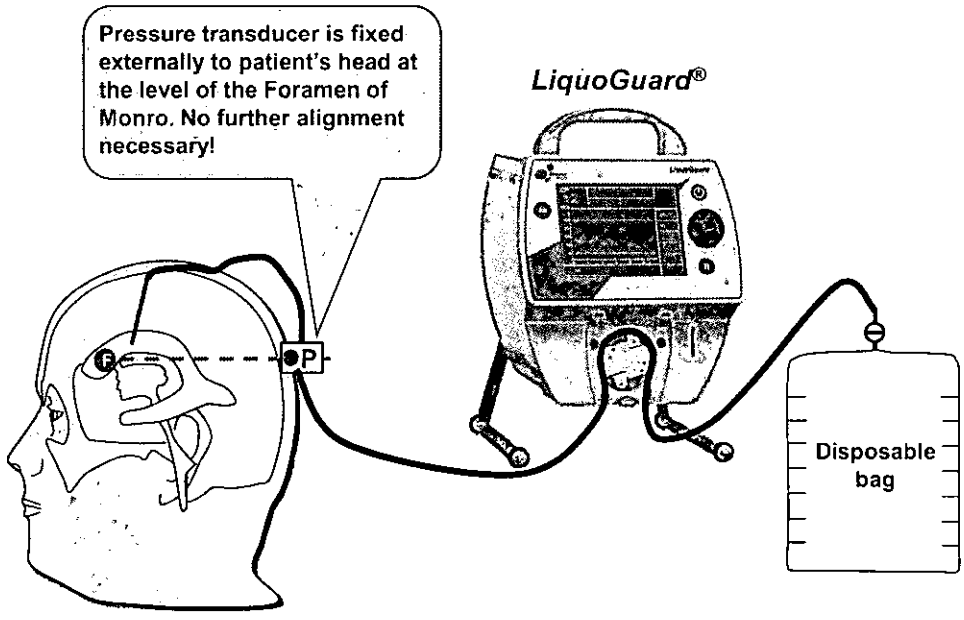

Figure 5: CSF drainage using LiquoGuard CSF System

Note the similarity between the LiquoGuard CSF System and the predicate device (dripping chamber):

- Both devices function completely ignorant of the medical indication, the protein/blood content of the drained CSF (unless that content leads to clogging), or the attached catheter.
- Both devices make use of Pascal's law and thus depend on a completely filled, unblocked fluid column in the catheter and the tubing. However, while in the case of the dripping chamber the whole tubing (1000-2000mm length) has to be filled and unblocked, for LiquoGuard CSF System only the small initial part of the tubing up to the pressure sensors (100mm) is relevant.

Note the key advantages of LiquoGuard CSF System:

- The pressure is electronically sensed and documented.
- The pressure is used by the device to monitor the drainage process.
- The device does not have to be aligned in height, only the sensor.

These advantages translate into lower risks:

- Underdrainage can happen with the dripping chamber, e.g. when the air vent or tubing is clogged, or the height alignment of the chamber is lost by a repositioning of the patient. In this context, refer to MAUDE # 1226348-2007-00216 where a blocked valve was followed by patient's death. With LiquoGuard CSF System, there is no air vent in the system, the relevant part of the tubing is much shorter (only the first 100mm to the pressure sensors are relevant), and no alignment is needed.

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Additionally, the pressure is constantly being monitored, and an alarm is signaled when the pressure leaves the pre-set safety boundaries.

- Overdrainage can happen with the dripping chamber, e.g. in the case of an accidental disconnection, or when the dripping chamber drops to the floor. In practice, medical personnel can be very hesitant to report such incidents, but an example can be found in MAUDE report # 1221649-1996-00006. In the case cited there, the drip chamber fell to the floor, subarachnoidal bleeding and death of the patient followed. Another example is MAUDE report # 2648988-2003-00009, where a malfunctioning stopcock led to over-drainage of 200 cc. Many MAUDE reports mention leakages of drip chamber-based drainage sets, which may lead to accidental and unnoticed over-drainage.

