

II. 510(k) Summary

AUG 18 2004

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles, New York 13153

Contact Person: David Klementowski
Regulatory Affairs Manager

Date Prepared: 20 February 2004

Proprietary Name: Welch Allyn Spot Ultra Vital Signs

Common Name: Vital Signs Measurement Device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure System

Predicate Device: Welch Allyn Spot Vital Signs
Welch Allyn, Inc.
510(k) Document Control Number *K002530 and K024005*

Description of the Device:

Indications For Use of the Device:

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO₂) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Contraindication For Use of the Device:

SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATAL PATIENTS. Welch Allyn defines neonates as children 28 days or less of age if born at term (37 weeks gestation or more); otherwise up to 44 gestational weeks. This definition comes from the AAMI SP10:2002 standard.

Spot Vital Signs Ultra is designed for medical clinician use. Although this manual may illustrate medical spot check techniques, only a trained clinician who knows how to take and interpret a patient's vital signs should use this system. Spot Vital Signs Ultra is not intended for use in environments that are without health care practitioner supervision.

Spot Vital Signs Ultra is not intended for continuous monitoring and is therefore not defibrillator proof. **Do not leave the device unattended while taking measurements on a patient.**

Spot Ultra is not intended for use during the transport of a patient.
WARNING: This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.

Blood Pressure Warnings

To ensure pediatric blood pressure accuracy and safety, the Small Child Durable One-Piece Cuff (5082-203-4) and the Small Child Disposable One-Piece Cuff (5083-93-4) are the smallest cuffs approved for use with young children and infants. The child's arm must fit within the range markings on the cuff.

You may experience inaccurate blood pressure measurements if cuffs and/or hoses other than those provided for Spot Vital Signs Ultra by Welch Allyn are used. To ensure patient safety, use only accessories and supplies (i.e., cuffs, hoses, temperature probes, SpO₂ sensors, etc.) recommended for or supplied with Spot Vital Signs Ultra.

Avoid compression of the cuff tubing or pressure hose of Spot Vital Signs Ultra. Compression of the cuff tubing or pressure hose may cause system errors to occur in the device.

Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air. Check all operating functions.

A qualified service person should check any Spot Vital Signs Ultra that has been dropped or damaged to ensure proper operation prior to use.

Every three months, inspect the temperature probe, SpO2 cord, and accessories for fraying or other damage. Replace as necessary.

Do not use Spot Vital Signs Ultra on patients who are linked to heart/lung machines.

There are no user-serviceable parts inside the device other than battery replacement.

Spot Vital Signs Ultra does not operate effectively on patients who are experiencing convulsions or tremors.

This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices.

As a precaution, avoid using this device in close proximity to other equipment.

This device is not intended for hand-held use during operation.

Welch Allyn recommends that the battery is left in the device, regardless if the device is not used for long periods of time. There is no hazard of leaving the battery in the device.

Using unapproved Welch Allyn accessories with Spot Vital Signs Ultra can affect patient and/or operator safety.

Do not autoclave.

Welch Allyn is NOT responsible for the integrity of any wall-mounting interface. Welch Allyn recommends that the customer contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory

Patients that are experiencing moderate to severe arrhythmias may give inaccurate blood pressure measurements.

When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.

SpO2 Warnings

The operation of the SpO2 sensor in MRI environments is specifically not recommended.

Only use Spot Vital Signs Ultra with Nellcor or Masimo pulse oximetry option with Nellcor or Masimo brand sensors and accessories, respectively. Using the wrong or unapproved sensors or cables may cause improper performance.

The SpO2 sensor and extension cables are intended for use only for pulse oximetry measurements. Do not attempt to connect these cables to a PC or any similar device.

Before using, carefully read the sensor Operator's Manual, including all warnings, cautions, and instructions.

Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed optical components.

Incorrect application or a long duration of use of an SpO2 sensor may cause tissue damage. Inspect the sensor site periodically as directed in the sensors' direction for use.

SpO2 readings and pulse signal is affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Do not immerse or wet the sensor.

Do not use the pulse oximetry cable or power cord to lift the pulse oximeter because the cable or cord may disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

The SpO2 is NOT intended for use as an apnea monitor.

Consider the pulse oximeter an early warning device. As a trend toward patient hypoxemia is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.

Carefully route patient cabling to reduce the possibility of patient enlargement or strangulation.

Severe anemia may cause erroneous SpO2 readings.

Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.

Temperature Warnings

SureTemp Plus™

Use single-use, disposable probe covers to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

Do not take a patient's temperature without using a disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, or erroneous temperature readings.

Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Biting the probe tip while taking a temperature may result in damage to the probe.

Oral/axillary probes (blue ejection button at top of probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the probe at the wrong site will result in temperature errors. Use of the incorrect removable probe well could result in patient cross-contamination.

The thermometer connectors and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all functions for proper operation.

Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

The SureTemp Plus thermometer consists of high-quality precision parts. Protect it from severe impact and shock. A qualified service technician must check any SureTemp Plus thermometer that is dropped or damaged to ensure proper operation prior to further use. Do not use the thermometer if you notice any signs of damage to the probe. Contact the Welch Allyn Customer Service Department for assistance.

Do not autoclave.

General Cautions

If the accuracy of any measurement is in question, check the patient's vital sign(s) with an alternate method, then check to make sure the device is functioning properly.

Place the device on a secure surface or use one of the optional mounting accessories.

Do not place fluids on or near the device.

Blood Pressure Cautions

Minimize extremity and cuff motion during blood pressure determinations.

If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect. Add the value of 1.80 mmHg (.2 kPa) to the displayed reading for every inch (2.5 cm) above heart level. Subtract the value of 1.80 mmHg (.2 kPa) from the displayed reading for every inch (2.5 cm) below heart level.

Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See "Chart for Determining Cuff Size" on page 23 for cuff sizing information.

Pulse Oximetry Cautions

The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxy hemoglobin or methemoglobin may affect the accuracy of the measurement.

Some intravascular dyes, depending on the concentration, may affect the accuracy of the SpO₂ measurement. Some sensors may not be appropriate for a particular patient. If at least 10 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type for perfusion to resume.

The sensor disconnect message indicates that the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, pulse oximetry cable, or both.

NOTE: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring.

Technological Characteristics:

The Welch Allyn Spot Ultra Vital Signs Device utilizes an Oscillometric BP Algorithm and temperature technology, similar to Spot Vital Signs and utilizes the same SpO2 OEM as the Welch Allyn Spot Vital Signs. The new Spot Ultra Vital Signs will incorporate a new temperature module (Braun 4000) and a new SpO2 OEM module the Masimo SET as options. The FDA, under 510(k) numbers K002530 and K024005, approved Spot Vital Signs. The following table summarizes the similarities between the Welch Allyn Spot Vital Signs Device and the new Welch Allyn Spot Ultra Vital Signs Device.

Table 1
 Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	Intelligent Target inflation, (which can return a BP reading) or 160 mmHg (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-2002
Heart Rate	+/- 5% (BP Determination)	+/- 5% (BP Determination)

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 typical, 165 max.	15 to 30 typical, 150 max.
Mean Arterial Pressure	Calculated	Calculated
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model Used	MP506	MP506
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 3% <70% unspecified	70-100% +/- 3% <70% unspecified
Heart Rate	+/- 3 bpm	+/- 3 bpm
Massimo OEM SpO2		
Spo2 Measurement	No	Yes
OEM Model Used	NA	NCT-11
Measurement Range		
SpO2	NA	40-100%
Heart Rate	NA	25-245 bpm
Measurement Accuracy		
SpO2	NA	70-100% +/- 3% <70% unspecified
Heart Rate	NA	+/- 3 bpm
SureTemp® OEM Temperature		
Temperature	Yes	Yes
Measurement Range	84°F (30°C) to 109.4°F (43.0°C)	80.0° to 109.4° F (34.5°-43.0°C)
Measurement Accuracy	per ASTM E1112-86 (1991)	per ASTM E1112-00 (2000)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
Braun 4000 IR Thermometer		
Temperature	No	Yes
Measurement Range	NA	68° to 108° F / 20° to 42.2° C
Measurement Accuracy	NA	Per EN12470
Temperature Determination	NA	Ear IR
HHP 3800PDF Bar Code Scanner		
	No	Yes

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Overall System		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR wireless Capable Communication	Wireless (802.11b) Capable Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-25 to 55 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2004

Welch Allyn, Inc.
c/o Mr. Christopher Klaczyk
Senior Regulatory Engineer
4341 State Street Road
P.O. Box. 220
Skaneateles Falls, NY 13153-0220

Re: K040490
Trade Name: Welch Allyn Spot Ultra Vital Signs Device
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 22, 2004
Received: July 23, 2004

Dear Mr. Klaczyk:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Page 2 – Mr. Christopher Klaczyk

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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D. for
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Welch Allyn, Inc. Spot Ultra Vital Signs Pre-Market Notification

VII. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn Spot Ultra Vital Signs Device

Indications for use: The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO2) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Prescription Use X Or Over-The-Counter Use

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Oyster for 302

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040490



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D. *for*
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

Welch Allyn, Inc. Spot Ultra Vital Signs Pre-Market Notification

VII. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn Spot Ultra Vital Signs Device

Indications for use: The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO2) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Prescription Use X Or Over-The-Counter Use

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Opler for 302
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040490

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Welch Allyn, Inc.
c/o David Klementowski
Regulatory Affairs Manager
4341 State Street Road
Skaneateles NY 13153

APR 21 2004

Re: K040490

Trade Name: Welch Allyn Spot Ultra Vital Signs Device
Dated: February 20, 2004
Received: February 26, 2004

Dear Mr. Klementowski:

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 you provided. To complete the review of your submission, we require the following information:

1. You provide a signed statement of conformance to recognized and non-recognized standards on page 15 of the submission. Among the standards to which you certify conformance is ANSI/AAMI SP10 (2002). The FDA does not recognize the 2002 version of the ANSI/AAMI SP10 standard. The latest revision of the standard that is FDA recognized is the 1992 version. Please use the ANSI/AAMI SP-10 (1992) standard and not the ANSI/AAMI SP-10 (2002) standard to demonstrate substantial equivalence of the blood pressure measurement component of the proposed device. You can provide either:
 - the bench top and clinical data to demonstrate the safety and effectiveness of the blood pressure measurement module of the proposed device, or
 - a signed statement of conformance to the 1992 version of ANSI/AAMI SP-10.
2. You provide a signed statement of conformance to recognized and non-recognized standards on page 15 of the submission. Among the standards to which you certify conformance is EN865 (1997). The FDA does not recognize the EN865 (1997) standard. You may still use the standard to establish substantial equivalence to legally marketed devices if you provide detailed protocols, data, and conclusions of the tests specified in the

Page 2 – Mr. David Klementowski

standard. Additional data may be requested if the protocols specified in the standard are not sufficient to demonstrate safety and effectiveness of the proposed device. Please refer to the FDA Draft Guidance Document on Non-Invasive Pulse Oximeter, which is available at <http://www.fda.gov/cdrh/ode/guidance/997.pdf>, and to deficiencies 3 and 4 below.

3. You tabulate a specifications and technological comparison between the predicate and proposed devices that includes information regarding the different OEM modules and sensors, as well as general information comparing the overall system performance. However, you do not provide a comparison of the hardware, firmware, and algorithms of the two devices. Are the only differences between the predicate and proposed devices the accessories that can be used, -the addition of a second thermometer option, and the ability to function with a second SpO2 sensor? Are the hardware, firmware, and algorithms identical to those in the predicate device? Please expand the table on page 12 of the submission (repeated on page 44 as table 3) to include a comparison of the hardware, firmware, and algorithms in the predicate and proposed devices.

(b)(4)

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(b)(4)

- Please provide the detailed clinical protocol and raw data for our review.
- For more guidance on this testing, please refer to the FDA Draft Guidance Document on Non-Invasive Pulse Oximeter, which is available at <http://www.fda.gov/cdrh/ode/guidance/997.pdf>.
- Provide in detail, your exclusion criteria for excluding data points. How have you validated that your exclusion criteria are evaluated.

If the data and protocols of the non-recognized standards cited in deficiency 2 (i.e. EN865 (1997)) conform to the above list, providing detailed test reports including protocols, data, and conclusions may suffice to address deficiency 4.

(b)(4)

Page 4 – Mr. David Klementowski

(b)(4)

When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at <http://www.fda.gov/cdrh/ode/guidance/1131.pdf> for additional guidance.

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 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/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page 5 – Mr. David Klementowski

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:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Felipe Aguel at (301) 443-8517, extension 152 or fxa@cdrh.fda.gov. 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) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Bram D. Zuckerman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

302

Welch Allyn, Inc.
c/o David Klementowski
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APR 21 2004

Re: K040490

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Page 2 – Mr. David Klementowski

standard. Additional data may be requested if the protocols specified in the standard are not sufficient to demonstrate safety and effectiveness of the proposed device. Please refer to the FDA Draft Guidance Document on Non-Invasive Pulse Oximeter, which is available at <http://www.fda.gov/cdrh/ode/guidance/997.pdf>, and to deficiencies 3 and 4 below.

3. You tabulate a specifications and technological comparison between the predicate and proposed devices that includes information regarding the different OEM modules and sensors, as well as general information comparing the overall system performance. However, you do not provide a comparison of the hardware, firmware, and algorithms of the two devices. Are the only differences between the predicate and proposed devices the accessories that can be used, -the addition of a second thermometer option, and the ability to function with a second SpO2 sensor? Are the hardware, firmware, and algorithms identical to those in the predicate device? Please expand the table on page 12 of the submission (repeated on page 44 as table 3) to include a comparison of the hardware, firmware, and algorithms in the predicate and proposed devices.

(b)(4)

Page 3 – Mr. David Klementowski

(b)(4)

Page 4 – Mr. David Klementowski

(b)(4)

When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at <http://www.fda.gov/cdrh/ode/guidance/1131.pdf> for additional guidance.

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 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/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page 5 – Mr. David Klementowski

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:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Felipe Aguel at (301) 443-8517, extension 152 or fxa@cdrh.fda.gov. 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) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Department of Health & Human Services
Page 6 – Mr. David Klementowski

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 DCD
D.O.

Final : Linda Bessacque:04/21/04

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z 450	Aguel	4/21/04			
Z-450	Malla	04/21/04			

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 09, 2004

WELCH ALLYN, INC.
MEDICAL
4341 STATE ST. RD.
SKANEATELES FALLS, NY 13153

510(k) Number: K040490
Received: 08-MAR-2004
Product: WELCH ALLYN SPOT
ULTRA VITAL SIGNS
DEVICE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HPZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 26, 2004

WELCH ALLYN, INC.
MEDICAL
4341 STATE ST. RD.
SKANEATELES FALLS, NY 13153

510(k) Number: K040490
Received: 26-FEB-2004
Product: WELCH ALLYN SPOT
User Fee ID Number: 13082L SIGNS
DEVICE

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

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Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

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K070490

Form Approved OMB No. 0910-0511 Expiration Date: August 31, 2006 See instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER Write the Payment Identification Number	(b)(4)
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
<ol style="list-style-type: none"> Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 			
1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) WELCH ALLYN, INC. 4341 STATE STREET ROAD SKANEATELES FALLS, NY 13153 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 002062340		2. CONTACT NAME DAVID KLEMENTOWSKI 2.1 E-MAIL ADDRESS klementowskiD@welchallyn.com 2.2 TELEPHONE NUMBER (Include Area Code) 315-685-4133 2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 315-685-2532	
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: <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		3.1 Select one of the types below: <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. 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).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004) (b)(4)			

Form FDA 3601 (08/2003)

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USA

20 February 2004

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: Abbreviated 510(k) Notification
Noninvasive Blood Pressure Measurement System

FDA/CDRH/OCE/PMO
2004 FEB 20
A 9:35

Dear Sir or Madam:

This submission is being made in compliance with Section 510(k) of the Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997, and the Office of Device Evaluation guidance for Abbreviated 510(k) requirements. The enclosed information is being submitted for the Welch Allyn Spot Ultra Vital Signs Device. Two copies of this Pre-market Notification are being submitted in accordance with 21 CFR 807.

The purpose of this submission is to notify FDA, in accordance with the 510(k) provisions of the Act, of our intent to introduce this new product, the Welch Allyn Spot Ultra Vital Signs Device into commercial distribution.

If you have any questions regarding this submission, please telephone (315) 685-4100 ext. 4133.

Sincerely yours,



David Klementowski
Regulatory Affairs Manager
Welch Allyn Inc.

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CDRH SUBMISSION COVER SHEET

Date of Submission:

FDA Document Number:

Section A		Type of Submission		
PMA Original Submission <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	PDP <input type="checkbox"/> Presubmission Summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	510(k) Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Report Amendment	Meeting <input type="checkbox"/> Pre-IDE mtg. <input type="checkbox"/> Pre-PMA mtg. <input type="checkbox"/> Pre-PDP mtg. <input type="checkbox"/> 180-Day mtg. <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	Class II Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission Describe Submission:

Section B					Applicant or Sponsor				
Company/Institution Name: Welch Allyn, Inc.				Establishment registration number: 1316463					
Division Name (if applicable): Medical				Phone number (include area code): 315-685-4133					
Street Address: 4341 State Street Road				Fax number (include area code): 315-685-2532					
City: Skaneateles		State/Province: New York			Zip code: 13153		Country: USA		
Contact Name: David Klementowski									
Contact Title: Sr. Manager Regulatory Affairs						Contact e-mail address: klementowskiid@welchallyn.com			

Section C					Submission Correspondent (if different from above)				
Company/Institution Name:				Establishment registration number:					
Division name (if applicable)				Phone number (include area code):					
Street Address:				Fax number (include area code):					
City:		State/Province:			Zip Code:		Country		
Contact Name:									

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Section D1

Reason for Submission – PMA,PDP, or HDE

- New Device
- Withdrawal
- Additional or Expanded Indications
- Licensing Agreement
- Change in design, component, or specification:
 - Software
 - Color Additive
 - Material
 - Specifications
 - Other (specify below)
- Processing Change:
 - Manufacturing
 - Sterilization
 - Packaging
 - Other (specify below)
- Response to FDA correspondence:
 - Request for applicant hold
 - Request for removal of applicant hold
 - Request for extension
 - Request to remove or add manufacturing site
- Other Reason (specify):
- Location Change:
 - Manufacturer
 - Sterilizer
 - Packager
 - Distributor
- Labeling Change:
 - Indications
 - Instructions
 - Performance Characteristics
 - Shelf Life
 - Trade Name
 - Other (specify below)_
- Report Submission:
 - Annual or Periodic
 - Post Approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment
- Change in Ownership
- Change in correspondent

Section D2

Reason for Submission - IDE

- New device
- Addition of institution
- Expansion/extension of study
- IRB certification
- Request hearing
- Request waiver
- Termination of study
- Withdrawal of application
- Unanticipated adverse effect
- Notification of emergency use
- Compassionate use request
- Treatment IDE
- Continuing availability request
- Change in:
 - Correspondent
 - Design
 - Informed consent
 - Manufacturer
 - Manufacturing process
 - Protocol – feasibility
 - Protocol – other
 - Sponsor
- Report Submission:
 - Current investigator
 - Annual progress
 - Site waiver limit reached
 - Final
- Response to FDA letter concerning:
 - Conditional approval
 - Deemed approval
 - Deficient final report
 - Deficient progress report
 - Deficient investigator report
 - Disapproval
 - Request extension for time to respond to FDA
 - Request meeting
- Other reason (specify):

Section D3

Reason for Submission – 510(k)

- New Device
- Additional or expanded indications
- Other reason (specify):
- Change in technology
- Change in design
- Change in materials
- Change in manufacturing process

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Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1 DQA	2 DXN	3	4	
5	6	7	8	

510(k) Number	Trade or Proprietary or model name	Manufacturer
1 K022163	1 Spot Vital Signs	1 Welch Allyn, Inc.
2 K002530	2 Spot Vital Signs	2 Welch Allyn, Inc.
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name:
 Non-invasive Blood Pressure Measurement System

Trade or proprietary or model name	Model Number
1 Spot Ultra Vital Signs	1 45XXX
2	2
3	3
4	4
5	5

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

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

Data included in submission: Laboratory Testing Animal Trials Human Trials

Section G Product Classification – Applicable to All Applicants

Product code: DXN	C.F.R. Section 21 CFR 870.1130	Device Class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel: Cardiovascular	Indications (from labeling): Reference indications in the 510(k) submission (see attached)	

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:
---	----------------------

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1316463	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: Welch Allyn, Inc.		Establishment registration number: 1316463	
Division name (if applicable): Medical		Phone number (include area code): 315-685-4133	
Street address: 4341 State Street Road		FAX number (include area code): 315-685-2532	
City Skaneateles	State/Province NY	Zip code: 13153	Country USA
Contact name: Divid Klementowski			

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution Name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title		Contact e-mail address:	

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TRUTHFUL AND ACCURATE STATEMENT

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.93)**

I certify that, in my capacity as Vice President, Quality and Regulatory Affairs, Welch Allyn Inc., I believe to the best of my knowledge that all data and information submitted in this 510(k) Pre-market Notification Submission is truthful and accurate and that no material fact has been omitted.



Oscar Sanchez
VP Quality and Regulatory Affairs
Welch Allyn Inc.

2/23/04

Date

I. General Information

A. Submitter's Name & Address

Dave Klementowski
Senior Regulatory Manager
4341 State Street Road
Skaneateles, New York 13153
Phone: (315) 685-4133
Fax: (315) 685-2546

B. Other Contact Persons

Joseph D. Buchanan
Senior Quality Assurance Engineer
Welch Allyn Inc.
4341 State Street Road
Skaneateles, NY 13153
Phone: (315) 291-3587
Fax: (315) 291-3530

Stephen Wilson
Project Manager
4341 State Street Road
Skaneateles Falls, New York 13153
Phone: (315) 291-3548
Fax: (315) 291-3530

C. Establishment Registration Number of Submitter

Registration NO.: 1316463
Owner/Operator NO.: 1316463

D. Manufacturing Facilities

Establishment Registration		Manufacturing Facility
Registration NO.:	1316463	Welch Allyn Inc.
Owner/Operator NO.:	1316463	4341 State Street Road Skaneateles, New York 13153

E. Device Name

Proprietary Name: Welch Allyn Spot Ultra Vital Signs Device
Common Name: Vital Signs Measurement Device
Classification Name: Noninvasive Blood Pressure Measurement System

F. Device Classification

Class II (21 CFR 870.1130 Noninvasive Blood Pressure Measurement System).

G. Action Taken to Comply with Section 514 of the Act

The agency has recognized the following standards:

- a) IEC60601-1: 1990
- b) IEC60601-1-2: 2002
- c) IEC60601-1-4: 1997
- d) IEC60601-2-49: 2001
- e) AAMI SP10: 2002
- f) ASTM 1112: 2000
- g) EN865: 1997

The Welch Allyn Spot Ultra Vital Signs Device will meet the requirements called out for in these standards prior to, or at the time of, introduction of the product to market in December 2004.

H. Reason for 510(k) Submission

- Initial Product Introduction
- New Model for Product-line Extension
- Initial Import into the USA
- Other

I. Predicate Device

Welch Allyn Spot Vital Signs Device

Welch Allyn

510(k) Document Control Number *K002530 and K024005*

II. 510(k) Summary

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles, New York 13153

Contact Person: David Klementowski
Regulatory Affairs Manager

Date Prepared: 20 February 2004

Proprietary Name: Welch Allyn Spot Ultra Vital Signs

Common Name: Vital Signs Measurement Device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure System

Predicate Device: Welch Allyn Spot Vital Signs
Welch Allyn, Inc.
510(k) Document Control Number *K002530 and K024005*

Description of the Device:

Indications For Use of the Device:

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO₂) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Contraindication For Use of the Device:

SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATAL PATIENTS. Welch Allyn defines neonates as children 28 days or less of age if born at term (37 weeks gestation or more); otherwise up to 44 gestational weeks. This definition comes from the AAMI SP10:2002 standard.

Spot Vital Signs Ultra is designed for medical clinician use. Although this manual may illustrate medical spot check techniques, only a trained clinician who knows how to take and interpret a patient's vital signs should use this system. Spot Vital Signs Ultra is not intended for use in environments that are without health care practitioner supervision.

Spot Vital Signs Ultra is not intended for continuous monitoring and is therefore not defibrillator proof. **Do not leave the device unattended while taking measurements on a patient.**

Spot Ultra is not intended for use during the transport of a patient.
WARNING: This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.

Blood Pressure Warnings

To ensure pediatric blood pressure accuracy and safety, the Small Child Durable One-Piece Cuff (5082-203-4) and the Small Child Disposable One-Piece Cuff (5083-93-4) are the smallest cuffs approved for use with young children and infants. The child's arm must fit within the range markings on the cuff.

You may experience inaccurate blood pressure measurements if cuffs and/or hoses other than those provided for Spot Vital Signs Ultra by Welch Allyn are used. To ensure patient safety, use only accessories and supplies (i.e., cuffs, hoses, temperature probes, SpO2 sensors, etc.) recommended for or supplied with Spot Vital Signs Ultra.

Avoid compression of the cuff tubing or pressure hose of Spot Vital Signs Ultra. Compression of the cuff tubing or pressure hose may cause system errors to occur in the device.

Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air. Check all operating functions.

A qualified service person should check any Spot Vital Signs Ultra that has been dropped or damaged to ensure proper operation prior to use.

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Every three months, inspect the temperature probe, SpO2 cord, and accessories for fraying or other damage. Replace as necessary.

Do not use Spot Vital Signs Ultra on patients who are linked to heart/lung machines.

There are no user-serviceable parts inside the device other than battery replacement.

Spot Vital Signs Ultra does not operate effectively on patients who are experiencing convulsions or tremors.

This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices.

As a precaution, avoid using this device in close proximity to other equipment.

This device is not intended for hand-held use during operation.

Welch Allyn recommends that the battery is left in the device, regardless if the device is not used for long periods of time. There is no hazard of leaving the battery in the device.

Using unapproved Welch Allyn accessories with Spot Vital Signs Ultra can affect patient and/or operator safety.

Do not autoclave.

Welch Allyn is NOT responsible for the integrity of any wall-mounting interface. Welch Allyn recommends that the customer contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory

Patients that are experiencing moderate to severe arrhythmias may give inaccurate blood pressure measurements.

When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.

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SpO2 Warnings

The operation of the SpO2 sensor in MRI environments is specifically not recommended.

Only use Spot Vital Signs Ultra with Nellcor or Masimo pulse oximetry option with Nellcor or Masimo brand sensors and accessories, respectively. Using the wrong or unapproved sensors or cables may cause improper performance.

The SpO2 sensor and extension cables are intended for use only for pulse oximetry measurements. Do not attempt to connect these cables to a PC or any similar device.

Before using, carefully read the sensor Operator's Manual, including all warnings, cautions, and instructions.

Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed optical components.

Incorrect application or a long duration of use of an SpO2 sensor may cause tissue damage. Inspect the sensor site periodically as directed in the sensors' direction for use.

SpO2 readings and pulse signal is affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Do not immerse or wet the sensor.

Do not use the pulse oximetry cable or power cord to lift the pulse oximeter because the cable or cord may disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

The SpO2 is NOT intended for use as an apnea monitor.

Consider the pulse oximeter an early warning device. As a trend toward patient hypoxemia is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.

Carefully route patient cabling to reduce the possibility of patient enlargement or strangulation.

Severe anemia may cause erroneous SpO2 readings.

Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.

Temperature Warnings

SureTemp Plus™

Use single-use, disposable probe covers to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

Do not take a patient's temperature without using a disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, or erroneous temperature readings.

Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Biting the probe tip while taking a temperature may result in damage to the probe.

Oral/axillary probes (blue ejection button at top of probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the probe at the wrong site will result in temperature errors. Use of the incorrect removable probe well could result in patient cross-contamination.

The thermometer connectors and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all functions for proper operation.

Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

The SureTemp Plus thermometer consists of high-quality precision parts. Protect it from severe impact and shock. A qualified service technician must check any SureTemp Plus thermometer that is dropped or damaged to ensure proper operation prior to further use. Do not use the thermometer if you notice any signs of damage to the probe. Contact the Welch Allyn Customer Service Department for assistance.

Do not autoclave.

General Cautions

If the accuracy of any measurement is in question, check the patient's vital sign(s) with an alternate method, then check to make sure the device is functioning properly.

Place the device on a secure surface or use one of the optional mounting accessories.

Do not place fluids on or near the device.

Blood Pressure Cautions

Minimize extremity and cuff motion during blood pressure determinations.

If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect. Add the value of 1.80 mmHg (.2 kPa) to the displayed reading for every inch (2.5 cm) above heart level. Subtract the value of 1.80 mmHg (.2 kPa) from the displayed reading for every inch (2.5 cm) below heart level.

Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See “Chart for Determining Cuff Size” on page 23 for cuff sizing information.

Pulse Oximetry Cautions

The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxy hemoglobin or methemoglobin may affect the accuracy of the measurement.

Some intravascular dyes, depending on the concentration, may affect the accuracy of the SpO₂ measurement. Some sensors may not be appropriate for a particular patient. If at least 10 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type for perfusion to resume.

The sensor disconnect message indicates that the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, pulse oximetry cable, or both.

NOTE: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter’s ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

When selecting a sensor, consider the patient’s weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring.

Technological Characteristics:

The Welch Allyn Spot Ultra Vital Signs Device utilizes an Oscillometric BP Algorithm and temperature technology, similar to Spot Vital Signs and utilizes the same SpO2 OEM as the Welch Allyn Spot Vital Signs. The new Spot Ultra Vital Signs will incorporate a new temperature module (Braun 4000) and a new SpO2 OEM module the Masimo SET as options. The FDA, under 510(k) numbers K002530 and K024005, approved Spot Vital Signs. The following table summarizes the similarities between the Welch Allyn Spot Vital Signs Device and the new Welch Allyn Spot Ultra Vital Signs Device.

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
<u>Blood Pressure</u>		
BP Determination Method	Oscillometric	Oscillometric
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	Intelligent Target inflation, (which can return a BP reading) or 160 mmHg (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
<u>Measurement Range</u>		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
<u>Measurement Accuracy</u>		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-2002
Heart Rate	+/- 5% (BP Determination)	+/- 5% (BP Determination)

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	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 typical, 165 max.	15 to 30 typical, 150 max.
Mean Arterial Pressure	Calculated	Calculated
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model Used	MP506	MP506
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 3% <70% unspecified	70-100% +/- 3% <70% unspecified
Heart Rate	+/- 3 bpm	+/- 3 bpm
Massimo OEM SpO2		
SpO2 Measurement	No	Yes
OEM Model Used	NA	NCT-11
Measurement Range		
SpO2	NA	40-100%
Heart Rate	NA	25-245 bpm
Measurement Accuracy		
SpO2	NA	70-100% +/- 3% <70% unspecified
Heart Rate	NA	+/- 3 bpm
SureTemp® OEM Temperature		
Temperature	Yes	Yes
Measurement Range	84°F (30°C) to 109.4°F (43.0°C)	80.0° to 109.4° F (34.5°-43.0°C)
Measurement Accuracy	per ASTM E1112-86 (1991)	per ASTM E1112-00 (2000)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
Braun 4000 IR Thermometer		
Temperature	No	Yes
Measurement Range	NA	68° to 108° F / 20° to 42.2° C
Measurement Accuracy	NA	Per EN12470
Temperature Determination	NA	Ear IR
HHP 3800PDF Bar Code Scanner		
	No	Yes

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	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Overall System		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR wireless Capable Communication	Wireless (802.11b) Capable Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-25 to 55 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

III. Statement of Conformance to Recognized and non-Recognized Standards

The following mentioned product will be tested in typical configuration (BP, SpO2, and Temperature) by a third party testing facility (ITS Cortland, NY), and will be found to be in compliance with the requirements of the standards listed below before Welch Allyn begins the sale of this device.

Equipment:

Type of Product - Non-invasive Blood Pressure Device

Model Number – 45XXX

Produced By:

Company Name: Welch Allyn, Inc.

Company Address: 4341 State Street Road,
Skaneateles, New York 13153

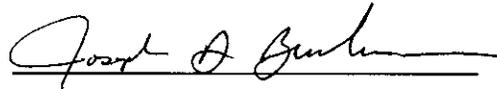
Applied Standards:

- 1) **IEC 60601-1 (1990)** - Medical electrical equipment. Part 1: General requirements for safety. *Compliance to the standard.*
- 2) **IEC 60601-1, Amendment 1 (1993)** - Medical electrical equipment. Part 1: General requirements for safety. *Compliance to the standard.*
- 3) **IEC 60601-1, Amendment 2 (1995)** - Medical electrical equipment. Part 1: General requirements for safety. *Compliance to the standard.*
- 4) **IEC 60601-1-2 (2001)** - Medical electrical equipment. Part 1. General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and testing (Compliance with CISPR 55011, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-7, IEC 61000-4-8, IEC 61000-4-9, IEC 61000-4-10, IEC 61000-4-11 will be tested). *Compliance to the standard.*
- 5) **IEC 60601-1-4 (1996)** - Medical electrical equipment. Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems. *Compliance to the standard.*
- 6) **AAMI SP10 (2002)** - Standard for electronic or automated sphygmomanometers. *Compliance to all sections except for the following:*
 - a) Sections 4.2.4.1 - Rational: The Spot Ultra Vital Signs Device is battery-powered device and only uses AC to charge the battery. AC alone will not run the Device. Therefore this section is not applicable.
 - b) Section 4.3.3 - Rational: The Spot Ultra Vital Signs Device and it accessories does not utilize anything that is conductive. There for this section is not applicable.

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- 8) **ASTM1112-86 (2000)** - Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature. *Compliance to all sections except for the following:*
- a) Section 4.4.1 - Rational: The Spot Ultra Vital Signs Device utilizes a digital display. Therefore this section is not applicable.
 - b) Section 4.6.1 - Rational: This will be tested in IEC 60601-1.
- 9) **EN 865 (1997)- Pulse Oximeters - Particular Requirements** – *Compliance to all sections per test evidence from the OEM (Nelcor and Massimo).*

Evidence of compliance to the above mentioned standards shall be on file at Welch Allyn, Inc. 4341 State Street Road, Skaneateles, NY 13153 on or before the release of the product for sale. Estimated launch date for the device listed above is December 2004.



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Date

IV. Description of Device

The Welch Allyn Spot Ultra Vital Signs Device is not a monitor, but a one-time vital signs measurement device. This product will not have continuous monitoring capability with timed cycle intervals or any various programmable alarm features. Welch Allyn Spot Ultra Vital Signs Device will include BP with Temp, as the base feature, SpO2 is an option. A mobile stand, custom wall mount, an external printer, a bar code reader, and 802.11b wireless communications are accessories that Welch Allyn Spot Ultra Vital Signs Device can be configured.

The Welch Allyn Spot Ultra Vital Signs Device is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature, and oxygen saturation (SpO2) for adult and pediatric patients. The Welch Allyn Spot Ultra Vital Signs Device will also calculate Mean Arterial Pressure (MAP). All blood pressure, pulse, temperature, and SpO2 values are displayed on a large, easy-to-read LCD display, and may be printed via an external thermal printer, as desired. The rechargeable battery and wide variety of mounting accessories make the Welch Allyn Spot Ultra Vital Signs Device convenient for many locations. The Spot Ultra device will also allow for data entry for weight, height, pain and will calculate BMI.

The Welch Allyn Spot Ultra Vital Signs Device is intended for use in a wide variety of health care settings. This includes hospital departments; alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes. ***The Welch Allyn Spot Ultra Vital Signs Device is not intended for the monitoring of patients.*** The Welch Allyn Spot Ultra Vital Signs Device is not intended for use in environments that are not supervised by a health care practitioner.

System Architecture

Hardware Description

Spot Ultra's hardware design will use the Motorola Dragon Ball MXL microcontroller, FLASH, RAM, and a series of Welch Allyn and 3rd party hardware components. The software design will use a "C" language compiler and Real Time Operating System (ThreadX).

The following list gives a brief overview of the hardware components which will make up Spot Ultra.

1. Real Time Clock / Calendar
2. Watchdog/Reset

- 3.
4. Non-volatile Storage
 - Configuration
 - Event Logging
 - Data Collection
 - Patient Data Storage
5. NIBP
 - Mod F / FastBP Algorithm
6. Thermometry
 - SureTemp[®] Plus OEM or
 - Braun Pro4000
7. SpO2
 - Nellcor MP506 or
 - Masimo NCT-11
8. User Interface
 - ¼ VGA Graphics LCD Display
 - Keypad
 - Audio Annunciator
 - Power / Charger LEDs
9. Printer
 - 2" External Thermal
10. Bar Code Scanner
 - Hand Held Products' Image Team Linear Scanner
11. Connectivity
 - RS-232 Serial - Host PC / Barcode
 - USB 1.1 Device
 - RS-232 Serial - Printer
 - Wireless
12. External Charger
13. MMC/SD

The following is a brief description of the Hardware components that make up Spot Ultra Vital Signs.

Real Time Clock / Calendar

Spot Ultra will include a real time clock / calendar which will be used to time stamp patient data. The time stamp will be included as part of any patient data displayed or output generated by Spot Ultra.

Watchdog/Reset

Spot Ultra will include an external watchdog and reset component which will be used to reset Spot Ultra in the case of system malfunctions.

Non-volatile Storage

1. Configuration

Spot Ultra will include non-volatile storage to be used to store such information as device serial number, language selection, etc. Configuration storage will be implemented using dedicated sectors of the program code FLASH.

2. Event Logging

Spot Ultra will include non-volatile storage to be used to store an event log. The event log will be used to record the history of user interface and device functionality (i.e. button press, air leak, etc.). Event logging storage will be implemented using dedicated sectors of the program code FLASH.

3. Data Collection

Spot Ultra will include non-volatile storage to be used for data collection. The data collected will be used for NIBP algorithm development, compliance testing and validation. Data collection storage will be implemented using a Secure Digital (SD) Memory Card.

4. Patient Data Storage

Spot Ultra will include non-volatile storage to store up to 50 patient records even if the power to the unit is turned off.

NIBP – Mod F Module

Spot Ultra will use the NIBP Mod F Module for NIBP. This Mod F module contains the Welch Allyn FastBP Algorithm that Spot will utilize for its NIBP measurement.

Power to the module will be controllable by Spot Ultra.

Communications between Spot Ultra and Mod F will be bi-directional, serial.

Communications will be implemented using a H/W UART. The baud rate used will default to 9600 bps, but shall be capable of running at baud rates up to 19200 bps.

Thermometry

Spot Ultra will support one of two Thermometer options: the Welch Allyn SureTemp[®] Plus OEM Module or the Braun Pro4000 OEM Module.

SureTemp[®] Plus OEM

Power to the SureTemp[®] Plus OEM Module will be controllable by Spot Ultra.

Communications between Spot Ultra and the SureTemp[®] Plus OEM Module will be bi-directional, serial.

Communications will be implemented using a H/W UART. The baud rate used will be fixed at 9600 bps.

Braun Pro4000

Power to the Braun Pro4000 Module will be controllable by Spot Ultra.

Communications between Spot Ultra and Braun Pro4000 Module will be half duplex, current loop serial.

Communications will be implemented using a H/W UART. The baud rate used will be fixed at 1200 bps.

SpO2

Spot Ultra will support one of two SpO2 options: the Nellcor MP506 OEM Module or the Masimo NCT-11 OEM Module.

Nellcor MP506

Power to the Nellcor MP506 OEM Module will be controllable by Spot Ultra.

Communications between Spot Ultra and the Nellcor MP506 OEM Module will be uni-directional.

Communications will be implemented using a H/W UART. The baud rate to be used will be fixed at 2400 bps.

Masimo NCT-11

Power to the Masimo NCT-11 OEM Module will be controllable by Spot Ultra.

Communications between Spot Ultra and the Masimo NCT-11 OEM Module will be uni-directional.

Communications will be implemented using a H/W UART. The baud rate to be used will be fixed at 9600 bps.

User Interface

The user interface will consists of three parts:

- Nan Ya ¼ VGA Graphics LCD Display
- Keypad
- Audio Annunciator
- Power / Charger LEDs

The LCD display and keypad will comprise a subsystem which will be connected the Spot Ultra main circuit board by a flat ribbon cable.

LCD Display

The Nan Ya ¼ VGA Graphics LCD display will be implemented on a separate assembly, including the LCD and ballast. The interface to the LCD by the MXL's LCD controller will be uni-directional and will comply with the hardware interface required of the Nan Ya LCD Display. Figure 1 shows the layout of the LCD display.

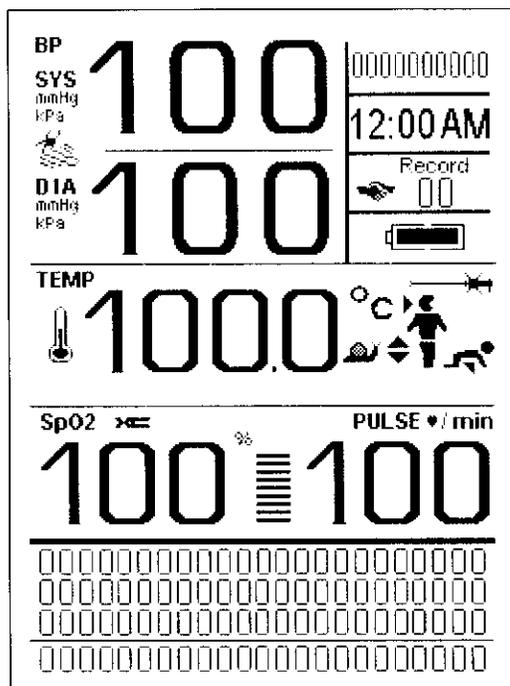


Figure 1 - LCD Display Composite Representation of Normal Mode

Keypad

The keypad will consist of 5 isoelastomer buttons, laid out on the LCD circuit assembly. Figure 2 shows the layout of the keypad. The keypad buttons serve multiple purposes depending of the current mode of operation. Table 1 notes the primary function for each button when the device is operating in Normal Mode.