  With LiquoGuard CSF System, overdrainage because of a leaking tube set, disconnected catheter, or malfunctioning stop cock, etc. is simply impossible because the pump will stop whenever low pressure is sensed. Additionally, an alarm is signaled when the pressure leaves the pre-set safety boundaries. Please see **Section 18** test reports 41 and 52, where the reliability of pressure alarms and the detection of disconnections are confirmed.

- Catheter or tube clogging: The required fluid column has to be complete and unblocked starting from the ventricle only up to the sensors, which is only the catheter plus about 100mm of the LiquoGuard CSF System tubing. In the case of the dripping chamber, the fluid column has to be complete and unblocked all the way from the catheter to the dripping chamber (1000-2000mm). Obviously, the chances of tube clogging increase with the length of the tubing. Additionally, LiquoGuard CSF System monitors the physiological CSF pressure pulsations of the patient, and when these pulsations are lost, it sounds an alarm, indicating that something is wrong – possibly a clogged catheter.

LiquoGuard's pulsation alarm catches some of the dangerous situations not determined when using a drip chamber: As described above LiquoGuard CSF System offers an additional safety feature which is unmatched by the drip chamber. The LiquoGuard CSF System continuously monitors the physiological pressure pulsations caused by the heartbeat. With suitable settings, the LiquoGuard CSF System will sound an alarm as soon as this pressure pulsation is not present. This will in many cases detect if the liquid column between the ventricle and the pressure sensors is indeed present, i.e. if catheter is not occluded or its holes covered by brain tissue in the case of collapsed ventricles. However, although the bench test results indicate that this alarm reliably detects catheter occlusions and collapsed ventricles, Möller does **not** claim that the pulsation alarm of the LiquoGuard CSF System will determine all the aforementioned medical situations and thus sound an alarm in all these conditions. It is merely a safety feature not matched by the drip chamber. The operation of the pump is in all cases equivalent to the drip chamber, the described pulsation monitoring and alarm function is just an additional safety feature.

LiquoGuard CSF System cannot accidentally aspirate brain tissue: The pump measures the pressure **inside the tubing** and drains if **that** pressure is too high. In most cases, the pressure inside the tubing will be equal to the ICP by the laws of hydrostatics. The crucial point to note is that, if catheter occlusion occurs or the ventricles are collapsed such that brain tissue covers the catheter holes, the two pressures may be different. The LiquoGuard CSF System measures **inside the tubing** and will operate the pump only if it

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determines the pressure **inside the tubing** as excessive. The drip chamber does exactly the same – it drains if there is excessive pressure inside the tubing. Therefore, the two drainage methods are substantially equivalent. To aspirate brain tissue (which would be dangerous for the patient), a negative pressure **inside the tubing** would have to be induced by pump activity. The LiquoGuard CSF System never does that, because it is using exactly that crucial pressure **inside the tubing** to control the pump.

Patients with collapsed ventricles can drain less than 100ml/24 hours, no matter if a traditional drainage system or the LiquoGuard CSF System is being used. Therefore, a patient who has either system is at equal risk for intraventricular catheter occlusion. Since the LiquoGuard CSF System pump starts to drain CSF only in a positive pressure range, the system only drains excess pressure. This is comparable to a passive pressure valve system, such as the highly abundant implanted shunting systems which open in a positive pressure range. The LiquoGuard CSF System does not "suck out CSF"; "sucking" implies the generation of negative pressure in the tubing, which the LiquoGuard CSF System by design never allows to occur. Therefore, the LiquoGuard CSF System is equivalent to a drip chamber draining excess pressure by the principle of hydrostatics. All safety aspects of the drainage operation are therefore comparable to the predicate device of a traditional drip chamber mounted over the zero level of the patient (positive pressure).