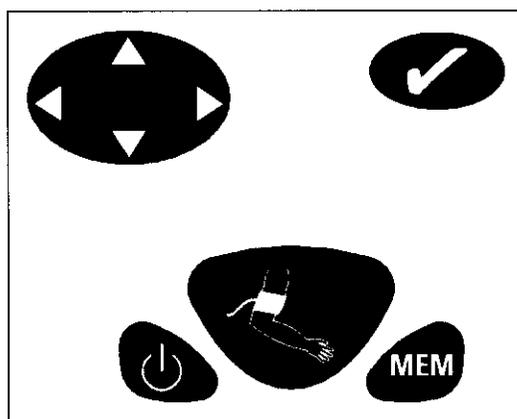


Figure 2 - Keypad

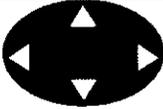
Icon	Button	Function
	Power	Powers the unit on or off.
	BP Start/Stop	Starts/Stops a BP cycle.
	Memory Recall	Displays stored patient data sets.
	Navigation	Allows navigation through LCD displayed options.
	Select	Select responses to Spot Ultra prompts.

Table 1 - Keypad Button Functions - Normal Mode

Audio Annunciator

The audio annunciator will be a simple beeper, located on the Spot Ultra main circuit board.

Power / Charger LEDs

A power LED will provide visual indicating of the On/Off state of Spot Ultra. A charger LED will provide a visual indication of the fact that Spot Ultra is plugged into a charger and is in the act of charging or is fully charged.

Printer

Spot Ultra will use an external printer.

Communications with the printer may be bi-directional.

Communications will be implemented using a H/W UART. The baud rate to be used will be fixed at 9600 bps.

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Bar Code Scanner

Spot Ultra will support use of a pre-configured Hand Held Products' ImageTeam Linear Bar Code Scanner.

Communications between Spot Ultra and the Bar Code Scanner will be uni-directional.

Communications will be implemented using a H/W UART. The baud rate to be used will be fixed at 9600 bps.

Connectivity

1. RS-232 Serial Interface - Host / Barcode

One of the RS-232 serial interfaces is intended to support connection to either a host PC or a barcode scanner. The interface consists of a DB-9F connector using pin assignments compatible with PC and barcode scanner use. Communications will be implemented using a H/W UART.

1.1. Host

Communications between Spot Ultra and a PC host will be bi-directional.

Spot Ultra will also be responsible for handling the communications between a PC host and the NIBP Module F in a seamless manner for purposes for factory test and module programming.

The default baud rate will be 9600 bps, but shall be capable of running at baud rates up to 38400 bps.

1.2 Barcode

Communications between Spot Ultra and a pre-configured Hand Held Products ImageTeam 1-D Linear Barcode Scanner will be supported through this interface as noted in the Bar Code Scanner Section.

2. USB 1.1 Device Interface

Spot Ultra will support a USB 2.0, 1.1 subset certified device interface intended to support connection to a host PC. The interface consists of a standard USB mini-B connector. Communications will be implemented using the MXL's internal USB device controller.

Communications between Spot Ultra and a PC host will be bi-directional.

3. RS-232 Serial Interface – Printer

A second RS-232 serial interface is intended to support connection to an external printer. The interface consists of a RJ-45 6-pin connector. Communications will be implemented using a H/W UART.

4. Wireless

Spot Ultra will support an 802.11b wireless interface using a VyTek 802.11 OEM Module.

4.1 VyTek 802.11 OEM Module

Power to the VyTek 802.11 OEM Module will be controllable by Spot Ultra.

Communications between Spot Ultra and VyTek 802.11 OEM Module will be bi-directional, serial (VyTek 802.11 OEM Module to/from Spot Ultra) and will comply with the software interface of the VyTek 802.11 OEM Module.

Communications will be implemented using a H/W UART. The default baud rate will be 9600 bps, but shall be capable of running at baud rates up to at least 38400 bps.

Note: Spot Ultra will not be capable of supporting the maximum 802.11b data rates due to the fact that the interface between Spot Ultra and the VyTek 802.11 OEM Module is serial.

The 802.11 b wireless interface is intended to support connection to a host PC. Communications between Spot Ultra and a PC host will be bi-directional.

External Charger

The internal battery will be charged via an external medical grade charger. The Spot Ultra hardware / software will control the rate and degree of charging allowed and will provide visual cues as to the state of battery charge and the connected state to an external charger.

MMC/SD

Spot Ultra will support use of a Secure Digital (SD) Memory Card for the purpose of collecting data for use in NIBP Mod F algorithm development, compliance testing and validation.

Software Description

General.

The Spot Ultra software architecture is based on a pseudo object oriented design model. Each software module or “object” consists of encapsulated data and function objects and helper functions, “methods”, which access the data or manipulates functionality in a controlled manner. Most modules contain one or more RTOS threads which implements the main functionality of the module. Communications between threads usually performed with messages or semaphores. Message passing and event signaling (semaphores) is generally encapsulated within each module; outside access is done with helper functions. Figure 3 presents the design for a generic system module as used in Spot Ultra.

Most of the goals of object oriented design can be achieved following these guidelines, using only a regular C-compiler.

(b) (4)

Implementation of the ThreadX real-time kernel

To ease portability, a relatively small subset of available ThreadX services will be utilized. Only preemptive thread scheduling will be used. This means that no two threads have the same priority. Only static threads are employed. Kernel objects that are used to their full potential are threads, semaphores, message queues, memory partitions, mutexes and timers. No threads are ever terminated.

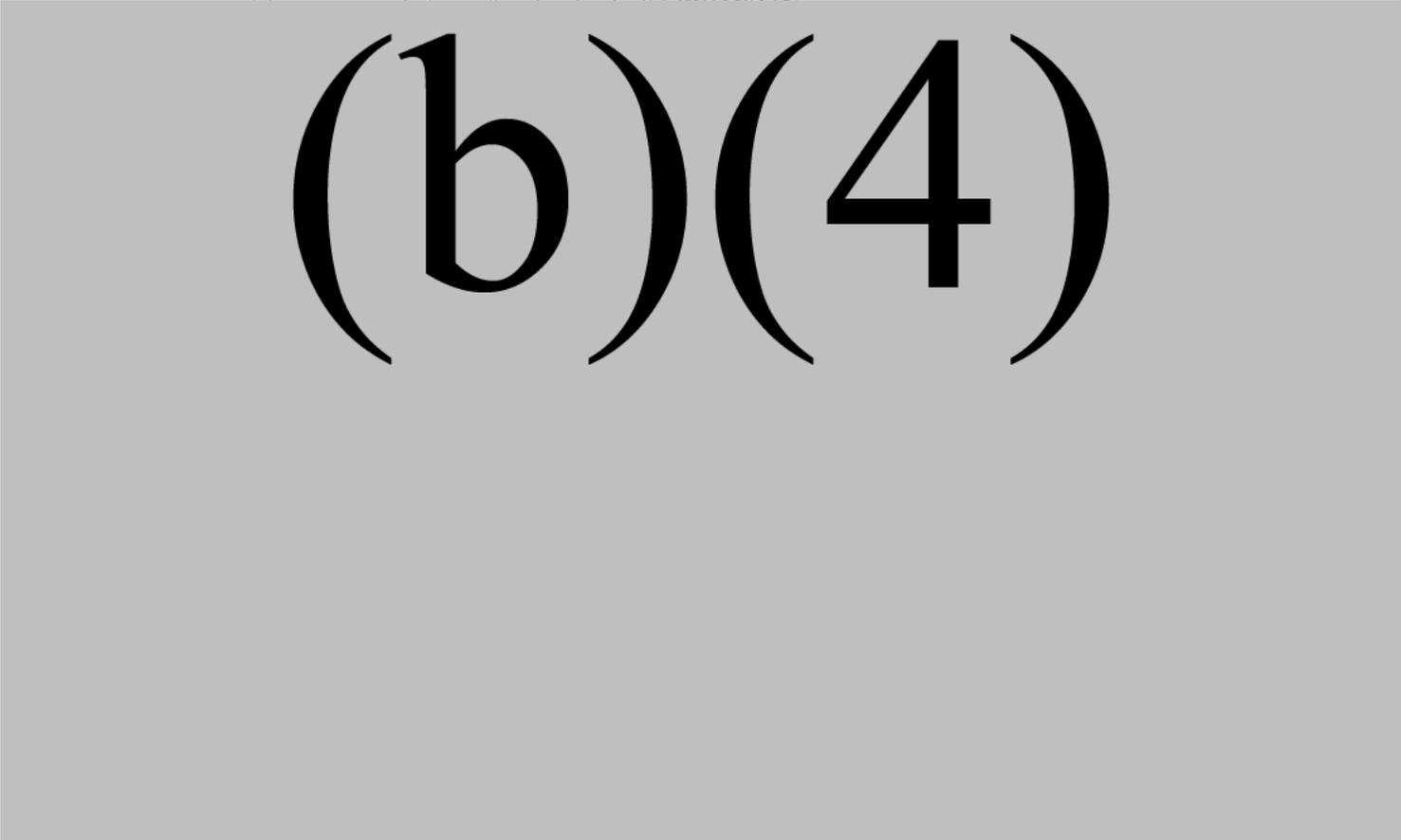
Overview

The device will operate in a multi-threading fashion. It will allow for the execution of a blood pressure cycle, temperature measurement and SpO2 monitoring concurrently. It will be capable of communicating to an external host PC either via the RS-232 serial, USB and/or optional 802.11 b wireless interfaces concurrently with any ongoing vital signs measurement(s). It must also be responsive to user interaction via the user interface, as well as monitoring operational parameters to insure that its environment is able to support both accurate measure and patient safety.

Central within the Spot Ultra software is the passing of events from one subsystem to one or more receiving subsystems. Events are sent to the receiving subsystem(s) using one message queue for each receiving subsystem.

System Modules

The following figure represents the software architecture for the Spot Ultra device. It shows all System Modules and their external interfaces.



(b)(4)

User Interface Module

The User Interface (UI) module is responsible for handling button presses from the keypad and processing requests from other software modules for changes in the operation of the device. The UI is the primary control module for the device; providing an extensive set of public functions for use by the other software modules. It operates as a state machine, keeping track of and changing the system state, based on the current system state and events which may cause a change of state.

Communications Modules

- RS232 Comm
- USB Comm
- Wireless Comm

These Communications modules handle all communications between the device and an external device, such as a PC, in a concurrent manner. The modules process commands received and, if it is a support command, responds accordingly. If the command is not supported by the device or the command pass through flag is set, the command is re-directed to the NIBP Module F sub-system for processing; the device then returns the NIBP Module's response to the command to the external device.

TheRS232 Comm Communications module will also handle all communications from a suitably pre-configured barcode scanner

Time Module

The Time module maintains various device timers; these include the 10ms. tick timer, the one and two second flash timers and the system time. It runs off a hardware timer with a 10 ms. interval.

Display Module

The Display module provides the ability to update the display of any of the major fields on the LCD: systolic, diastolic, heart rate, SpO2 % and pleth, temperature, as well as individual symbols (heart, thermometer probe, etc.). It also provides the means to turn on or off all LCD pixels via a single message.

Beeper Module

The Beeper module handles controlled access to the audio annunciator. It provides for several different types of annunciator outputs.

Therm Modules

- LaJolla
- Braun

These Thermometer modules communicate with either the SureTemp[®] Plus OEM hardware sub-system or the Braun Pro4000 docking cradle (depending on which option is installed) and are responsible for monitoring and controlling the thermometer modality.

Printer Module

The Printer module is responsible for handling requests to print to the external thermal printer. The module handles the various printout selections and the necessary formatting of the output.

NIBP Module

The NIBP module communicates with the Mod F NIBP module sub-system and is responsible for monitoring and controlling the NIBP modality.

SpO2 Modules

- Nellcor SpO2
- Masimo SpO2

These Spo2 modules handle communications with either the Nellcor OEM or Masimo OEM SpO2 hardware module (depending on which option is installed). They capture the data stream from the hardware module, parse it and format the resulting data into a SpO2 data record. they also issue display update requests for the SpO2 % and pleth to the Display module. They also handle SpO2 sensor error detection and notification.

Battery/Charge Monitor Module

The Battery/Charge Monitor module is responsible for determining if a charger is plugged in; determining if the battery should be charged fast or slow; determining if the battery voltage level is low; and handling the battery/charging LCD icon and LED displays.

Service Modules

Service Modules are similar to System Modules except that they do not contain RTOS threads and may in fact contain only a set of public helper functions. The service modules provide what the name implies, a set of services for use by other service modules or system modules.

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POST Module

The POST (Power On Self-Test) module provides service to log a POST error, read POST errors and clear the error log.

Event Logger Module

The Event Logger module provides services to log an event; read the event log; erase the event log; lock and unlock the event log; and write the event log to FLASH.

Non-volatile Storage Module

The Non-volatile Storage module provides services to read and write to non-volatile storage, as well as restore factory defaults in the event of a read error. These services are performed on the FLASH and are used in configuration of the Spot Ultra device.

Utilities Module

The Utilities module provides a basic set of utility services such as byte swapping of 16-bit and 32-bit variables (the H8 processor is a big endian machine, while most PC hosts are little endian).

Flash Module

The Flash module provides a basic set of services for programming the FLASH memory device.

Version Info Module

The Version Info module provides a set of functions used to access device specific information, including the device software version and signature.

FPRM Module

The FPRM module is responsible for reprogramming the FLASH memory. It provides an alternate method of programming a FLASH memory which has already been programmed via the normal masked ROM bootloader.

Software Level of Concern

Determination of the Level of Concern for the software components and therefore the Welch Allyn Spot Ultra Vital Signs Device was performed following the May, 1998, *Office of Device Evaluation document, Guidance for FDA Reviewers and Industry - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. Considering the nature of the device, its indications for use, and the severity of harm the device could inflict or permit as a result of device failure, Welch Allyn, Inc. has concluded that latent design flaws would not be expected to result in death or injury to the user. Therefore, using the rationale discussed in the above guidance, The Welch Allyn Spot Ultra Vital Signs Device and software have been determined to convey a Low Level of Concern. A review of the rationale for this determination and salient points are provided below.

Safety Concern

The Welch Allyn Spot Ultra Vital Signs Device supports the taking and display of blood pressure, temperature measurement and SpO2 measurements. It has the capability of printing these measurements with a date and time stamp via the external printer. Data is displayed on the LCD until the next patient vitals are taken, the unit is powered down or the display is automatically blanked.

The device will operate in a multi-tasking fashion. It will allow for the execution of a blood pressure cycle, temperature measurement and SpO2 measurement concurrently. It must also be responsive to user interaction via the user interface, as well as monitoring operational parameters to insure that its environment is able to support both accurate measure and patient safety.

A software risk analysis has resulted in certain software modules contributing directly to the level of concern, others contributing indirectly and others to be of no concern regarding safety. The following table (Table 2) identifies and describes each software module and ranks them as to level of concern.

Table 2

MODULE NAME/ DESCRIPTION	LEVEL OF CONCERN	DESCRIPTION OF THE MODULE AND AREA OF CONCERN
User Interface Module	Minor	The User Interface module is responsible for handling button presses from the keypad and issuing required messages to control revised operation of the device. No Concern regarding safety
Communications Module	Minor	The Communications module handles all communications between the device and an external device. The module processes each command received and if it is a support command, responds accordingly. If the command is not supported by the device or the command pass through flag is set, the command is re-directed to the Module for processing; the Welch Allyn Spot Ultra device then returns the Module's response to the command to the external device. No Concern regarding safety
Time Module	Minor	The Time module maintains various device timers; these include the 20ms. tick timer, the one and two second flash timers and the system time. It runs off a hardware timer with a 20 ms. Interval No Concern regarding safety
Display Module	Minor	The Display module provides the ability to update the display of any of the major fields on the LCD: systolic, diastolic, heart rate, MAP, SpO2 % and Plethismograph, temperature, as well as individual symbols (heart, thermometer probe, etc.). It also provides the means to turn on or off all LCD segments via a single message. No Concern regarding safety
Beeper Module	Minor	The Beeper module handles controlled access to the audio annunciator. It provides for several different types of annunciator outputs. No Concern regarding safety
Therm Modules	Minor	The Therm(ometer) modules is responsible for monitoring and controlling the temperature modality. Minor Concern regarding safety
Printer Module	Minor	The Printer module is responsible for handling requests to print to the external thermal printer. The module handles the various printout selections and the necessary formatting of the output. No Concern regarding safety

MODULE NAME/ DESCRIPTION	LEVEL OF CONCERN	DESCRIPTION OF THE MODULE AND AREA OF CONCERN
NIBP Module	Minor	The NIBP module communicates with the Spot Ultra Host sub-system and is responsible for monitoring and controlling the BP modality. Minor Concern regarding safety
SpO2 Modules	Minor	The SpO2 module handles communications with the SpO2 hardware module. It captures the data stream from the hardware module, parses it and formats the resulting data into a SpO2 data record. It also issues display update requests for the SpO2 % and plethismograph to the Display module. Also handles SpO2 sensor error detection and notification. The SpO2 system module contains two tasks: the SpO2 task handles the operations described above; The SpO2 Watch task monitors for a continuous data stream from the SpO2 hardware module and handles communication failures if they occur. Minor Concern regarding safety
Battery/Charge Monitor Module	Minor	The Battery/Charge Monitor module is responsible for determining if a charger is plugged in; determining if the battery should be charged fast or slow; determining if the battery voltage level is low; and handling the battery/charging LCD segment displays. No Concern regarding safety
POST Module	Minor	The POST (Power On Self-Test) module provides service to log a POST error, read POST errors and clear the error log. No Concern regarding safety
Event Logger Module	Minor	The Event Logger module provides services to log an event; read the event log; erase the event log; lock and unlock the event log; and write the event log to FLASH. No Concern regarding safety
Non-volatile Storage Module	Minor	The Non-volatile Storage module provides services to read and write to non-volatile storage, as well as restore factory defaults in the event of a read error. These services are performed on the EEPROM and are used in configuration of the Welch Allyn Spot Ultra Device. No Concern regarding safety
Utilities Module	Minor	The Utilities module provides a basic set of utility services such as byte swapping of 16-bit and 32-bit variables. No Concern regarding safety

MODULE NAME/ DESCRIPTION	LEVEL OF CONCERN	DESCRIPTION OF THE MODULE AND AREA OF CONCERN
Flash Module	Minor	The Flash module provides a basic set of services for programming the FLASH memory device. No Concern regarding safety
Version Info Module	Minor	The Version Info module provides a set of functions used to access device specific information, including the device software version and signature. No Concern regarding safety
FPROM Module	Minor	The FPROM module is responsible for reprogramming the FLASH memory. It provides an alternate method of programming a FLASH memory which has already been programmed via the normal masked ROM bootloader No Concern regarding safety

The evaluation of each software module has resulted in Minor Level of Concern being the highest level of concern determined.

Conclusion

Thus, based on the nature of the Welch Allyn Spot Ultra Vital Signs Device, its indications for use, and the severity of harm the device could inflict or permit as a result of failure, latent design flaws would not be expected to result in death or injury to the patient. Therefore, using the rationale discussed in the above guidance, and supported by the analyses and information presented in the above section, the Welch Allyn Spot Ultra Vital Signs Device and the embedded software have been determined to convey a Minor Level of Concern.

Unit Performance Specifications

Patient Population

Spot Vital Signs Ultra is designed for use with adult and pediatric patients. Welch Allyn defines a pediatric patient as 29 days old or older.

THE SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATES.

Welch Allyn defines neonates as children 28 days or less of age, born at term (37 weeks of gestation or more), otherwise up to 44 gestational weeks. This is the definition from the AAMI SP10:2002 Standard.

CUFF PRESSURE RANGE

0 mmHg to 300 mmHg

SYSTOLIC RANGE

60 to 250 mmHg

DIASTOLIC RANGE

30 to 160 mmHg

BLOOD PRESSURE ACCURACY

Blood pressure accuracy meets or exceeds SP10:2002 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: ± 5 mmHg mean error, 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.

BLOOD PRESSURE DETERMINATION TIME

Typical: 15 seconds Maximum: 150 seconds

MEAN ARTERIAL PREASURE RANGE

40 to 190 mmHg

PULSE RATE RANGE (USING SPO2 DETERMINATION)

25 to 245 bpm

PULSE RATE RANGE (USING BLOOD PRESSURE DETERMINATION)

35 to 199 bpm

PULSE RATE ACCURACY (USING SPO2 DETERMINATION)

Without Motion: 25 to 245 bpm ± 3 digits***

With Motion: normal physiologic range (55 to 125 bpm) ± 5 digits

Low Perfusion: 25 to 245 bpm ± 3 digits***

*** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

PULSE RATE ACCURACY (USING BLOOD PRESSURE DETERMINATION

±5.0%

OVERPRESSURE CUTOFF

315 mmHg ±15 mmHg

TEMPERATURE RANGES

SureTemp Plus

Normal Mode: 94.0° to 109.4° F (34.5° to 43.0° C)

Monitor Mode: 80.0° to 110° F (26.7° to 43.0° C)

Braun PRO 4000

68° to 108° F / 20° to 42.2° C

TEMPERATURE CALIBRATION ACCURACY

+ 0.2°F (+ 0.1°C)

TEMPERATURE DETERMINATION TIME

Oral: 4 to 6 seconds

Adult Axillary: 12 to 15 seconds (age 18 years and older)

Pediatric Axillary: 10 to 13 seconds (age 17 years and younger)

Rectal: 10 to 13 seconds

OXYGEN SATURATION RANGE (SpO₂%)

40 to 100% oxygen saturation

SpO₂ ACCURACY

Without Motion: Adults: 70 to 100% ± 2 digits*

With Motion: Adults: 70 to 100% ± 3 digits**

Low Perfusion: 70 to 100% ± 2 digits***

<70% unspecified by the OEM

Biocompatibility testing has been conducted on Nellcor sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

* Adult specifications are shown for OxiMax MAX-A sensors. Sensor type will vary the saturation accuracy. Refer to the following Sensor Accuracy Guide.

**Applicability: OxiMax MAX-A, MAX-AL, MAX-P, and MAX-I sensors.

*** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO₂ range. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as + "X" digits. This variation equals + one standard deviation (+ 1 SD), which encompasses 68% of the population.

V. Statement of Substantial Equivalence

Indications For Use of the Device:

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO₂) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Contraindications For Use of the Device:

SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATAL PATIENTS. Welch Allyn defines neonates as children 28 days or less of age if born at term (37 weeks gestation or more); otherwise up to 44 gestational weeks. This definition comes from the AAMI SP10:2002 standard.

Spot Vital Signs Ultra is designed for medical clinician use. Although this manual may illustrate medical spot check techniques, only a trained clinician who knows how to take and interpret a patient's vital signs should use this system. Spot Vital Signs Ultra is not intended for use in environments that are without health care practitioner supervision.

Spot Vital Signs Ultra is not intended for continuous monitoring and is therefore not defibrillator proof. **Do not leave the device unattended while taking measurements on a patient.**

Spot Ultra is not intended for use during the transport of a patient.

WARNING: This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.

Blood Pressure Warnings

To ensure pediatric blood pressure accuracy and safety, the Small Child Durable One-Piece Cuff (5082-203-4) and the Small Child Disposable One-Piece Cuff (5083-93-4) are the smallest cuffs approved for use with young children and infants. The child's arm must fit within the range markings on the cuff.

You may experience inaccurate blood pressure measurements if cuffs and/or hoses other than those provided for Spot Vital Signs Ultra by Welch Allyn are used. To ensure patient safety, use only accessories and supplies (i.e., cuffs, hoses, temperature probes, SpO2 sensors, etc.) recommended for or supplied with Spot Vital Signs Ultra.

Avoid compression of the cuff tubing or pressure hose of Spot Vital Signs Ultra. Compression of the cuff tubing or pressure hose may cause system errors to occur in the device.

Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air. Check all operating functions.

A qualified service person should check any Spot Vital Signs Ultra that has been dropped or damaged to ensure proper operation prior to use.

Every three months, inspect the temperature probe, SpO2 cord, and accessories for fraying or other damage. Replace as necessary.

Do not use Spot Vital Signs Ultra on patients who are linked to heart/lung machines.

There are no user-serviceable parts inside the device other than battery replacement.

Spot Vital Signs Ultra does not operate effectively on patients who are experiencing convulsions or tremors.

This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices.

As a precaution, avoid using this device in close proximity to other equipment.

This device is not intended for hand-held use during operation.

Welch Allyn recommends that the battery is left in the device, regardless if the device is not used for long periods of time. There is no hazard of leaving the battery in the device.

Using unapproved Welch Allyn accessories with Spot Vital Signs Ultra can affect patient and/or operator safety.

Do not autoclave.

Welch Allyn is NOT responsible for the integrity of any wall-mounting interface. Welch Allyn recommends that the customer contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory

Patients that are experiencing moderate to severe arrhythmias may give inaccurate blood pressure measurements.

When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.

SpO2 Warnings

The operation of the SpO2 sensor in MRI environments is specifically not recommended.

Only use Spot Vital Signs Ultra with Nellcor or Masimo pulse oximetry option with Nellcor or Masimo brand sensors and accessories, respectively. Using the wrong or unapproved sensors or cables may cause improper performance.

The SpO2 sensor and extension cables are intended for use only for pulse oximetry measurements. Do not attempt to connect these cables to a PC or any similar device.

Before using, carefully read the sensor Operator's Manual, including all warnings, cautions, and instructions.

Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed optical components.

Incorrect application or a long duration of use of an SpO2 sensor may cause tissue damage. Inspect the sensor site periodically as directed in the sensors' direction for use.

SpO2 readings and pulse signal is affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Do not immerse or wet the sensor.

Do not use the pulse oximetry cable or power cord to lift the pulse oximeter because the cable or cord may disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

The SpO2 is NOT intended for use as an apnea monitor.

Consider the pulse oximeter an early warning device. As a trend toward patient hypoxemia is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.

Carefully route patient cabling to reduce the possibility of patient enlargement or strangulation.

Severe anemia may cause erroneous SpO2 readings.

Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.

Temperature Warnings

SureTemp Plus™

Use single-use, disposable probe covers to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

Do not take a patient's temperature without using a disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, or erroneous temperature readings.

Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Biting the probe tip while taking a temperature may result in damage to the probe.

Oral/axillary probes (blue ejection button at top of probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the probe at the wrong site will result in temperature errors. Use of the incorrect removable probe well could result in patient cross-contamination.

The thermometer connectors and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all functions for proper operation.

Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

The SureTemp Plus thermometer consists of high-quality precision parts. Protect it from severe impact and shock. A qualified service technician must check any SureTemp Plus thermometer that is dropped or damaged to ensure proper operation prior to further use. Do not use the thermometer if you notice any signs of damage to the probe. Contact the Welch Allyn Customer Service Department for assistance.

Do not autoclave.

General Cautions

If the accuracy of any measurement is in question, check the patient's vital sign(s) with an alternate method, then check to make sure the device is functioning properly.

Place the device on a secure surface or use one of the optional mounting accessories.

Do not place fluids on or near the device.

Blood Pressure Cautions

Minimize extremity and cuff motion during blood pressure determinations.

If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect. Add the value of 1.80 mmHg (.2 kPa) to the displayed reading for every inch (2.5 cm) above heart level. Subtract the value of 1.80 mmHg (.2 kPa) from the displayed reading for every inch (2.5 cm) below heart level.

Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See "Chart for Determining Cuff Size" on page 23 for cuff sizing information.

Pulse Oximetry Cautions

The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxy hemoglobin or methemoglobin may affect the accuracy of the measurement.

Some intravascular dyes, depending on the concentration, may affect the accuracy of the SpO₂ measurement. Some sensors may not be appropriate for a particular patient. If at least 10 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type for perfusion to resume.

The sensor disconnect message indicates that the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, pulse oximetry cable, or both.

NOTE: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring.

Technological Characteristics:

The Welch Allyn Spot Ultra Vital Signs Device utilizes an Oscillometric BP Algorithm and temperature technology, similar to Spot Vital Signs and utilizes the same SpO2 OEM as the Welch Allyn Spot Vital Signs. The new Spot Ultra Vital Signs will incorporate a new temperature module (Braun 4000) and a new SpO2 OEM module the Masimo SET as options. The FDA, under 510(k) numbers K002530 and K024005, approved Spot Vital Signs. The following table summarizes the similarities between the Welch Allyn Spot Vital Signs Device and the new Welch Allyn Spot Ultra Vital Signs Device.

Table 3

Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-2002
Heart Rate	+/- 5% (BP Determination) +/- 3 bpm (SpO2 Determination)	+/- 5% (BP Determination) +/- 3 bpm (SpO2 Determination)
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 sec. typical, 165 sec. max.	15 typical, 150 sec. max.
Mean Arterial Pressure	Calculated	Calculated
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model Used	MP506	MP506

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	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 3% <70% unspecified	70-100% +/- 3% <70% unspecified
Heart Rate	+/- 3 bpm	+/- 3 bpm
Massimo OEM SpO2		
Spo2 Measurement	No	Yes
OEM Model Used	NA	NCT-11
Measurement Range		
SpO2	NA	40-100%
Heart Rate	NA	25-245 bpm
Measurement Accuracy		
SpO2	NA	70-100% +/- 3% <70% unspecified
Heart Rate	NA	+/- 3 bpm
SureTemp® OEM Temperature		
Temperature	Yes	Yes
Measurement Range	84°F (30°C) to 109.4°F (43.0°C)	80.0° to 109.4° F (34.5°-43.0°C)
Measurement Accuracy	per ASTM E1112-86 (1991)	per ASTM E1112-00 (2000)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
Braun 4000 IR Thermometer		
Temperature	No	Yes
Measurement Range	NA	68° to 108° F / 20° to 42.2° C
Measurement Accuracy	NA	Per EN12470
Temperature Determination	NA	Ear IR
HHP 3800PDF Bar Code Scanner		
	No	Yes

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	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Overall System		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR Capable Communication	802.11b Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C (except temperature which is 16 to 40 °C)
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-20 to 50 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

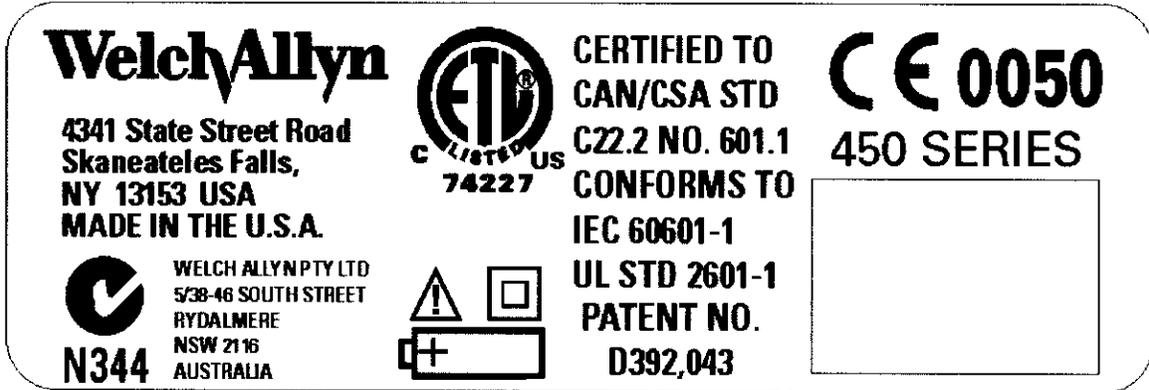
VI. Labels, Labeling and Advertisements

Labeling

Draft labels, draft sales literature, and a draft User's Manual for the Model 45XXX Welch Allyn Spot Ultra Vital Signs Device follows this page.

***Example of the Labels that will appear on the Welch Allyn Spot Ultra
Vital Signs Device***

1) Unit Identification Label



2) Nellcor® works here label for Units with Nellcor SpO2



3) Caution Label



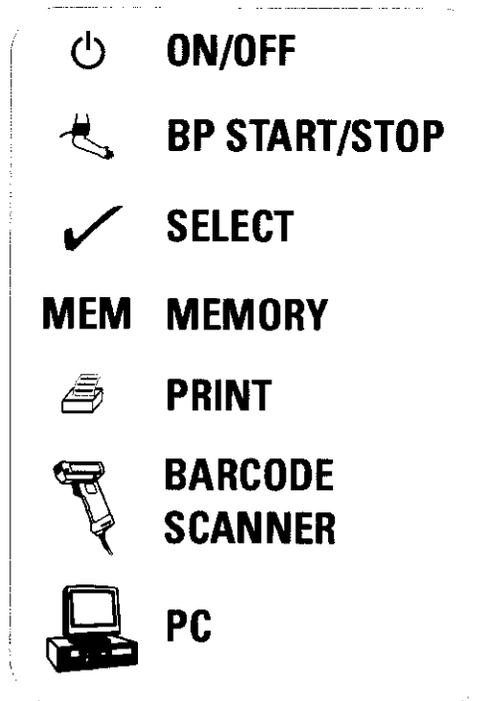
4) Label, Masimo for Units with Masimo SpO2



5) Label, SureTemp
(Will be updated when SureTemp Plus label available)



6) Label, Icon ID



Example of Quick Reference Guide For Welch Allyn Spot Ultra Device

Front Of Card

For detailed operating instructions, refer to the Directions for Use manual.

Blood Pressure Operation

To begin a blood pressure measurement, press the BP Start/Stop button.

To stop the current blood pressure measurement, press the BP Start/Stop button again.

SureTemp Ultra Temperature Operation

1. Remove the probe from the holder and apply a new probe cover.
2. Place the probe in contact with patient tissue as directed in the Directions for Use manual.
3. When done, you will hear a single beep and the unit will display the temperature.

Braun Temperature Operation

1. Remove the probe from the holder and apply a new probe cover; the device will beep when it's ready.
2. Fit the probe snugly in the ear canal as directed in the Directions for Use manual.
3. Press the activation button. A long beep will signal the end of the measurement process. The probe will display the temperature.
4. Eject the probe cover and return the probe to the holder. The Spot Vital Signs Ultra display will show the temperature.

SpO2 Operation

1. Apply the sensor to the patient and ensure an adequate signal from pulse signal bar graph.
2. SpO2 measurement and pulse rate will update continuously for 10 minutes.

Memory Recall Operation

1. With the unit powered on, press the Memory button once to review the last saved record.
2. Press the Memory button again to review the last four records saved. From this screen, you can use the Navigation button to sort the records by patient.
3. Press the Memory button again to return to a blank Status window.

Weight Entry

You may only enter Weight values if this option is enabled in the Internal Configuration Mode; see Directions for Use manual for details.

1. With the arrow in front of the Weight option in the Navigation window, press the Select button.
2. Press the Navigation button up or right to increase values and down or left to decrease values. Press the Select button to accept the entry.

Back Of Card:

Height Entry

You may only enter Height values if this option is enabled in the Internal Configuration Mode; see Directions for Use manual for details.

1. Use the Navigation button to move the arrow to the front of the Height option in the Navigation window.
2. Press the Select button.
3. Press the Navigation button up or right to increase values and down or left to decrease values.
4. Press the Select button to accept the entry.

BMI Calculation Operation

You may only calculate BMI if this option is enabled in the Internal Configuration Mode; see Directions for Use manual for details.

1. Use the Navigation button to move the arrow to the front of the BMI option in the Navigation window.
2. Press the Select button.
3. Weight and Height entries must already be entered for BMI to be calculated.
4. A BMI value will appear above the Navigation button. Press the Select button to accept the value.

Respiration Rate Entry

You may only enter Respiration Rates if this option is enabled in the Internal Configuration Mode; see Directions for Use manual for details.

1. Use the Navigation button to move the arrow to the front of the Respiration option in the Navigation window.
2. Press the Select button.
3. Press the Navigation button up or right to increase values or down or left to decrease values.
4. Press the Select button to accept the entry.

Pain Level Entry

You may only enter Pain Level if this option is enabled in the Internal Configuration Mode; see Directions for Use manual for details.

1. Use the Navigation button to move the arrow to the front of the Pain Level option in the Navigation window.
2. Press the Select button.
3. Press the Navigation button up or right to increase values and down or left to decrease values.
4. Press the Select button to accept the entry.

Save Operation

You may program Spot Vital Signs Ultra to Save Automatically or Manually in the Internal Configuration Mode; see Directions for Use manual for details.

If the Manual Save Mode is enabled in the Internal Configuration Mode:

1. Use the Navigation button to move the arrow to the front of the Save option in the Navigation window.
2. Press the Select button. The device will save the data in Memory. A blank status window will appear.
3. If, however, the amount of time pre-configured in the Internal Configuration Mode expires before the Save button is pressed (0 to 30 minutes), the device will save the entered data automatically and a blank Status window will appear.

422206 Rev. A

- ***Example of the Draft Sells Literature for the Welch Allyn Spot Ultra Vital Signs Device can be found in Attachment 3***

- ***Example of the Draft Operator's Manual for the Welch Allyn Spot Ultra Vital Signs Device can be found in Attachment 4***

VII. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn Spot Ultra Vital Signs Device

Indications for use: The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO2) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-The-Counter Use

(Per 21 CFR 801.109)

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Attachment 1 - Device Description - Pictures



Front View of Spot Ultra



Back View of Spot Ultra

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Attachment 2 - Typical (Average) Product Specifications

Performance Specifications

Patient Population

Spot Vital Signs Ultra is designed for use with adult and pediatric patients. Welch Allyn defines a pediatric patient as 29 days old or older.

THE SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATES.

Welch Allyn defines neonates as children 28 days or less of age, born at term (37 weeks of gestation or more), otherwise up to 44 gestational weeks. This is the definition from the AAMI SP10:2002 Standard.

CUFF PRESSURE RANGE

0 mmHg to 300 mmHg

SYSTOLIC RANGE

60 to 250 mmHg

DIASTOLIC RANGE

30 to 160 mmHg

BLOOD PRESSURE ACCURACY

Blood pressure accuracy meets or exceeds SP10:2002 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: ± 5 mmHg mean error, 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.

BLOOD PRESSURE DETERMINATION TIME

Typical: 15 seconds Maximum: 150 seconds

MEAN ARTERIAL PREASURE RANGE

40 to 190 mmHg

PULSE RATE RANGE (USING SPO2 DETERMINATION)

25 to 245 bpm

PULSE RATE RANGE (USING BLOOD PRESSURE DETERMINATION)

35 to 199 bpm

PULSE RATE ACCURACY (USING SPO2 DETERMINATION)

Without Motion: 25 to 245 bpm ± 3 digits***

With Motion: normal physiologic range (55 to 125 bpm) ± 5 digits

Low Perfusion: 25 to 245 bpm ± 3 digits***

*** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

PULSE RATE ACCURACY (USING BLOOD PRESSURE DETERMINATION
 $\pm 5.0\%$

OVERPRESSURE CUTOFF

315 mmHg ± 15 mmHg

TEMPERATURE RANGES

SureTemp Plus

Normal Mode: 94.0° to 109.4° F (34.5° to 43.0° C)

Monitor Mode: 80.0° to 110° F (26.7° to 43.0° C)

Braun PRO 4000

68° to 108° F / 20° to 42.2° C

TEMPERATURE CALIBRATION ACCURACY

+ 0.2°F (+ 0.1°C)

TEMPERATURE DETERMINATION TIME

Oral: 4 to 6 seconds

Adult Axillary: 12 to 15 seconds (age 18 years and older)

Pediatric Axillary: 10 to 13 seconds (age 17 years and younger)

Rectal: 10 to 13 seconds

OXYGEN SATURATION RANGE (SpO₂%)

40 to 100% oxygen saturation

SpO₂ ACCURACY

Without Motion: Adults: 70 to 100% ± 2 digits*

With Motion: Adults: 70 to 100% ± 3 digits**

Low Perfusion: 70 to 100% ± 2 digits***

<70% unspecified by the OEM

Biocompatibility testing has been conducted on Nellcor sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

* Adult specifications are shown for OxiMax MAX-A sensors. Sensor type will vary the saturation accuracy. Refer to the following Sensor Accuracy Guide.

**Applicability: OxiMax MAX-A, MAX-AL, MAX-P, and MAX-I sensors.

*** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO₂ range. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as + "X" digits. This variation equals + one standard deviation (+ 1 SD), which encompasses 68% of the population.

Mechanical Specifications

Dimensions

Height 25 cm
Length 15 cm
Depth 10 cm

Weight

6.5 lbs

Portability

May be hand-carried when held by the rear handle.

Mounting

Self-supporting on rubber feet
Custom mobile stand
Custom wall mount

Electrical Specifications

Power Requirements

Patient-Rated isolation transformer is connected to AC mains:
North American Version: 120VAC, 60Hz. 0.20A Input, 8VDC, 0.75A Output
International Version: 240VAC, 50Hz 0.10A Input, 8VDC, 0.75A Output
Australian Version: 240VAC, 50Hz, 13VA Input, 8VDC, 0.75A Output

Battery

Sealed lead acid, with external charger.