In **traditional lumbar CSF drainage**, the volume of drained CSF is dependent on more than the pressure head of CSF and the level of drip chamber. It is dependent on:

a. Level of the head of the patient (positioning).

b. Level of the dripping chamber.

c. Diameter of lumbar drainage tube (small tube = less drainage).

d. Consistence of CSF (viscosity).

e. Passage of CSF.

f. Adaptation of dripping chamber to movement of the patient (e.g. patient stands up during drainage).

g. Intermitted occlusion of lumbar drainage due to compression e.g. by processi spinosi during retroflexion of the patient.

h. Absence of nurse during CSF drainage (system open).

i. Unnoticed disconnection of the lumbar drainage leading to high CSF outflow (which drains mostly into the bed).

This means that in several situations, uncontrolled CSF outflow can occur with traditional lumbar CSF drainage with high risks for the patient.

Patients with continued lumbar CSF drainage to a pressure of 0 mmHg may be at risk for cerebral herniation. Exactly this condition can easily and accidentally occur when using a conventional dripping chamber. This applies in particular to conditions f, h, i of the list above. In all these conditions, the traditional lumbar drainage offers **zero** safety against these risks. In contrast, the LiquoGuard CSF System safeguards against all three critical conditions:

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If the patient stands up, pressure increases, but the sampling flow of the LiquoGuard CSF System (e.g. 10 ml/h or whatever the chosen value is) will remain unchanged. Contrast this to the drip chamber, which allows in this situation an unlimited (!) outflow of CSF, e.g. more than 200 ml within a few minutes depending on parameters a-e in the list above.

The LiquoGuard CSF System is able to drain CSF continuously over an extended period of time. With the drip chamber, however, a nurse has to count the drops and adjust the level of the dripping chamber. If the nurse leaves the patient even for some minutes, the flow rate can change quickly, endangering the patient.

In this case, the LiquoGuard CSF System will detect a pressure drop to zero immediately due to the disconnection. This will lead to an alarm of the LiquoGuard CSF System. In contrast, the traditional lumbar drainage using a drip chamber does not offer any alarm system.

12.2.2 Secondary predicate device: Intracranial pressure monitor

The Multi Parameter Monitor is to be used for continuously monitoring of intracranial pressure with a pressure measurement range of -10 to 250 mmHg. In addition temperature is measured and displayed.

The Multi Parameter Monitor is compact and portable and displays the ICP value, pressure waveform, records data continuously, stores data in memory and displays trend on command. The Multi Parameter Monitor can be connected to hospital bedside monitor system and is designed for standalone use even when not connected to the mains as built in rechargeable battery permit monitoring during patient transport.

The model 110-4BT is made for use by qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma. The model 110-4HMT is made for use by qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and during the cerebrospinal fluid drainage. Both intend to be used with an external drainage system as indicated by individual manufacturers when CSF drainage is needed.

The pressure transducer generally measures the pressure of the surrounding medium. In this special case the pressure of the surrounding CSF (ventricular use) respectively the brain tissue (parenchymal use).

The pressure signal is converted into a pressure value by the software / micro controller and then displayed to the operator and device internal used for numerous functionality e.g. comparison with user set high pressure alarm value.

Note the similarity between the LiquoGuard CSF System and the secondary predicate device (intracranial pressure monitor):

The Multi Parameter Monitor and the Möller Medical LiquoGuard CSF System consist of the following main components:

- Connection between patient and device
- Data processing unit
- Data storage
- Human interfaces

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  - Screen
  - Buttons
- Connecting ports for data in- and output
- Power supply
- Casing

Both, the Multi Parameter Monitor and the Möller Medical LiquoGuard CSF System consist of all mentioned components. Differences only exist in some details without having effect on the general functionality or comparability. The Multi Parameter Monitor for example uses a fiber optical data transmission between pressure transducer and processing unit while Möller Medicals LiquoGuard CSF System uses wired communication. More differences between Multi Parameter Monitor and Möller Medicals LiquoGuard CSF System are given in **Table 4**.