A fully charged battery supports 120 typical blood pressure determinations taken at 7-minute intervals. The battery is 90 to 100% charged after 12 hours of charging. The battery automatically charges when Spot Vital Signs Ultra is powered through the AC power transformer. An operator can use the device while the battery is charging; however, the battery charges faster when the instrument is not in operation.

Environmental Specifications

Operating Temperature

50° to 104°F (10° to 40°C)

Storage Temperature

Device with SureTemp Plus

-13° to 131°F (-25° to 55°C)

Device with Braun PRO 4000

50° to 104°F (10° to 40°C)

Relative Humidity

15 to 95% (non-condensing)

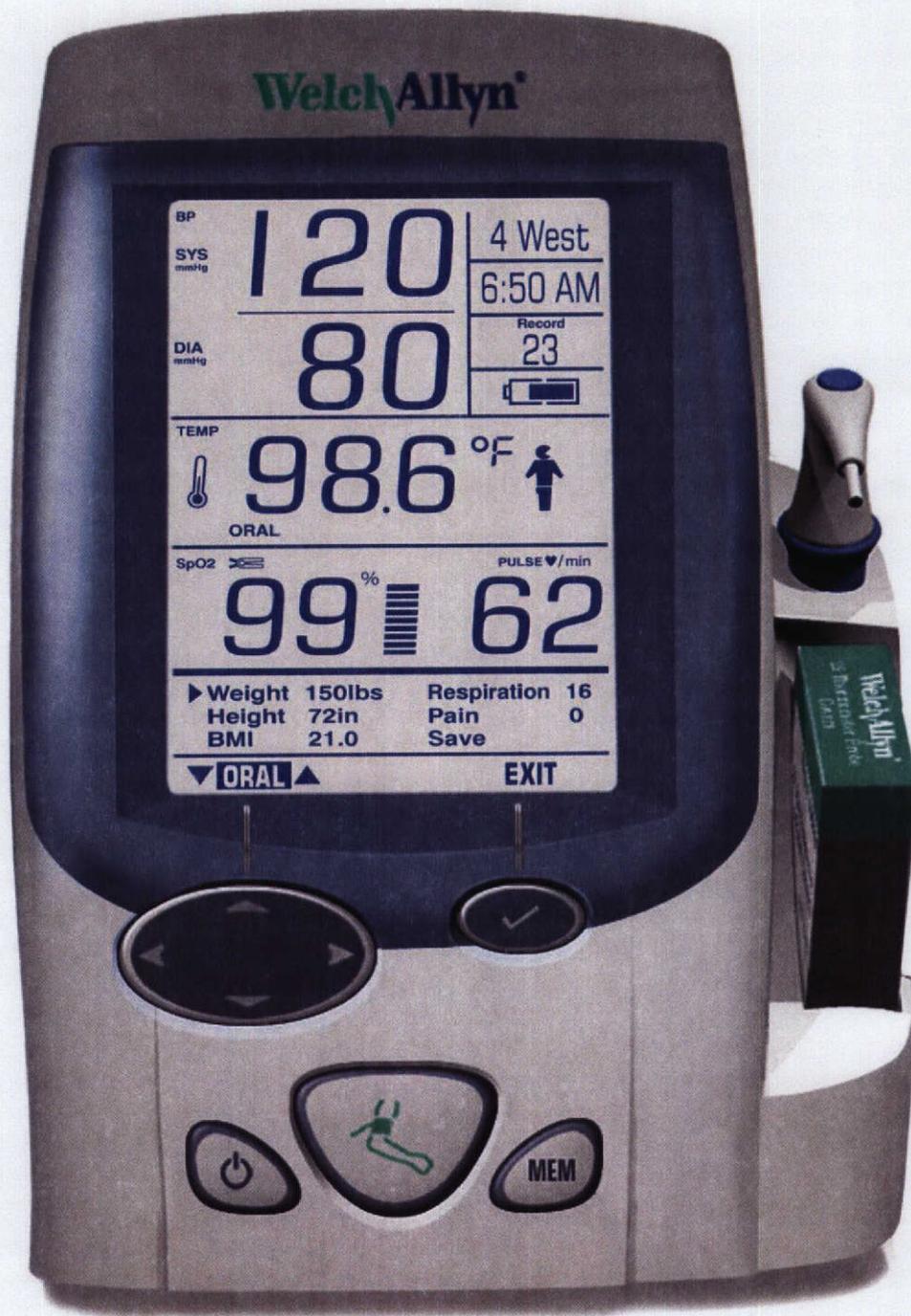
Operating Altitude

-557 to 16,000 ft. (-170 to 4877 m)

Attachment 3 – Welch Allyn Spot Ultra Device Advertisement

The following two sheets are the proposed sells literature sheets for the Spot Ultra Vital Signs Device.

Vital signs in seconds, payback in no time.



WelchAllyn

Spot Vital Signs Ultra

Advanced vital signs made affordable.

Welch Allyn, Inc. Spot Ultra Vital Signs Pre-Market Notification

Welch Allyn's Spot Vital Signs Ultra combines the spot-checking parameters you need into one hospital-grade device at an affordable price. And it offers features not available in any other single device manufactured today.

Choose the parameters you need.

Each Spot Vital Signs Ultra comes with:

- Welch Allyn's Fast NIBP technology that measures blood pressures in approximately 15 seconds, saving you time and providing more comfort to your patients;
- Choice of Welch Allyn SureTemp Plus oral, axillary, and rectal thermometry or Braun PRO 400 ear thermometry;
- Ability to enter weight, height, respiration rate, and pain level;
- Automatic calculation of Body Mass Index (BMI);
- Memory that stores 50 patient records for review; and
- A big, bright LCD that's easy to read.

Spot Ultra options include:

- Nellcor or Masimo pulse oximetry;
- Bar code scanner to enter patient and/or clinician identification;
- Connectivity to send data into Electronic Medical Records;
- External printer with choice of standard or label paper; and
- Mobile stand or wall mount.

The device that does so much yet it's simple to use!

Spot Ultra offers the simplicity you've come to expect from Welch Allyn spot-check devices!

- Intuitive design makes operation virtually self-explanatory.
- Training video provides concise, easy training for your staff.
- Welch Allyn representatives are available to provide complete in-service training.

The support you've come to expect.

The Welch Allyn Spot Vital Signs Ultra device is backed by a two-year warranty on all parts and labor.

- If warranty service is required, a loaner will be provided at no charge.
- A technical service hotline is available.

ORDERING INFORMATION

Model	Description
450T0	NIBP w/ oral temperature
450E0	NIBP w/ ear temperature
45NT0	NIBP, Nellcor SpO2, oral temp
45NE0	NIBP, Nellcor SpO2, ear temp
45MT0	NIBP, Masimo SpO2, oral temp
45ME0	NIBP, Masimo SpO2, ear temp
450TC	NIBP, oral temp, connectivity
450EC	NIBP, ear temp, connectivity
45NTC	NIBP, Nellcor SpO2, oral temp, connectivity
45NEC	NIBP, Nellcor SpO2, ear temp, connectivity
45MTC	NIBP, Masimo SpO2, oral temp, connectivity
45MEC	NIBP, Masimo SpO2, ear temp, connectivity

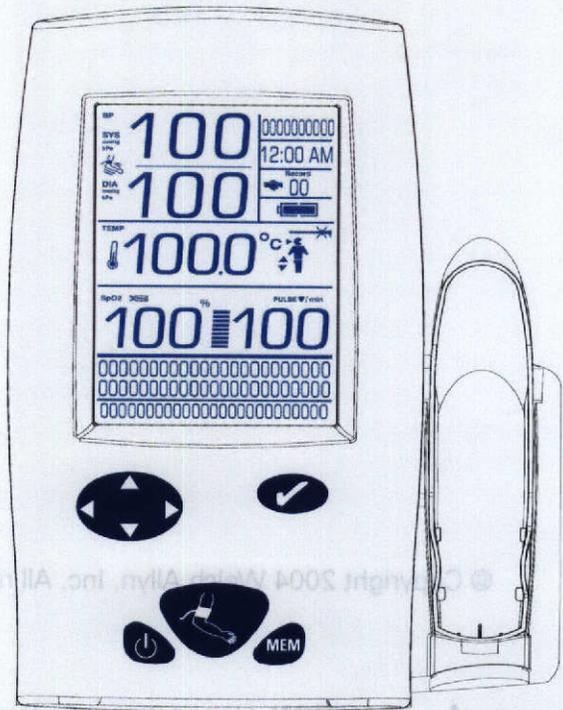
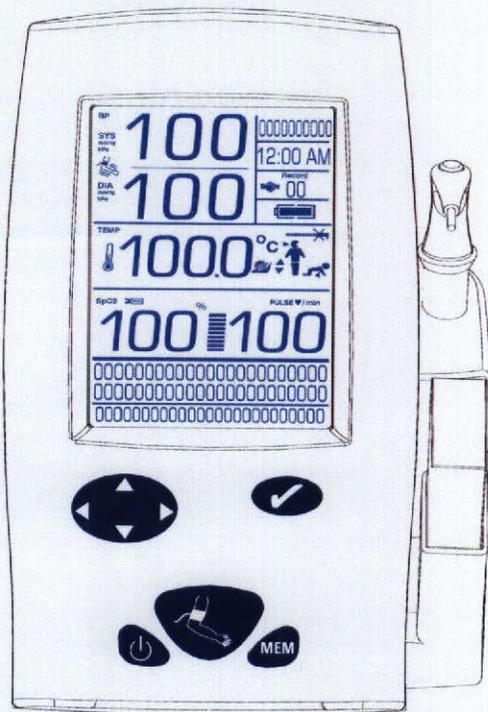
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**Attachment 4 - Welch Allyn Spot Ultra Vital Signs Device User's Manual
(Draft Copy)**



WelchAllyn®

Spot Vital Signs Ultra 450 Series



Directions for Use

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CAUTION: United States Federal law restricts this device to sale by or on the order of a health care practitioner.

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Introduction

The Directions for Use manual is designed to help you understand the capabilities and operation of your Spot Vital Signs Ultra. The information in this manual includes all options available with Spot Vital Signs Ultra (e.g., pulse oximetry, bar code scanner, printer, mobile stand, and wall mount). The applicability of some sections of this manual depends on the configuration of your particular device.

REF	Description
450T0	Blood Pressure with Oral Thermometer
450E0	Blood Pressure with Ear Thermometer
45NT0	Blood Pressure with Nellcor SpO ₂ and Oral Thermometer
45NE0	Blood Pressure with Nellcor SpO ₂ and Ear Thermometer
45MT0	Blood Pressure with Masimo SpO ₂ and Oral Thermometer
45ME0	Blood Pressure with Masimo SpO ₂ and Ear Thermometer
450TC	Blood Pressure with Oral Thermometer and Connectivity
450EC	Blood Pressure with Ear Thermometer and Connectivity
45NTC	Blood Pressure, Nellcor SpO ₂ , Oral Thermometer, and Connectivity
45NEC	Blood Pressure, Nellcor SpO ₂ , Ear Thermometer, and Connectivity
45MTC	Blood Pressure, Masimo SpO ₂ , Oral Thermometer and Connectivity
45MEC	Blood Pressure, Masimo SpO ₂ , Ear Thermometer and Connectivity

This manual is a comprehensive guide to the operation of the Spot Vital Signs Ultra. Read this manual thoroughly before attempting to use the device.

Intended Use

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO₂) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Symbols and Descriptions

Familiarize all operating personnel with the general safety information in this summary. Operators will also find specific warnings and cautions throughout this manual. Such specific warnings and cautions may not appear here in this summary.

	Caution: Consult Directions For Use for additional information		Type BF Equipment
	Handle with Care		Transport Temperature
	Storage Humidity		Internally Powered, Lead Acid Battery
	Class II Equipment	IPX0	Equipment is not protected against the ingress of liquid.
	Mode of Operation: Continuous		On/Off
	Select		Blood Pressure
MEM	Memory		

Connection Symbols

	RS-232 Connection		Serial Port Connection
	USB Connection		

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Agency Symbols

	<p>CERTIFIED TO: CAN/CSA STD C22.2 NO. 601.1 CONFORMS TO: IEC 60601, UL STD 2601-1</p>
	<p>EMC Framework of Australia</p>
	<p>The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive. Authorized European Representative Address: European Regulatory Manager Welch Allyn LTD. Navan Business Park Dublin Road Navan, County Meath, Republic of Ireland Tel.: 353-46-67700 Fax: 353-46-27128</p>

Safety Warnings and Precautions

All operating personnel should be familiarized with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual. Such specific warnings and cautions may not appear here in this summary.

General Warnings



SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATAL PATIENTS. Welch Allyn defines neonates as children 28 days or less of age if born at term (37 weeks gestation or more); otherwise up to 44 gestational weeks. This definition comes from the AAMI SP10:2002 standard.



Spot Vital Signs Ultra is designed for medical clinician use. Although this manual may illustrate medical spot check techniques, only a trained clinician who knows how to take and interpret a patient's vital signs should use this system.



Spot Vital Signs Ultra is not intended for use in environments that are without health care practitioner supervision.



The information in this manual is a comprehensive guide to the operation of Spot Vital Signs Ultra. For best results, read this manual thoroughly before using the device.



Spot Vital Signs Ultra is not intended for continuous monitoring and is therefore not defibrillator proof. **Do not leave the device unattended while taking measurements on a patient.**



Spot Ultra is not intended for use during the transport of a patient.



WARNING: This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.



To ensure patient safety, use only accessories and supplies (i.e., cuffs, hoses, temperature probes, SpO₂ sensors, etc.) recommended for or supplied with Spot Vital Signs Ultra. See "Supplies and Accessories" on page 47.



Avoid compression of the cuff tubing or pressure hose of Spot Vital Signs Ultra. Compression of the cuff tubing or pressure hose may cause system errors to occur in the device.



Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air. Check all operating functions.



A qualified service person should check any Spot Vital Signs Ultra that has been dropped or damaged to ensure proper operation prior to use.



Every three months, inspect the temperature probe, SpO₂ cord, and accessories for fraying or other damage. Replace as necessary.



Do not use Spot Vital Signs Ultra on patients who are linked to heart/lung machines.



There are no user-serviceable parts inside the device other than battery replacement. For service, refer the device to an Authorized Service Center listed on page 52.



Spot Vital Signs Ultra does not operate effectively on patients who are experiencing convulsions or tremors.



This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.



This device is not intended for hand-held use during operation.



Welch Allyn recommends that the battery is left in the device, regardless if the device is not used for long periods of time. There is no hazard of leaving the battery in the device.



Using unapproved Welch Allyn accessories with Spot Vital Signs Ultra can affect patient and/or operator safety.



Do not autoclave.



Welch Allyn is NOT responsible for the integrity of any wall mounting interface. Welch Allyn recommends that the customer contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory.



Blood Pressure Warnings

- To ensure pediatric blood pressure accuracy and safety, the Small Child Durable One-Piece Cuff (5082-203-4) and the Small Child Disposable One-Piece Cuff (5083-93-4) are the smallest cuffs approved for use with young children and infants. The child's arm must fit within the range markings on the cuff.
- You may experience inaccurate blood pressure measurements if cuffs and/or hoses other than those provided for Spot Vital Signs Ultra by Welch Allyn are used.

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- Patients that are experiencing moderate to severe arrhythmias may give inaccurate blood pressure measurements.
- When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.



SpO₂ Warnings

- The operation of the SpO₂ sensor in MRI environments is specifically not recommended.
- Only use Spot Vital Signs Ultra with Nellcor or Masimo pulse oximetry option with Nellcor or Masimo brand sensors and accessories, respectively. Using the wrong or unapproved sensors or cables may cause improper performance.
- The SpO₂ sensor and extension cables are intended for use only for pulse oximetry measurements. Do not attempt to connect these cables to a PC or any similar device.
- Before using, carefully read the sensor Operator's Manual, including all warnings, cautions, and instructions.
- Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed optical components.
- Incorrect application or a long duration of use of an SpO₂ sensor may cause tissue damage. Inspect the sensor site periodically as directed in the sensors' direction for use.
- SpO₂ readings and pulse signal is affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.
- Do not immerse or wet the sensor.
- Do not use the pulse oximetry cable or power cord to lift the pulse oximeter because the cable or cord may disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.
- The SpO₂ is NOT intended for use as an apnea monitor.
- Consider the pulse oximeter an early warning device. As a trend toward patient hypoxemia is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.
- Carefully route patient cabling to reduce the possibility of patient enlargement or strangulation.
- Severe anemia may cause erroneous SpO₂ readings.
- Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.



Temperature Warnings

SureTemp Plus™

- Use single-use, disposable probe covers to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.
- Do not take a patient's temperature without using a disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, or erroneous temperature readings.
- Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.
- Biting the probe tip while taking a temperature may result in damage to the probe.
- Oral/axillary probes (blue ejection button at top of probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the probe at the wrong site will result in temperature errors. Use of the incorrect removable probe well could result in patient cross-contamination.
- The thermometer connectors and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all functions for proper operation.

- Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.
- The SureTemp Plus thermometer consists of high-quality precision parts. Protect it from severe impact and shock. A qualified service technician must check any SureTemp Plus thermometer that is dropped or damaged to ensure proper operation prior to further use. Do not use the thermometer if you notice any signs of damage to the probe. Contact the Welch Allyn Customer Service Department for assistance.
- Do not autoclave.

Braun PRO 4000

- Review the enclosed Braun PRO 4000 Operator's Manual.



General Cautions

- If the accuracy of any measurement is in question, check the patient's vital sign(s) with an alternate method, then check to make sure the device is functioning properly.
- Place the device on a secure surface or use one of the optional mounting accessories.
- Do not place fluids on or near the device.



Blood Pressure Cautions

- Minimize extremity and cuff motion during blood pressure determinations.
- If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect. Add the value of 1.80 mmHg (.2 kPa) to the displayed reading for every inch (2.5 cm) above heart level. Subtract the value of 1.80 mmHg (.2 kPa) from the displayed reading for every inch (2.5 cm) below heart level.
- Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See "Chart for Determining Cuff Size" on page 23 for cuff sizing information.



Pulse Oximetry Cautions

- The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Some intravascular dyes, depending on the concentration, may affect the accuracy of the SpO₂ measurement.
- Some sensors may not be appropriate for a particular patient. If at least 10 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type for perfusion to resume.
- The sensor disconnect message indicates that the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, pulse oximetry cable, or both.

NOTE: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

- When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring.

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Contents Checklist

Unpack Spot Vital Signs Ultra and any applicable accessories then inspect for missing items. Retain the shipping materials in the event of shipping damage or for return, if necessary, to Welch Allyn for repair or warranty service.

All Spot Vital Signs Ultra devices include the following components:

Spot Vital Signs Ultra Device

This device automatically measures and displays blood pressure, pulse rate, and temperature. Options include SpO₂, printer, and bar code reader.

Directions for Use Manual

Read this manual thoroughly before attempting to use the Spot Vital Signs Ultra. Save this manual for reference.

Quick Reference Card

The Quick Reference Card (available with certain models) is a quick operating guide. Attach the card to the device handle, mobile stand, or wall mount.

Instrument Warranty Card

This card validates the Spot Ultra warranty. Fill out the warranty card and mail it today.

Durable Blood Pressure Cuff

At least one adult cuff with connector. Other size cuffs are available separately (see "Supplies and Accessories" on page 47).

Pressure Hose

Latex-free pressure hose with connector to connect various sizes of blood pressure cuffs to the Spot Vital Signs Ultra.

AC Power Transformer and Cord Assembly

Provides power to the Spot Vital Signs Ultra and charges the internal battery.

Optional Attachments

Spot Vital Signs Ultra may include the following items, based on the options purchased:

SureTemp Plus Temperature Probe and Covers

One oral temperature probe (blue ejection button) and one box of 25 single-use, disposable probe covers.

Braun PRO 4000

One ear thermometer, one box of 20 single-use, disposable probe covers, and Operator's Manual.

RS-232 Bar Code Scanner and Holder

Attach these items on the basket of the mobile stand or wall mount.

Pulse Oximetry (SpO₂)

The finger clip SpO₂ sensor and a 4-foot (122 cm) extension cord are for use with both adult and pediatric patients. Other sensors are available separately (see "Supplies and Accessories" on page 47).

Printer

- Attach to the basket of the mobile stand or wall mount.

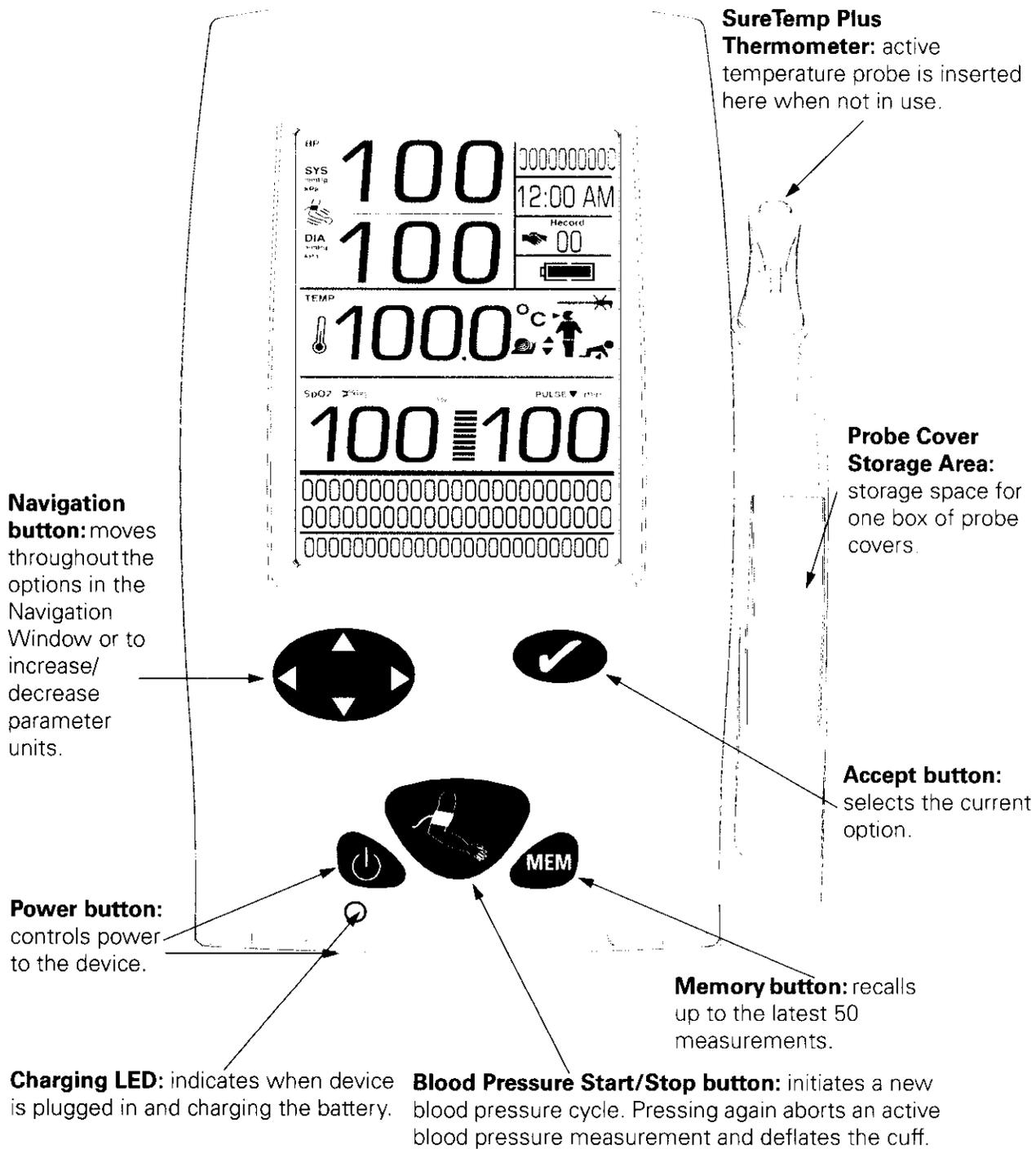
➔ Report any signs of shipping damage to the carrier. Report any missing or damaged items to the Welch Allyn Service Center near you.

Controls and Indicators

Drawings and text are representative of Spot Vital Signs Ultra with all available options. Your device may not include all functions, depending on the options purchased.

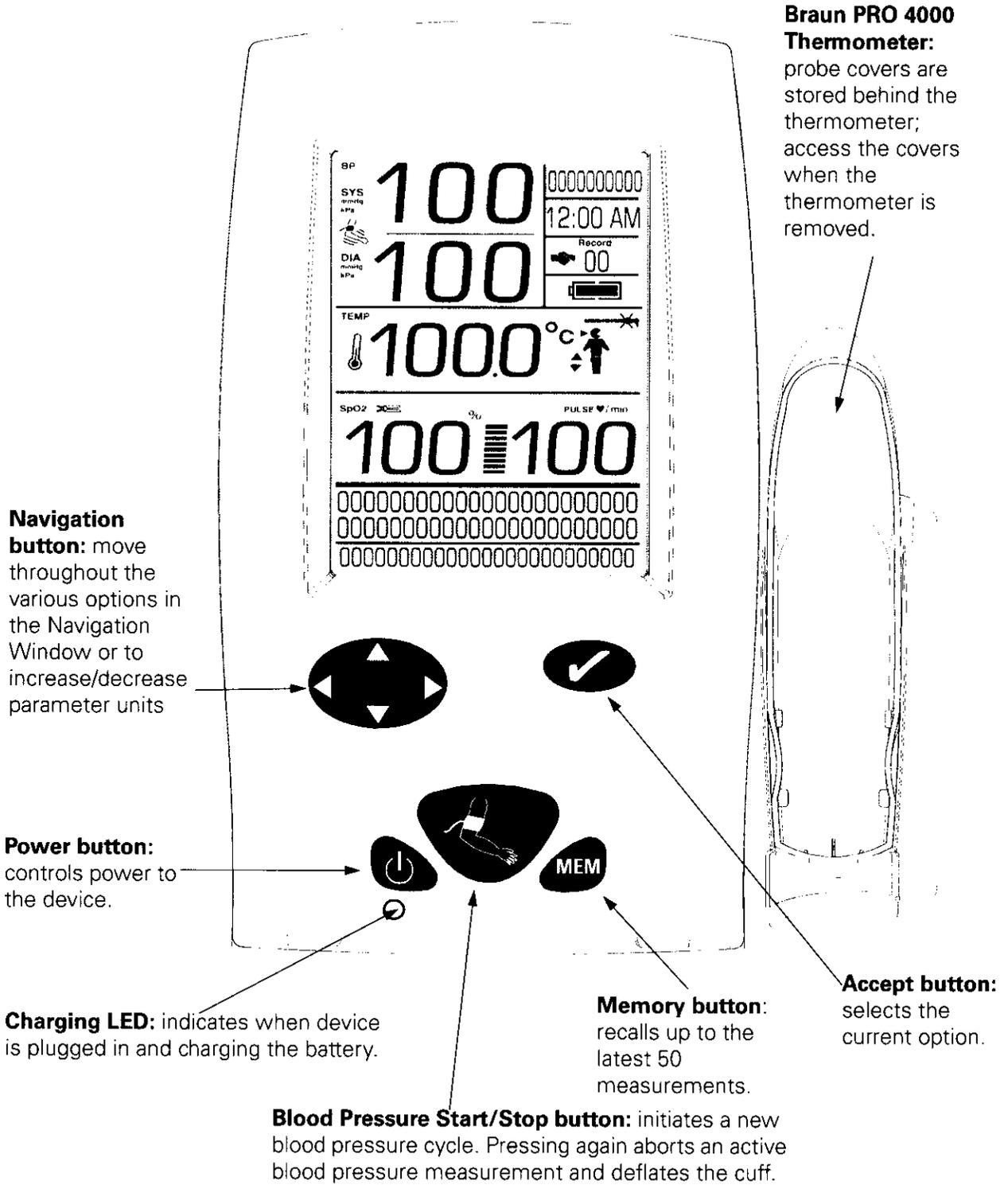
Front Panel

Spot Vital Signs Ultra with SureTemp Plus Thermometer



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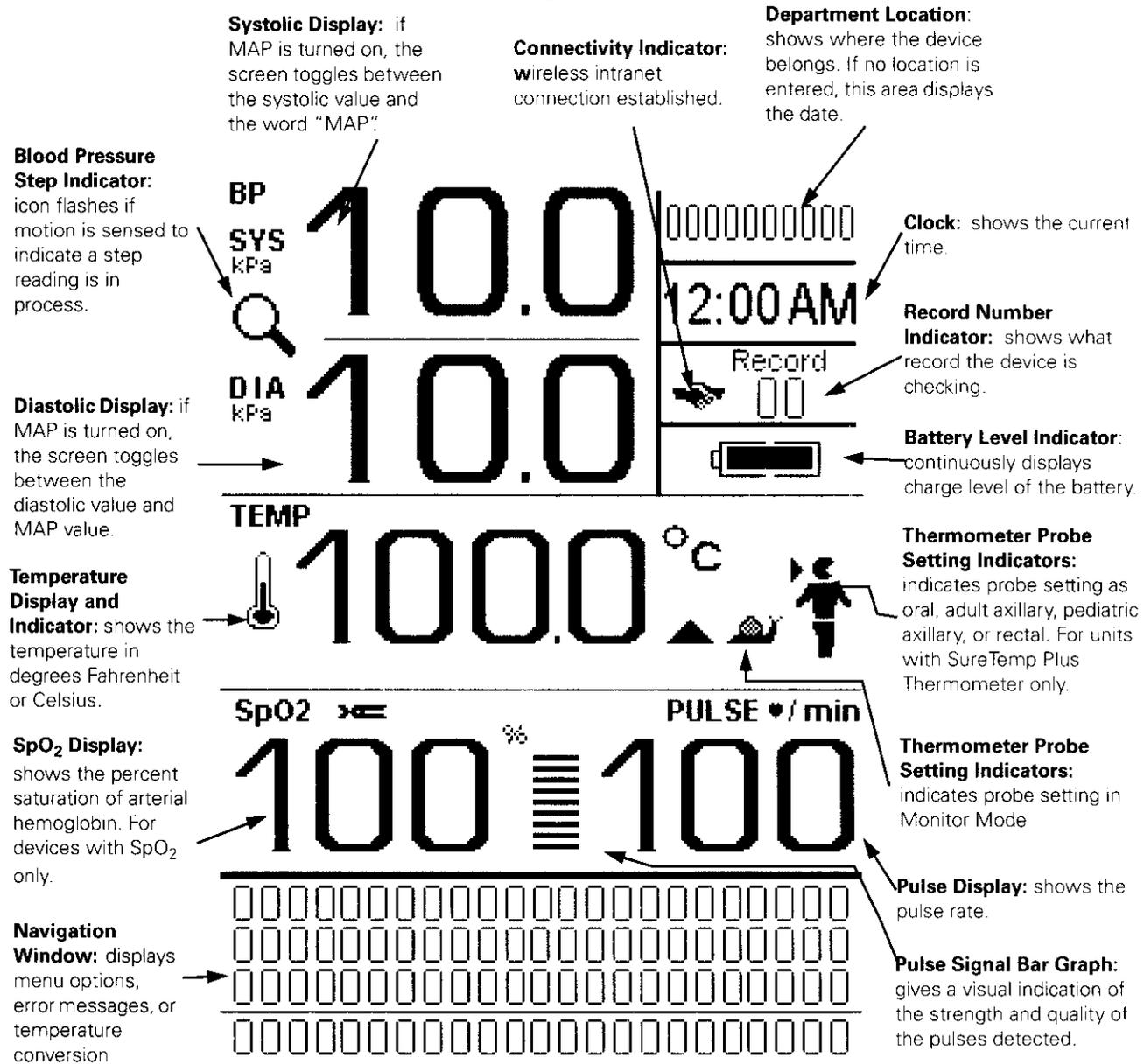
Spot Vital Signs Ultra with Braun PRO 4000 Thermometer



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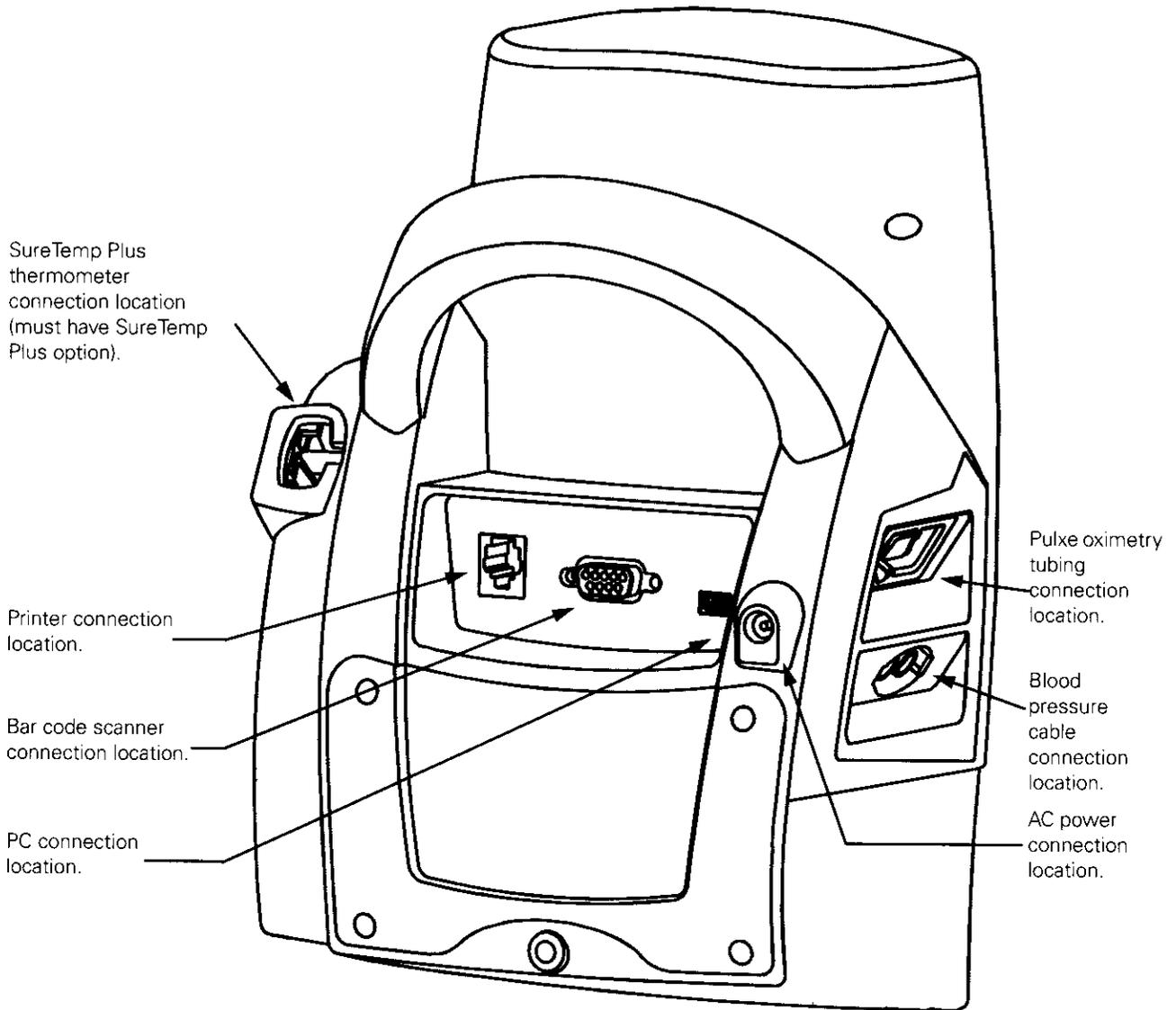
Display Window

The liquid crystal display may indicate any of the following: systolic blood pressure (mmHg or kPa), diastolic blood pressure (mmHg or kPa), MAP (mmHg or kPa), temperature (°F or °C), temperature method, pulse rate, pulse signal level, SpO₂, department location, time, record number, height, weight, BMI, respiration, pain level, save, and battery charge level.



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Side and Rear Panel



Connections

Blood Pressure Hose and Cuff

Identify and have each of the following items available:

- Spot Vital Signs Ultra
- One-piece blood pressure cuff
- Pressure hose

Perform the following set up procedure:

1. Inspect the pressure hose; note that one end has a single, gray connector fitting and the other end has two black metal fittings. To attach the end with the gray connector to the pressure hose connector on the side of Spot Vital Signs Ultra, squeeze in the side tabs. Completely insert the pressure hose connector and verify that the fit is snug.
2. Join the other end of the pressure hose to the pneumatic tubing attached to the cuff. Twist the connectors together until finger-tight. **DO NOT OVER TIGHTEN.**

Spot Vital Signs Ultra

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Temperature Probe

Spot Vital Signs Ultra is available with either the SureTemp Plus thermometer or the Braun PRO 4000 thermometer.

SureTemp Plus

The SureTemp Plus is available with two probes and matching wells; one for oral/axillary temperatures (blue) and one for rectal temperatures (red). The rectal probe and well are accessory items that are sold separately.

1. Install the probe well first with the tabs facing up and down into the round opening of the SureTemp Plus housing on the right side of Spot Vital Signs Ultra. Make sure it snaps into place. **Spot Vital Signs Ultra will only operate with the probe well in place.**
2. To install the temperature probe, press down the tab on top of the connector and insert the connector into the temperature probe connector port on the back of Spot Vital Signs Ultra. Verify the connector clicks into place. The operator can insert the probe connector only one way, with the tab on top.
3. Insert the temperature probe into the probe well on the side of the Spot Vital Signs Ultra.

To remove the temperature probe, press down on the connector tab and slide the connector out.

To remove the probe well, hold the well under the opening for the probe and pull gently.

Braun PRO 4000

1. Open the box of probe covers as directed on the box.
2. Insert the box with the opening at the top and perforation facing forward into the thermometer housing on the right side of Spot Vital Signs Ultra. Slide the box into the metal guides toward the back of the housing.
3. While holding the Braun thermometer at a 45° angle, insert the probe and the top of the thermometer into the housing until slightly covering the ExacTemp light. Lower the bottom portion of the thermometer into the housing until it snaps into place. If you do not properly seat the thermometer it could fall out and become damaged.
4. To remove the thermometer, pull the thermometer using the fingertip cutouts on the bottom of the housing.

Pulse Oximetry Sensor

Spot Vital Signs Ultra is available with a wide variety of SpO₂ sensors and ships with the reusable finger clip sensor. Order all other sensors separately as accessory items (see "Supplies and Accessories" on page 47).

Attach the Nellcor SpO₂ sensor to the pulse oximetry extension cable. Insert the connector end of the extension cable into the SpO₂ connector port on the left side of the Spot Vital Signs Ultra. Match the shape and pin configuration of the extension cable connector and insert it into the port. Push firmly.

→ Use only Nellcor or Masimo SpO₂ sensors and accessories with the Spot Vital Signs Ultra with Nellcor or Masimo configurations respectively.

Quick Reference Card

Attach the Quick Reference Card, if available, to the Spot Vital Signs Ultra handle, Mobile Stand, or Wall Mount.

AC Power

The operator can use the Spot Vital Signs Ultra with AC power or battery power (after charging the battery).

To connect the AC power transformer, insert the round transformer connector into the power port on the side of the Spot Vital Signs Ultra. Firmly insert the connector into the port. Insert the line cord into the line connector on the transformer, and plug the line cord into the AC main power source.

Battery

UPON RECEIVING SPOT VITAL SIGNS ULTRA, CHARGE THE BATTERY FOR 12 HOURS BEFORE INITIAL USE.

Attach the AC power transformer to Spot Vital Signs Ultra, and plug it into the AC main power source to charge the battery.

While Spot Vital Signs Ultra is charging, the AC/charging indicator ~ flashes and the battery level indicator segments on the display continuously sequence. When the battery is fully charged, the charging indicator ~ is steady and all battery level indicator segments on the display are shown continuously.

Power On/Off

Spot Vital Signs Ultra performs an internal self-diagnostic check each time an operator turns the device on.

To turn the device on or off, press the Power button.

Upon power up, the display lights up and each field or indicator turns on briefly and a beep sounds. If the internal self-check is successful, the displays assume their normal functions, and the device is ready for operation. If the self-check fails, an error code is shown in the Navigation Window.

Spot Vital Signs Ultra automatically turns off when powered up but not used for a period of time. You can change the period of time before the device turns off (default is 30 minutes) in the Internal Configuration Mode. See "Unit Time Out" on page 21.

Standby Mode

Spot Vital Signs Ultra goes into Standby Mode when powered up but not used for a period of time. Standby Mode conserves battery power.

You can change the period of time before the device goes into Standby Mode (default is 2 minutes) in the Internal Configuration Mode. See "Standby Mode Time Length" on page 20.

Press any button except the Power button to bring the Spot Vital Signs Ultra out of Standby Mode. Pressing the Power button will turn the device off.

Internal Configuration

You can change several device operating parameters in the Internal Configuration Mode. When changed, these settings become the default power-up settings. Also in this mode, you can see non-changeable device configurations for technical service purposes.

When the operator enters Internal Configuration Mode, the following menu will be visible on the device display:

Configuration Menu	
Version Numbers	Manual Parameters
Battery	External Devices
Location Identifier	Save Settings
▶ Date / Time	Time Out Settings
Blood Pressure	Wi-Fi
Temperature	Defaults
	Test Settings
ACCEPT	

Enter Internal Configuration Mode

To enter the Internal Configuration Mode, perform the following steps before locating the specific setting.