Beside such minor differences the Integra MPM 1 and the Möller Medical LiquoGuard CSF System consist of the same components and are therefore directly comparable.

Note the key advantages of LiquoGuard CSF System:

- LiquoGuard CSF System stores copies of safety relevant data directly onto the transducer unit (which is connected to the patient) to ensure e.g. abide of maximum usage time. Multi Parameter Monitor has no such safety functionality.
- In various studies sensor drift of ICP sensors has been identified as a major problem during ICP measurement. LiquoGuard CSF System solves this problem as it uses two pressure transducers. Both pressure values are constantly compared by the processing unit. The for device operation used and displayed pressure values can therefore be corrected from sensor drift effect or, when the drift gets too big, the device can refuse values or the whole tube set. The big and meaningful effect of sensor drift was reviewed several times. **Appendix 61** shows two such studies.

  As Multi Parameter Monitor, such as all other ICP monitors, only display ICP values without validation of these data, the physician has no chance to review these ICP values and normally no second and independent ICP value is available, the patient is in risk of maltreatment.
- LiquoGuard CSF System has an enlarged battery running time and can therefore be used during long duration consultations (e.g. x-ray).
- No need to set the zero point anymore because LiquoGuard CSF System tube sets are already zero set when delivered.
- Measurement, recording and display of drained CSF volume.

Note that LiquoGuard is not an intracranial pressure monitor – its intended application is CSF drainage, in replacement of a drip chamber. However, if correct height alignment of the pressure sensor affixed to the patient's head is ensured, and as long as the catheter is not blocked (e.g. by clotted blood), LiquoGuard may well be used to monitor CSF pressure in addition to performing CSF drainage.

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12.3 Summarizing

Many if not all risks leading to accidental, cerebral herniation in both systems (traditional drainage and ICP monitors) can be reduced or even eliminated by the LiquoGuard CSF System. There is no new risk introduced by the LiquoGuard CSF System.

The LiquoGuard CSF System is working equivalently to a drip chamber, with the additional safety that, using LiquoGuard CSF System, a partial or intermittent catheter occlusion may be detected in many cases: In difference to the dripping chamber which must be an open system during drainage the LiquoGuard CSF System can measure the hydrostatic pressure inside the tube (drainage system) during drainage because the drainage system is closed, combined with a CSF pressure monitor and its features like displaying pressure values, curves and trends and enabling alarm functionality. The principles of measurement are comparable to the ICP monitor and its pressure transducer as both systems measure the pressure of the surrounding liquid. The only difference is the position of the transducers, and the fact that LiquoGuard uses dual transducers for redundancy.

The LiquoGuard CSF System behaves comparable to a traditional drainage system even in the case of a clotted catheter or collapsed ventricles. It is able to sound and display alarms to operators, is portable, can be used while not connected to the mains, records and stores data and can be connected to bedside monitor systems, same as the Multi Parameter Monitor.

By combining the functionality of dripping chambers with the features of a computer operated device (ICP monitor) and adding a peristaltic pump the LiquoGuard CSF System benefit is potentiated as some major problems are solved (elimination of sensor drift problematic, protection of accidental over and / or under drainage, pressure measurement simultaneously with CSF drainage, etc.).

12.4 Common components of LiquoGuard CSF System and predicate devices

The Integra LifeSciences, the Codman & Shrutleff systems and the Camino Multi Parameter Monitor utilize components such as sterile tubing sets, pressure sensors, CSF drainage bags, microcontroller and interfaces that Möller Medical's LiquoGuard CSF System utilizes too. The LiquoGuard CSF System tubing set is made from polyvinyl chloride, the same material that the Integra and Codman external tubing sets are made of, along with numerous marketed I.V. administration tubing sets. The Möller Medical tubing set has two pressure transducers. The Integra tubing set and the Camino Multi Parameter Monitor also incorporate a transducer. Additionally, the Möller Medical, Integra and Codman systems all include CSF drainage bags. The Möller Medical system and the Camino Multi Parameter Monitor display values, curves and trends on a built in monitor, sound alarms via speaker and light emitting LED, are operated by pressing foil keypad buttons and are basically computer and software controlled.