1. Turn the Spot Vital Signs Ultra off.
2. Simultaneously, press the Power button and the Memory button for 5 seconds. The device enters its Internal Configuration Mode. Use the Navigation button to scroll to the desired menu option and follow the directions to customize your device.
3. When you are finished, press the Navigation button to scroll to the next menu option or turn the device off to exit the Internal Configuration Mode.

Location Identifier

Use this screen to enter a department name (up to 10 characters) that will appear in the upper right corner of the Spot Vital Signs Ultra display.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Location Identifier" on the display.
3. Press the Select button; the letter "A" appears in the Navigation window.
4. Use the Navigation button to scroll up or down between letters, numbers, and blank spaces. Press the Select button to accept each character. Once the department name is complete, press the Select button once more to save the entry.

Set the Date and Time

Date Format

Use this screen to enter the format so that the date will appear (either mm/dd/yyyy or dd/mm/yyyy).

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Date/Time" on the display and press the Select button.
3. Press the Navigation button to highlight "Date Format" on the display and press the Select button. The two formats appear on the display with the pre-selected format highlighted.
4. Use the Navigation button to scroll between the two formats.
5. Press the Select button to accept the highlighted format.

Date Change

This screen allows the operator to enter the date.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Date/Time" on the display and press the Select button.
3. Press the Navigation button to highlight "Date Change" on the display and press the Select button.
4. The day, month, and year or month, day, and year (depending on the order chosen in the "Date Format" section of Internal Configuration Mode) appear on the display.
5. Use the Navigation button to scroll up or down to select the first number. Press the Select button to accept the number. Repeat until the entire date is complete.
6. Press the Select button one additional time to save the entry.

Time Format

Use this screen to enter the format in which the time will appear (either 12-hour with a.m. and p.m. or 24-hour).

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Date/Time" on the display and press the Select button.
3. Press the Navigation button to highlight "Time Format" on the display and press the Select button.
4. The two formats (12-hour or 24-hour) appear on the display with the pre-selected format highlighted.
5. Use the Navigation button to toggle between the two formats. Press the Select button to accept the highlighted format.

Time Change

Use this screen to enter the time.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Date/Time" on the display and press the Select button.
3. Press the Navigation button to highlight "Time" on the display and press the Select button.
4. The hour (in 24-hour format) and minutes appear on the display, with the hour highlighted.
5. Press the Navigation button to select the hour. Press the Select button to accept the number.
6. The minutes appear on the display highlighted. Press the Navigation button to select the minutes.
7. Press the Select button to accept the number.

CUU

Blood Pressure Units (mmHg or kPa)

Use this screen to change the blood pressure units to mmHg or kPa. The default setting is mmHg for all countries except China, which uses kPa.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Blood Pressure" on the display and press the Select button.
3. Press the Navigation button to highlight "BP Units" on the display and press the Select button. The options – mmHg and kPa – appear on the display with the pre-selected units highlighted.
4. Use the Navigation button to toggle between mmHg and kPa.
5. Press the Select button to accept this change.

Mean Arterial Pressure (MAP) On/Off

Use this screen to turn On or Off the Mean Arterial Pressure (MAP) mode.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Blood Pressure" on the display and press the Select button.
3. Press the Navigation button to highlight "MAP On/Off" on the display and press the Select button. On and Off appear on the display with the pre-selected option highlighted.
4. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Temperature Units (°F or °C)

Use this screen to select measuring temperature in Fahrenheit or Celsius.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Temperature" on the display and press the Select button.
3. Press the Navigation button to highlight "Temperature Units" on the display and press the Select button. °F or °C appear on the display with the pre-selected units highlighted.
4. Use the Navigation button to toggle between °F and °C.
5. Press the Select button to accept this change.

Temperature Mode

This screen allows the operator to select from measuring temperatures in Oral, Adult Axillary, or Pediatric Axillary modes. The Spot Vital Signs Ultra will enter Rectal Mode only when the red rectal probe is attached.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Temperature" on the display and press the Select button.
3. Press the Navigation button to highlight "Temperature Mode" on the display and press the Select button.
4. Oral, Adult Axillary, and Pediatric Axillary appear on the display with the pre-selected option highlighted.
5. Use the Navigation button to toggle up or down between the options. Press the Select button to accept this change.

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Manual Weight On/Off

Use this screen to turn On or Off the ability to manually enter patients' weight.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button to highlight "Weight On/Off" on the display and press the Select button.
4. On and Off appear on the display with the pre-selected option highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Weight Units (lb or kg)

Use this screen to select the weight units in pounds or kilograms.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button to highlight "Weight Units" on the display and press the Select button.
4. The options – lb and kg – appear on the Navigation window with the pre-selected option highlighted. Use the Navigation button to toggle between lb and kg.
5. Press the Select button to accept this change.

Manual Height On/Off

Use this screen to turn On or Off the ability to manually enter patients' height.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button and highlight "Height On/Off" on the display and press the Select button.
4. On and Off appear on the display with the pre-selected option highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Height Units (in or cm)

Use this screen to select the height units in inches or centimeters.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button to highlight "Height Units" on the display and press the Select button.
4. The options – in and cm – appear on the display with the pre-selected option highlighted. Use the Navigation button to toggle between in and cm.
5. Press the Select button to accept this change.

Body Mass Index (BMI) On/Off

Use this screen to turn On or Off the Body Mass Index (BMI) calculator. Since a patient's BMI is calculated using Weight and Height, if either Weight or Height is turned Off in Internal Configuration Mode, Spot Vital Signs Ultra will automatically turn Off the BMI option. If Weight and Height are turned On in the Internal Configuration Mode, then the operator has the ability to turn BMI On or Off by following these steps.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button to highlight "BMI On/Off" on the display and press the Select button.
4. On and Off appear on the display with the pre-selected option highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Respiration Rate On/Off

Use this screen to turn On or Off the ability to manually enter patients' respiration rates.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button to highlight "Respiration On/Off" on the display and press the Select button.
4. On and Off appears in the display with the pre-selected option highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Pain Level On/Off

Use this screen to turn On or Off the ability to manually enter patients' pain levels.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Manual Parameters" on the display and press the Select button.
3. Press the Navigation button to highlight "Pain On/Off" on the display and press the Select button.
4. On and Off appear on the display with the pre-selected option highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Patient ID On/Off

Use this screen to turn On or Off the patient identification number capability through the use of a Welch Allyn bar code scanner. The Spot Vital Signs Ultra only works with approved bar code scanners, even if Patient ID is turned On. The device will not scan without an approved bar code scanner available and the Bar Code Scanner On/Off option turned On in Internal Configuration Mode.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "External Devices" on the display and press the Select button.
3. Press the Navigation button and highlight "Patient ID On/Off" on the display and press the Select button.

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4. On and Off appears in the display with the pre-selected choice highlighted.
5. Use the Navigation button to toggle between On and Off.
6. Press the Select button to accept this change.

Clinician ID On/Off

Use this screen to turn on or off the clinician identification capability through the use of a Welch Allyn bar code scanner. The Spot Vital Signs Ultra only works with Welch Allyn approved bar code scanners, even if Clinician ID is turned On. The device will not scan without an approved bar code scanner available and the Bar Code Scanner On/Off option turned on in Internal Configuration Mode.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "External Devices" on the display and press the Select button.
3. Press the Navigation button and highlight "Clinician ID On/Off" on the display and press the Select button.
4. On and Off appear on the display with the pre-selected choice highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Printer On/Off

Use this screen to turn On or Off the printing option. The Spot Vital Signs Ultra only works with Welch Allyn approved printers, regardless of how the Printing option is set.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "External Devices" on the display and press the Select button.
3. Press the Navigation button to highlight "Printer On/Off" on the display and press the Select button.
4. On and Off appears on the display with the pre-selected option highlighted. Use the Navigation button to toggle between On and Off.
5. Press the Select button to accept this change.

Printer Paper

Use this screen to select whether the printer will be using plain paper or label paper.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "External Devices" on the display and press the Select button.
3. Press the Navigation button to highlight "Printer Paper" on the display and press the Select button.
4. The pre-selected type of paper is highlighted. Use the Navigation button to scroll between the choices.
5. Press the Select button to accept the entry.

Save Mode (Automatic or Manual)

Spot Vital Signs Ultra is capable of saving 50 patient records in its memory. The operator must decide if the save should happen automatically or manually. This screen allows the operator to select how the device should save.

In the Automatic Save Mode, the Spot Vital Signs Ultra automatically saves the parameters measured in succession before a preselected amount of time between parameter readings expires. The operator can change the amount of time in Internal Configuration Mode. If the device is programmed to power down ("Unit Time Out" in Internal Configuration Mode) in an amount of time shorter than the time for the unit to automatically save a cycle into memory ("Save Time Length" in Internal Configuration Mode), the unit will save the cycle first then power down.

In the Manual Save Mode, the operator must elect to accept each parameter and finally to save each cycle in memory. If, however, the user does not save the cycle, the unit automatically saves into memory the parameters measured before a pre-selected amount of time expires. This is done as a failsafe measure so the Spot Vital Signs Ultra will not power down without the data being saved. The operator can change the amount of time ("Save Time Length" in Internal Configuration Mode). If the Spot Vital Signs Ultra is programmed to power down ("Unit Time Out" in Internal Configuration Mode) in an amount of time shorter than the time for the device to automatically save a cycle into memory, the device will save the cycle first then power down.

Follow these steps to select Automatic or Manual Save Mode.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Save Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Save Mode" on the display and press the Select button.
4. Automatic and Manual appear on the display with the pre-selected option highlighted. Use the Navigation button to toggle between the two choices.
5. Press the Select button to accept this change.

Automatic Save Interval

Whether Spot Vital Signs Ultra is programmed to Save Automatically or Manually, it will automatically save readings into memory. This is done, even in Manual mode, as a failsafe measure so the device will not power down without data being saved.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Save Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Auto Save Interval" on the display and press the Select button.
4. The pre-selected amount of time appears on the display with the pre-selected option highlighted. Use the Navigation button to scroll between the time choices. If the operator selects an amount of time to automatically save that is greater than the amount of time selected to power down the device, the device will save the data and then turn off.
5. Press the Select button to accept this change.

Standby Mode Time Length

Use this screen to select the amount of time to have the unit to enter a lower power mode to extend run time.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Time Out Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Standby Mode" on the display and press the Select button.
4. The pre-configured amount of time is highlighted. Use the Navigation button to scroll between the time choices.

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5. Press the Select button to accept the entry.

Disable Standby Mode

Use this screen to select whether the device should disable Standby Mode when it is connected to an external power supply.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Time Out Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Disable Standby" on the display and press the Select button.
4. On or Off is highlighted. Use the Navigation button to scroll between the choices.
5. Press the Select button to accept the entry.

Unit Time Out

Use this screen to select the amount of time to have the unit automatically turn off.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Time Out Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Unit Time Out" on the display and press the Select button.
4. The pre-configured amount of time is highlighted. Use the Navigation button to scroll between the time choices.
5. Press the Select button to accept the entry.

Disable Time Out

Use this screen to select whether the device should disable "Unit Time Out" when it is connected to an external power supply.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Time Out Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Disable Unit Time Out" on the display and press the Select button.
4. On or Off is highlighted. Use the Navigation button to scroll between the choices.
5. Press the Select button to accept the entry.

Display WiFi Identifier

DHCP Enable

If DHCP Enable is turned on, the device will dynamically assume whatever IP address the DHCP server assigns to it. If turned off, the user must specify a fixed IP address (e.g., 192.24.15.5) that the device will use when communicating wirelessly.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Wi-Fi" on the display and press the Select button.
3. Press the Navigation button to highlight "DHCP Enable" on the display and press the Select button.
4. On or Off is highlighted. Use the Navigation button to scroll between the choices.

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5. Press the Select button to accept the entry.
6. If Off then scroll down to the IP Address entry and press Select.
7. Use the Navigation to enter the IP address number or "." and press the Navigation button to the right to move to the next number (e.g., 192.24.15.5).
8. Press Select to accept the address.

Security Enable

If turned off, no security is used for the wireless transmissions. If on, then the operator can enter a 128 bit hex encryption key the server will use to authenticate and decrypt the patient record.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Wi-Fi" on the display and press the Select button.
3. Press the Navigation button to highlight "Security Enable" on the display and press the Select button.
4. On or Off is highlighted. Use the Navigation button to scroll between the choices.
5. Press the Select button to accept the entry.
6. If Off then scroll down to the "Security Key" entry and press Select.
7. Use the Navigation button up and down to enter the key as a alphanumeric character 0 to 9 or A to F and press the Navigation button to the right to move to the next number (e.g., 1234 5678 9102 ABCD).
8. Press Select to accept the key.

WiFi Server Name

Use this screen to enter a valid server name within the domain or an IP address for the server location.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Wi-Fi" on the display and press the Select button.
3. Press the Navigation button to highlight "Server Name" or "Server Address" on the display and press the Select button.
4. The number "0" appears in the Navigation window. Use the Navigation button to scroll up or down from 0 to 9 and from A through Z. No spaces are allowed.
5. Press the Navigation button to the right to accept each character. Once the name or address is complete, press the Select button once more to save the entry.
6. If the Server Address was selected, press the Navigation button up and down to enter the IP address number or "." and press the Navigation button to the right to move to the next number (e.g., 192.24.15.5).
7. Press Select to accept the Server Address.

Default Settings

Use this screen to reset all of the settings in the Internal Configuration Mode to the factory default settings.

1. Enter the Internal Configuration Mode (see page 14).
2. Press the Navigation button to highlight "Defaults" on the display and press the Select button.
3. Press the Navigation button to highlight "Reset Defaults" on the display and press the Select button.
4. Yes or No is displayed, with No highlighted. Use the Navigation button to scroll between the choices.
5. Press the Select button to accept the entry.

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Blood Pressure Information

Select the Blood Pressure Cuff

Research shows that an undersized cuff overestimates the true blood pressure by as much as 10 to 30 mmHg. Please refer to the reference markings on the cuff for correct cuff sizing. When there is an area of overlap for using a smaller or larger cuff, Welch Allyn recommends that you use the larger size cuff.

Careful sizing of the cuff is important to the accuracy of blood pressure readings. If the cuff is too small, you may have false high readings. If the cuff is too large, you may have false low readings.

You may find that the bottom of the cuff extends to the antecubital fossa (bend in the elbow) on many people, but because the device uses oscillometric technology, not auscultation technology, this does NOT result in an inaccurate blood pressure.

To accurately determine the correct cuff size, refer to the following chart.

Determine the Cuff Size with the Cuff Markings

To ensure the proper cuff size, wrap the cuff around the patient's upper arm and visually check it. There is a distinct artery index marker and two divisions that indicate "range" on the cuff. When the cuff fits properly, the artery index marker falls within the range.

Chart for Determining Cuff Size

You can measure the patient's arm circumference (midway between the elbow and shoulder), and then use the chart below to select the correct cuff.

Durable One-Piece Cuff (Single Unit)	Disposable One-Piece Cuffs (5 pack)	Cuff Size	Minimum/Maximum (cm)	Minimum/Maximum (inches)
5082-203-4	5082-93-4	Small Child	12.4 to 16.8	4.9 to 6.6
5082-204-4	5082-94-4	Child	15.8 to 21.3	6.2 to 8.4
5082-205-4	5082-95-4	Small Adult	20.0 to 27.0	7.9 to 10.6
5082-206-4	5082-96-4	Adult	25.3 to 34.3	10.0 to 13.5
5082-207-4	5082-97-4	Large Adult	32.1 to 43.4	12.6 to 17.1
5082-208-4	5082-98-4	Thigh	40.7 to 55.0	16.0 to 21.7

THE SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATAL PATIENTS.

To ensure pediatric blood pressure accuracy and safety, the Small Child Durable One-Piece Cuff (5082-203-4) and the Small Child Disposable One-Piece Cuff (5083-93-4) are the smallest cuffs approved for use with young children and infants. The child's arm must fit within the range markings on the cuff.

Position the Cuff

The preferred blood pressure measurement site for adults and children is the upper arm. Keep the patient's arm relaxed and motion-free during measurement(s). Alternate blood pressure measurement sites include the thigh, ankle, or forearm.



Warning: Do not place the cuff on any extremity that is used for intravenous infusions, or any area where circulation is compromised.



Using the same arm for cuff inflation and SpO₂ measurement may cause inaccurate SpO₂ results.

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Wrap the cuff around the patient's bare arm and position the artery index marker over the brachial artery. Wrap the cuff snugly with room between the cuff and the arm for two fingers. Excessive tightness may cause venous congestion and discoloration of the limb. Wrapping the cuff too loosely (preventing proper inflation) may result in errors. Check the tubing for twisting, kinking, or compression of the hose, as this may cause measurement errors.

Blood Pressure Measurement

To initiate blood pressure measurements:

1. Properly size the blood pressure cuff and wrap it around the patient's upper arm (or alternate site, as necessary).
2. Press the Blood Pressure Start/Stop button. Spot Vital Signs Ultra inflates the cuff to the appropriate level.
3. The systolic display shows the pressure in the cuff as the blood pressure determination is in process.
4. When complete, Spot Vital Signs Ultra displays the systolic, diastolic, and pulse rate* measurements. The device will display MAP if it is turned on in the Internal Configuration Mode.
5. Pressing the Blood Pressure Start/Stop button at any time during a blood pressure determination aborts the measurement and rapidly deflates the cuff.



* Spot Vital Signs Ultra displays the pulse rate, as determined from the blood pressure measurement method, with the BP reading only if the SpO₂ option is absent or disabled. If the SpO₂ function is operational, all pulse rate determinations are a result of the SpO₂ measurement method.

Temperature Information

Select Temperature Operation Mode

Spot Vital Signs Ultra with the SureTemp Plus thermometer takes a temperature in either Normal or Monitor Mode. The default setting is Normal Mode.

In the Normal Mode, the thermometer "predicts" body temperature. When used correctly, the SureTemp Plus thermometer takes an oral reading in 4 to 6 seconds, a pediatric axillary reading (ages 17 and younger) in 10 to 13 seconds, an adult axillary reading (ages 18 and older) in 12 to 15 seconds, and a rectal reading in 10 to 13 seconds. Use the Monitor Mode when difficult situations prevent taking an accurate temperature in the Normal Mode.

Temperature Measurement Range Indicators

If the device takes an out-of-range temperature measurement, the device will beep twice and display the temperature limit that was exceeded. In addition, a small arrow will flash to indicate whether the out-of-range temperature measurement is too high (up arrow) or too low (down arrow).

Oral Temperatures

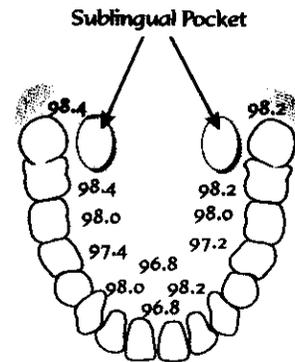
Oral Normal Mode

1. Ensure that the oral probe (blue) and probe well are installed. The device only obtains accurate oral temperatures by using the blue temperature probe.
2. Holding the probe handle with your thumb and two fingers on the indentations of the probe handle, withdraw the probe from the probe well.

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3. Verify that the oral mode is selected by observing the flashing head icon in Spot Vital Sign Ultra's temperature display area. If this icon is not flashing, press the Navigation button until "Oral" is highlighted in the Navigation Window and the appropriate icon is flashing in the temperature display area. Press the Select button. 
4. To load a probe cover, insert the probe into a probe cover and press the probe handle down firmly. The probe handle will move slightly to engage the probe cover.
 - ➔ Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.

5. With the Oral Mode icon flashing, quickly place the probe tip under the patient's tongue on either side of the mouth to reach the rear sublingual pocket. Have the patient close his/her lips around the probe.
6. Hold the probe in place, keeping the tip of the probe in contact with the oral tissue throughout the measurement process. Rotating "walking" segments appear in the temperature display area, indicating that measurement is in progress.
7. The device will beep when the final temperature is reached. The patient temperature, temperature scale, and measurement site will display in the temperature display area.



The temperature will also display in degrees Fahrenheit and degrees Celsius in the Navigation Window for 15 seconds. During the 15 seconds it is possible to override the preselected temperature scale and to save the reading in the alternate scale. Highlight the temperature in the alternate scale using the Navigation button and press the Select button. The temperature in the new scale will move to the temperature display area and the Navigation Window will return to its standard content. If the operator takes no action during the 15 seconds that the temperature appears in both scales, the temperature will remain in the temperature display area in the pre-selected scale and the Navigation Window will return to its standard content.

8. After the temperature measurement is complete, remove the probe from the patient's mouth. Eject the probe cover by firmly pressing the ejection button on the top of the probe.
9. Return the probe to the probe well.
 - ➔ Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking, or performing strenuous activity may affect temperature readings for up to 20 minutes after activity has ended.

If you cannot correctly measure the patient's temperature in Normal Mode, the device will automatically enter Monitor Mode. In this mode, measurement time is extended. Either repeat the temperature measurement in Normal Mode in the opposite sublingual pocket or follow the procedures below for Oral Monitor Mode beginning with Step 5.