By using the LiquoGuard CSF System, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement. Additional details for comparing these CSF Systems are contained in **Table 3** and **Table 4**.

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Table 3: System Comparison

Product / Component	Dipping chamber systems		ICP Monitor system	Combination
	Hermetic Plus External CSF Drainage System	CODMAN EDS 3 CSF	Multi-Parameter Monitor (MPM)	LiquoGuard CSF System
Tube set disposable	•	•		•
CSF drainage bag	•	•		•
Pressure transducer			•	•
Micro controller			•	•
Software operated			•	•
Data storage			•	•
Button / Foil keypad			•	•
Screen			•	•
Ports			•	•
Casing			•	•
Power supply			•	•

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Table 4: Device Comparison

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Secondary Predicate Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure and measurement of CSF pressure.	Externally draining of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients.	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and patient.	Measurement of intracranial pressure in the ventricles and during the cerebrospinal fluid (CSF) drainage.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.	**Tubing material:** Not applicable. **Pressure sensor:** Single transducer. **CSF Collection Bag:** Not applicable.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on pressure equivalence (Pascal's law of fluid statics) inside the head.
Height alignment	Device can be positioned	Alignment is critical	Alignment is critical	Device can be positioned

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	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Secondary Predicate Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
of patient and device	arbitrarily, only the pressure sensor needs to be aligned.	because it controls the target pressure.	because it controls the target pressure.	arbitrarily; the pressure sensors need to be incorporated.
Device adjusting fluid flow	LiquoGuard CSF System peristaltic pump controlled by pressure at sensor location.	None - fluid flow is not controlled or limited.	None - fluid flow is not controlled or limited.	No drainage.
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF System.	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.	Pressure, pressure curve and temperature are monitored and recorded.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high. * Pressure too low. * Physiological pressure pulsation lost. * Pressure remains constant for too long. * Dual sensors deviate in readings (defective sensor). * Watchdog or main controller does not respond to each other's requests	No integrated alarm functions.	No alarm functions.	Few integrated alarm functions: * Pressure too high. * Battery low.

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	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Secondary Predicate Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
	(device or software malfunction). * Battery low.			
Measured pressure range	-15mmHg to +75mmHg.	No measurement.	No measurement.	-10mmHg to +250mmHg.
Physical dimensions	315mm x 210 mm x 280 mm (H x W x D). 4.8 kg.	-	-	274 mm x 216 mm x 89 mm (H x W x D). 4.3 kg.
Displayed parameters	Actual ICP value, ICP waveform, ICP trend. Display resolution of 1 mmHg.	No display.	No display.	Actual ICP value, ICP waveform, ICP trend, intracranial temperature, Cerebral Perfusion Pressure. Display resolution of 1 mmHg.
Sensor type	Dual transducer.	Single transducer.	No sensor.	Fiber-optic single pressure transducer.
Scheduled preventive maintenance	Every 12 months	No	No	Every 18 months
Battery	Rechargeable sealed lead acid. Charge time: 8h. Operation time: 3h.	No battery.	No battery.	Rechargeable sealed lead acid. Charge time: 8-10h. Operation time: 1-2h.

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13. Proposed Labeling

13.1 Operating Manual

Please refer to **Appendix 7** for a copy of the Operating Manual for the LiquoGuard CSF System. This operating manual contains diagrams, dimensions, tolerances and identifies the available accessories.

13.2 Package Labeling

Please refer to **Appendix 8** for a copy of the labels for the LiquoGuard CSF System. Please refer to **Appendix 9** for a copy of the labels for the sterile LiquoGuard CSF System Tubing Set, 1500mm and **Appendix 10** for the copy of the labels for the sterile LiquoGuard CSF System Tubing Set, 2000mm.

Note: All labeling for product to be marketed in the U.S. will meet the U.S. labeling requirements of 21 CFR Part 801.

13.3 Catalog Numbers

The catalog number for the LiquoGuard CSF System is provided below in **Table 5**.

Table 5: Catalog Number for the LiquoGuard CSF System

Product Names	Catalog Number
LiquoGuard CSF System pump	00002563
LiquoGuard CSF System Tubing Set, 1500mm	00002650
LiquoGuard CSF System Tubing Set, 2000mm	00002911
Safety Cushion for LiquoGuard CSF System Tubing Set	00002701
LiquoGuard CSF System Attachment Clamp	00002672

14. Sterilization and Shelf Life

The LiquoGuard CSF System Tubing Sets are sterilized using the EtO sterilization method at the following facility:

(b)(4) [redacted]

The EtO sterilization process has been successfully validated in accordance with ISO 11135-1. In addition, the EtO residual analyze was performed according to ISO 10993-7 and all requirements were met.

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The initial sterilization validation was performed in 2006 according to ISO 11135:1994 and ISO 10993-7:1995. To meet all requirements of the revised standards a re-validation of the sterilization was performed in 2010. The validation of 2006 and 2010 together fulfill all requirements of the ISO 11135-1:2007 and the ISO 10993-7:2008.

Please refer to **Appendix 11** and **Appendix 12** for the sterility validation reports of 2006 and 2010 for the LiquoGuard CSF System Tubing Set.

The LiquoGuard CSF System Tubing Set is packaged in a blister of PETG (700µm, medical grade), sealed with a Tyvek foil which is in accordance with ISO 11607-1. Proposed shelf life is 2 years - please refer to **Appendix 13** for the accelerated aging test report.

15. Biocompatibility

Please refer to **Appendix 14** for the biocompatibility testing according to ISO 10993-1 of the LiquoGuard CSF System Tubing Set.

16. Software Validation

The software documentation is in accordance with FDA's May 2005 guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

16.1 Level of concern

The level of concern is, "Major Level of Concern", as failures or latent design flaws that could directly result in major injury or death to the patient or operator.

16.2 Software Description

The software controls the LiquoGuard CSF System pump, which means, the operation with the keys and the display as well as the rotation of the motor are controlled by software.

The LiquoGuard CSF System is constructed in a manner which enables at least one alarm trigger between pressure measurement and alarm generation during an error.

16.3 Device Hazard Analysis

A device hazard analysis has been conducted on the LiquoGuard CSF System pump. To mitigate identified risks, two pressure sensors and two microcontrollers are incorporated as a double check to ensure proper functioning of the pump. Additionally, the pump will give off an audible alarm in the case that the pump is not operating properly.

Please refer to **Appendix 15** for the detailed Device hazard analysis for the LiquoGuard CSF System including the software.

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16.4 Software Requirements Specification

All software has major level of concern. Therefore, all functions are described in the verification and validation testing for the Möller Medical LiquoGuard CSF System. Please refer to **Appendix 16**.

16.5 Software Architecture Design

The high level software architecture design document which includes a detailed depiction of the functional units and software modules is provided in **Appendix 17**.

16.6 Software Design Specification

The software design specifications are summarized in the software detailed design documents. The SDS documents are listed in **Table 6** below.

Table 6: Software Design Specification Documents

Software Design Specifications (SDS)	Appendix Reference
Serial communication interrupt	**Appendix 18**
Timer interrupt	**Appendix 19**
Watchdog communication	**Appendix 20**
Display	**Appendix 21**
Operation	**Appendix 22**
Alarm	**Appendix 23**
Motor control	**Appendix 24**
Data logging	**Appendix 25**
Patient monitor	**Appendix 26**
Measurement	**Appendix 27**
SD-Card	**Appendix 28**

16.7 Traceability Analysis

Traceability between system requirements and subsystem requirements is provided in **Appendix 29**.

16.8 Software Development Environment

The summary of the software life cycle development plan, including a summary of the configuration management and maintenance activities is provided in **Appendix 30**.

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16.9 Verification and Validation

Verification and validation of the LiquoGuard CSF System have been conducted. Please refer to **Appendix 31** for the list of bench tests that have been conducted.

17. Electromagnetic Compatibility and Electrical Safety

The Möller Medical LiquoGuard CSF System pump has been tested in accordance and meets the following electromagnetic compatibility and safety standards:

Relevant Directives:

93/42/EEC: Directive of 14 June 1993 concerning medical devices.

73/23/EEC: Directive of 19 February 1973 concerning low voltage, with modification of 93/68/EEC.

Electromagnetic Immunity and Emission:

DIN EN 60601-1-2, Publication date: 2002-10: Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility - Requirements and tests.

DIN EN 55011, Publication date: 2003-08: Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement (IEC/CISPR11:1997, modified + A1:1999 + A2:2002); German version EN5501:1998 + A1:1998 + A2:2002.

Copies of the Electromagnetic Compatibility reports for LiquoGuard CSF System are included in **Appendix 32**.

18. Performance Testing – Bench

(b)(4)

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19. Performance Testing – Animal

Because the LiquoGuard CSF System has the same indication for use as the primary predicate devices (external cerebral spinal fluid (CSF) drainage) and the same technological characteristics as the secondary predicate device (intracranial pressure measurement), and because all functions can be verified and tested in bench tests, animal performance testing was not deemed necessary based on the products risk assessment.

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20. Performance Testing – Clinical

The LiquoGuard CSF System has the same indication for use as the primary predicate devices (external cerebral spinal fluid (CSF) drainage) and the same technological characteristics as the secondary predicate device (intracranial pressure measurement), and because all functions can be verified and tested in bench tests, formal clinical performance testing was not deemed necessary based on the products risk assessment.

To present the safety of the LiquoGuard CSF System a clinical trial was started in 2009, 75 cases have been collected and are included in the study report. The LiquoGuard CSF System is CE marked in Europe since 2006 where the study was performed. Please refer to **Appendix 60** for the study protocols, the results and the discussion.

21. Others

The LiquoGuard CSF System is CE marked in Europe since 2006. The LiquoGuard CSF System is an innovation in the draining of CSF and some of neurosurgeons who are working with the LiquoGuard CSF System published their experience with the device. Please refer **Appendix 61** for some published reports.

- B.M. Hoelper "Clinical study report of a new pressure and volume controlled CSF drainage system (LiquoGuard)".
- N. Klemz, B. Luther, P. Köster, T. Nowak, E. Berendes "Continuous Controlled Lumbar Spinal Fluid Drainage for Prevention of Spinal Ischemia during Thoracoabdominal Surgery of the Aorta".
- Manfred Kudernatsch, Suleyman Nauros, Peter A. Winkler (Poster) "Automatical Pressure- and Flow-Controlled Ventricular CSF Drainage LiquoGuard®: Two Years of Experience with over 50 Children in Pediatric Neurosurgery and Epilepsy Surgery".

The mentioned publications for the comparison of the LiquoGuard CSF System with the secondary predicate device "intracranial pressure monitore" are submitted in **Appendix 61**.

- M. Gelabert-Gonzáles, V. Ginesta-Galan, R. Sernamito-Gareín, A.G. Allut, J. Bandin-Diéguez and R.M. Rumbo "The Camino intracranial pressure device in clinical practice. Assessment in a 1000 cases".
- Giuseppe Citerio, M.D., Ian Piper, Ph.D., Iain R. Chambers, Ph.D., Davide Gallo, M.D., Per Enblad, M.D., Karl Kiening, M.D., Arminas Ragauska, Ph.D., Juan Sahuquillo, M.D., Barbara Gregson, Ph.D. "Multicenter Clinical Assessment of the Raumedic Neurovent-P Intracranial Pressere Sensor: A Report by the BrainIT Group.".

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