Oral Monitor Mode

Monitor Mode displays the temperature of the probe as long as the probe remains in place at the measurement site and remains within the operating patient temperature range. The patient's oral temperature will reach final equilibrium in approximately three minutes in the Monitor Mode.

1. Ensure that blue probe and matching probe well are installed.
2. Holding the probe handle with your thumb and two fingers on the indentations of the probe handle, withdraw the probe from the probe well.

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3. To load a probe cover, insert the probe into a probe cover and press the probe handle down firmly. The probe handle will move slightly to engage the probe cover.
→ Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.
4. Take the patient's temperature using the Oral Normal Mode as previously described.
5. Continue to hold the probe in position after the temperature is displayed.
6. Press the Navigation button until the Monitor Mode indicator appears in the temperature display area.
7. Hold the thermometer in place for 3 minutes. The thermometer will not beep to indicate a final temperature. Record the temperature before removing the probe from the site as the monitored temperature is stored in memory for recall.

⚠ Long-term continuous monitoring beyond three minutes is not recommended in the Oral Mode.
8. Remove the probe from the patient's mouth. Eject the probe cover by firmly pressing the ejection button on the top of the probe.
9. Replace the probe in the probe well to reset the thermometer to Normal Mode.
→ If the thermometer is in Normal Mode, you can easily switch to Monitor Mode without taking a predictive temperature first. To do this, remove the probe from the probe holder, attach a new probe cover, and wait one minute (do not place probe in patient's mouth at this time). After one minute the thermometer automatically switches to Monitor mode. You may now proceed to take an oral temperature. After the probe is replaced in the holder, the device reverts back to preselected normal temperature mode.

Axillary Temperatures

Use the probe with the blue ejection button and the blue probe well.

Axillary Normal Mode

1. Ensure that the axillary probe (blue) and probe well are installed. The axillary probe and well are the same blue probe and well used for oral temperatures.
2. Holding the probe handle with your thumb and two fingers on the indentations of the probe handle, withdraw the probe from the probe well.
3. Verify that the axillary mode is selected by observing the correct flashing axillary icon in Spot Vital Signs Ultra's temperature display area. If the correct icon is not flashing, press the Navigation button until "Adult Axillary" or "Pediatric Axillary" is highlighted in the Navigation Window and the appropriate icon is flashing in the temperature display area. Press the Select button.

Adult Axillary
Mode Icon



Pediatric Axillary
Mode Icon



To ensure optimal accuracy, always confirm that the correct axillary mode is selected.

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4. Load a probe cover by inserting the probe into a probe cover and pressing the probe handle down firmly. The probe handle will move slightly to engage the probe cover.
 - ➔ Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.
5. With the correct axillary mode indicator flashing, lift the patient's arm so that the entire axilla is easily seen. Quickly place the probe as high as possible in the axilla. Do not allow the probe tip to come into contact with the patient until the probe is placed in the measurement site. Before this, any contact between the probe tip and the tissue or other material may cause inaccurate readings.



Do not take an axillary temperature through the patient's clothing. Direct contact between the patient's skin and the probe is required.

6. Verify that the probe tip is completely surrounded by axillary tissue and place the arm snugly at the patient's side. Hold the patient's arm in this position and do not allow the arm or probe to move during the measurement cycle. Rotating "walking" segments appear in the temperature display area, indicating that measurement is in progress.
7. The device will beep when the final temperature is reached. The patient temperature, temperature scale, and measurement site will display in the temperature display area.

The temperature will also display in degrees Fahrenheit and degrees Celsius in the Navigation Window for 15 seconds. During the 15 seconds it is possible to override the preselected temperature scale and to save the reading in the alternate scale. Highlight the temperature in the alternate scale using the Navigation button and press the Select button. The temperature in the new scale will move to the temperature display area and the Navigation Window will return to its standard content. If the operator takes no action during the 15 seconds that the temperature appears in both scales, the temperature will remain in the temperature display area in the preselected scale and the Navigation Window will return to its standard content.
8. After the temperature measurement is complete, remove the probe from the patient's axilla. Eject the probe cover by firmly pressing the ejection button on the top of the probe.
9. Return the probe to the probe well. The temperature measurement on the LCD display will go blank.
 - ➔ Probe contact with electrodes, bandages, etc., poor tissue contact, taking a temperature over clothing, or prolonged exposure of axilla to ambient air can cause inaccurate temperature readings.

If you cannot correctly measure the patient's temperature in Normal Mode, the device will automatically enter Monitor Mode. In this mode, measurement time is extended. Either repeat the temperature measurement in Normal Mode in the opposite axilla or follow the procedures below for Axillary Monitor Mode beginning with Step 5.

Axillary Monitor Mode

Monitor Mode displays the temperature of the probe for as long as the probe remains in place at the measurement site and remains within the operating patient temperature range. The patient's axillary temperature will reach final equilibrium in approximately five minutes in the Monitor Mode.

1. Ensure that blue probe and matching probe well are installed.
2. Holding the probe handle with your thumb and two fingers on the indentations of the probe handle, withdraw the probe from the probe well.
3. To load a probe cover, insert the probe into a probe cover and press the probe handle down firmly. The probe handle will move slightly to engage the probe cover.
 - ➔ Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.

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4. Take the patient's temperature using the Axillary Normal Mode as previously described.
5. Continue to hold the probe in position after the temperature is displayed.
6. Press the Navigation button until the Monitor Mode indicator appears in the temperature display area.
7. Hold the thermometer in place for 5 minutes. The thermometer will not beep to indicate a final temperature. Record the temperature before removing the probe from the site as the monitored temperature is not stored in memory for recall.



Long-term continuous monitoring beyond five minutes is not recommended in the Axillary Mode.

8. Remove the probe from the patient's axilla. Eject the probe cover by firmly pressing the ejection button on the top of the probe.
9. Replace the probe in the probe well to reset the thermometer to Normal Mode.
 - If the thermometer is in Normal Mode, you can easily switch to Monitor Mode without taking a predictive temperature first. To do this, remove the probe from the probe holder, attach a new probe cover, and wait one minute (do not place probe in patient's underarm at this time). After one minute the thermometer automatically switches to Monitor Mode. You may now proceed to take an axillary temperature. After the probe is replaced in the holder, the device reverts back to preselected normal temperature mode.

Rectal Temperatures

Use the probe with the red ejection button and the red probe well.

Rectal Normal Mode

1. Ensure that the rectal probe (**red ejection button**) and probe well are installed. The instrument will only operate in Rectal Mode when the red rectal probe and probe well are installed.
2. Holding the probe handle with your thumb and two fingers on the indentations of the probe handle, withdraw the probe from the probe well.
3. Observe the flashing lower-body icon on the device's display. 
4. To load a probe cover insert the probe into a probe cover and press the probe handle down firmly. The probe handle will move slightly to engage the probe cover.
 - Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.
5. With the Rectal Mode indicator flashing, separate the patient's buttocks with one hand. Using the other hand, gently insert the probe only 5/8 in. (1.5 cm) inside the rectum (less for infants and children). The use of a lubricant is optional.



Incorrect insertion of probe can cause bowel perforation.

6. Tilt the probe so that the tip is in contact with tissue. Keep the hand separating the buttocks in place and hold the probe in place throughout the measurement process. Rotating "walking" segments appear in the temperature display area indicating that measurement is in progress.
7. The device will beep when the final temperature is reached. The patient temperature, temperature scale, and measurement site will display in the temperature display area.

The temperature will also display in degrees Fahrenheit and degrees Celsius in the Navigation Display Window for 15 seconds. During the 15 seconds it is possible to override the pre-selected temperature

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scale and save the reading in the alternate scale. Highlight the temperature in the alternate scale using the Navigation button and press the Select button. The temperature in the new scale will move to the temperature display area and the Navigation Window will return to its standard content. If the operator takes no action during the 15 seconds that the temperature appears in both scales, the temperature will remain in the temperature display area in the pre-selected scale and the Navigation Window will return to its standard content.

8. After the temperature measurement is complete, remove the probe from the patient's rectum. Eject the probe cover by firmly pressing the ejection button on the top of the probe.
9. Return the probe to the probe well.
10. Wash your hands.
→ Washing hands greatly reduces the risk of cross-contamination and nosocomial infection.

If you cannot correctly measure the patient's temperature in Normal Mode, the device will automatically enter Monitor Mode. In this mode, measurement time is extended. Either repeat the temperature measurement in Normal Mode or follow the procedures below for Rectal Monitor Mode beginning with Step 5.

Rectal Monitor Mode

Monitor Mode displays the temperature of the probe for as long as the probe remains in place at the measurement site and remains within the operating patient temperature range. The patient's rectal temperature will reach final equilibrium in approximately three minutes in the Monitor Mode.

1. Ensure that red probe and matching probe well are installed.
2. Holding the probe handle with your thumb and two fingers on the indentations of the probe handle, withdraw the probe from the probe well.
3. To load a probe cover, insert the probe into a probe cover and press the probe handle down firmly. The probe handle will move slightly to engage the probe cover.
→ Use only Welch Allyn probe covers. Using other manufacturers' probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.
4. Take the patient's temperature using the Rectal Normal Mode as previously described.
5. Continue to hold the probe in position after the temperature is displayed.
6. Press the Navigation button until the Monitor Mode indicator appears in the temperature display area.
7. Hold the thermometer in place for 3 minutes. The thermometer will not beep to indicate a final temperature. Record the temperature before removing the probe from the site as the monitored temperature is not stored in memory for recall.



Long-term continuous monitoring beyond three minutes is not recommended in the Rectal Mode.

8. Remove the probe from the patient's rectum. Eject the probe cover by firmly pressing the ejection button on the top of the probe.
9. Replace the probe in the probe well to reset the thermometer to Normal Mode.
→ If the thermometer is in Normal Mode, you can easily switch to Monitor Mode without taking a predictive temperature first. To do this, remove the probe from the probe holder, attach a new probe cover, and wait one minute (do not place probe in patient's rectum at this time). After one minute the thermometer automatically switches to Monitor Mode. You may now proceed to take a rectal temperature. After the probe is replaced in the holder, the device reverts back to preselected normal temperature mode.

Ear Temperatures

Use the finger tip cut-outs on the bottom of the housing to remove the Braun PRO 4000 thermometer from its holder.

1. To attach a new probe cover, insert the probe tip into the probe cover box located inside the thermometer housing. Use a new, clean probe cover each time to achieve accurate readings.
2. The thermometer turns on automatically, when the probe cover is in place. Wait for the ready signal beep.

3. Fit the probe snugly into the ear canal, then push the activation button.

If the probe fits correctly into the ear canal during the complete measuring process, the «ExacTemp» light will flash and then continuously illuminate. A long beep signals the end of the measuring process. This signal assures that the thermometer has taken a temperature reading, and the result is shown in the Temperature Window Display.

4. If the probe is positioned incorrectly in the ear canal or is moved during the measuring process, a sequence of short beeps will sound, the «ExacTemp» light will go out, and the display will show an error message («POS» = position error).
5. When you are finished taking the temperature, eject the used probe cover.
6. Return the thermometer to its holder. The patient's temperature and temperature scale will display in Spot Vital Signs Ultra's temperature display area.

The temperature will also display in degrees Fahrenheit and degrees Celsius in the Navigation Window for 15 seconds. During the 15 seconds it is possible to override the preselected temperature scale and to save the reading in the alternate scale. Highlight the temperature in the alternate scale using the Navigation button and press the Select button. The temperature in the new scale will move to the temperature display area and the Navigation Display Window will return to its standard content. If the operator takes no action during the 15 seconds that the temperature appears in both scales, the temperature will remain in the temperature display area in the pre-selected scale and the Navigation Window will return to its standard content.

Pulse Oximetry Information

Certain configurations of the Spot Vital Signs Ultra incorporate a pulse oximetry system that determines arterial oxyhemoglobin saturation (SpO₂%). Spot Vital Signs Ultra uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO₂).

Because a measurement of SpO₂ is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is read to hemoglobin oxygen saturation. To identify the oxygen saturation of

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arterial hemoglobin, the device uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO₂ measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Oxygen saturation percent is calculated with each pulse detected, and the Spot Vital Signs Ultra display is continually updated. The pulse signal bar graph is an indicator of the strength and quality of the detected pulses.

SpO₂ is normally measured via pulses detected using a finger clip sensor. For certain situations, measurement and alternate site measurements for SpO₂ can include the earlobe, forehead, and toes.

Factors that may degrade the performance of the pulse oximeter:

- Excessive ambient light
- Excessive motion
- Electrosurgical interference
- Arterial catheters, blood pressure, and infusion lines, etc.
- Moisture in the sensor
- Improperly attached sensor
- Incorrect sensor for patient
- Poor patient perfusion
- Venous pulsations
- Anemia or low hemoglobin concentrations
- Cardiovascular dyes
- Fingernail polish (if finger sensor is used)
- Sensor not at heart level

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO₂.

During measurement, the instrument's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO₂.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Finger Clip Sensor Use



Warning: Use only Nellcor or Masimo SpO₂ sensors and accessories with Spot Vital Signs Ultra with Nellcor or Masimo configurations, respectively.

The finger clip pulse oximeter sensor is designed for spot check measurements of pediatric and adult patients.

Insert the patient's finger completely into the sensor. The thumb is specifically not recommended for use with the finger clip sensor.

- ➔ If blood pressure measurement is occurring simultaneously, ensure that the finger clip SpO₂ sensor is attached to the opposite limb with the blood pressure cuff.
- ➔ Check sensor sites periodically to determine circulation, sensor positioning, and skin sensitivity.

Other Sensors

A wide variety of reusable and disposable pulse oximetry sensors are available for use with Spot Vital Signs Ultra. These sensors expand the utility of the pulse oximetry component of the device.

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Pulse Oximetry Measurement

To take an SpO₂ measurement:

1. Properly attach the appropriate sensor to the patient.
2. The pulse signal bar graph illuminates, indicating the relative strength and quality of the patient's pulses at the sensor site. The sensor takes approximately 10 seconds to determine the initial SpO₂% value and pulse rate. When the initial values are determined, they are shown in the SpO₂ display and the pulse rate display, respectively.
3. The SpO₂% and pulse rate are updated approximately every second. Spot Vital Signs Ultra measures a patient's SpO₂ for up to 10 minutes. After 10 minutes, a C9 error code is displayed. This error code means that the 10-minute time has been exceeded.
4. If you remove the sensor from the patient, the SpO₂ reading flashes for 8 seconds. If the sensor is not reattached to the patient in 8 seconds, a beep sounds, signalling that the measurement period has ended. The device will continue to display the last SpO₂ reading.

Weight

Users can manually enter a patient's weight into Spot Vital Signs Ultra if the Weight parameter is turned on in the Internal Configuration Mode. The default is on.

If the Weight parameter is turned on, the word "Weight" appears in the Navigation Window.

To enter a patient's weight:

1. Ensure that the cursor is in front of the word "Weight" in the Navigation Window. If it is not, press the Navigation button until the cursor is in the appropriate location, then press the Select button.*
2. A default weight (that was pre-selected in Internal Configuration Mode) appears and flashes above the Navigation button. Press the Navigation button to increase or decrease the value.
3. When you scroll to the accurate weight, press the Select button again to accept the value. The Navigation Window will return to its previous state with the accepted weight value appearing next to "Weight" in the list.

*If you accidentally pressed the Select button to enter the Weight parameter, immediately press the Select button again to exit and return to the previous screen.

Height

Users can manually enter a patient's height into Spot Vital Signs Ultra if the Height parameter is turned on in the Internal Configuration Mode. The default is on.

If the Height parameter is turned on, the word "Height" appears in the Navigation Window.

To enter a patient's height:

1. Ensure that the cursor is in front of the word "Height" in the Navigation Window. If it is not, press the Navigation button until the cursor is in the appropriate location, then press the Select button.*
2. A default height (that was pre-selected in Internal Configuration Mode) appears and flashes above the Navigation button. Press the Navigation button to increase or decrease the value.
3. When you scroll to the accurate height, press the Select button again to accept the value. The Navigation Window will return to its previous state with the accepted height value appearing next to "Height" in the list.

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*If you accidentally pressed the Select button to enter the Height parameter, immediately press the Select button again to exit and return to the previous screen.

Body Mass Index

Spot Vital Signs Ultra can automatically calculate a patient's body mass index (BMI) if the Body Mass Index is turned on in the Internal Configuration Mode (the default is on) and if the operator manually entered a patient's height and weight.

If the BMI parameter is turned on, "BMI" appears in the Navigation Window.

To calculate a patient's BMI:

1. Ensure that you entered the patient's height and weight, using the directions above.
2. Move the cursor in front of "BMI" in the Navigation Window by pressing the Navigation button. Once the cursor is in the appropriate location, press the Select button.
3. The BMI value will appear next to "BMI" in the Navigation Window.

Respiration Rate

Users can manually enter a patient's respiration rate into Spot Vital Signs Ultra if the Respiration Rate parameter is turned on in the Internal Configuration Mode. The default is on.

If the Respiration Rate parameter is turned on, the word "Respiration" appears in the Navigation Window.

To enter a patient's respiration rate:

1. Ensure that the cursor is in front of the word "Respiration" in the Navigation Window. If it is not, press the Navigation button until the cursor is in the appropriate location, then press the Select button.*
2. A default respiration rate (that was pre-selected in Internal Configuration Mode) appears and flashes above the Navigation button. Press the Navigation button to increase or decrease the value.
3. When you scroll to the accurate respiration rate, press the Select button again to accept the value. The Navigation Window will return to its previous state with the accepted respiration rate appearing next to "Respiration" in the list.

*If you accidentally pressed the Select button to enter the Respiration Rate parameter, immediately press the Select button again to exit and return to the previous screen.

Pain Level

Users can manually enter a patient's pain level into Spot Vital Signs Ultra if the Pain Level parameter is turned on in the Internal Configuration Mode. The default is on.

If the Pain Level parameter is turned on, the word "Pain" appears in the Navigation Window.

To enter a patient's pain level:

1. Ensure that the cursor is in front of the word "Pain" in the Navigation Window. If it is not, press the Navigation button until the cursor is in the appropriate location, then press the Select button.*
2. A default pain level (that was pre-selected in Internal Configuration Mode) appears and flashes above the Navigation button. Press the Navigation button to increase or decrease the value.
3. When you scroll to the accurate pain level, press the Select button again to accept the value. The Navigation Window will return to its previous state with the accepted pain level appearing next to "Pain" in the list.

*If you accidentally pressed the Select button to enter the Pain Level parameter, immediately press the Select button again to exit and return to the previous screen.

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Saving Records – Automatic

Spot Vital Signs Ultra will automatically save entered data as a record if this feature is turned on in the Internal Configuration Mode. The default option is turned on.

In the Automatic Save Mode, Spot Ultra automatically saves into memory the parameters measured before a pre-selected amount of time between parameter readings expires. The operator can change the amount of time in Internal Configuration Mode; the default is 2 minutes (see "Automatic Save Interval" on page 20).

Saving Records – Manual

Users must manually save each record into memory if this feature is turned on in the Internal Configuration Mode. The default option is turned off.

To save data in Manual Save Mode:

1. Enter all patient data into Spot Vital Signs Ultra. Once complete, move the cursor in the Navigation Display Window in front of the words "Save/Next Record" by pressing the Navigation button.
2. Press the Select button. The data is saved, the display is cleared for the next record, and the Record number on the top right of the display is changed to the next record.

Note that as a failsafe measure Spot Vital Signs Ultra will automatically save a record when the device is powered down or a preselected amount of time expires. That amount of time can be changed in "Internal Configuration Mode." (See "Automatic Save Interval" on page 20.) When the Manual Save Mode is turned on, the amount of time before the device saves a record defaults to 15 minutes.

Sending Data to Electronic Medical Records

Spot Vital Signs Ultra with the Wireless Connectivity option can transfer data to Electronic Medical Records. For proper association users must scan a patient identification bar code before the data is saved.

Review Previous Records

Spot Vital Signs Ultra holds 50 patient records in memory including blood pressure, MAP, pulse rate, temperature, SpO₂, weight, height, BMI, pain level, and respiration rate. Press the Memory button once to review the last record. Pressing it again allows the user to review all previous readings in memory in a list format and to sort the records by time or patient identification.

Spot Vital Signs Ultra holds the information in memory until the record is overwritten with patient data 50 records later. To intentionally delete the information hold the Memory button for five seconds.

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Troubleshooting

Error Codes

The following table of conditions and error codes provides a quick reference of the descriptions and probable causes of error codes. For service-level troubleshooting, refer to the Service Manual (422207).

Press the Select button to reset flashing patient alarm conditions.

General Error Codes		
Code	Description	Corrective Action
E11	Internal safety violation	Check patient, contact Technical Service.
C12	Ambient temperature out of range	Adjust temperature or device location.
C13	Battery failure	Use wall transformer.
E0.0 - E9.9	Temperature module malfunction	Contact Technical Service.
E38	Date and time not set	Set the Date and Time, see "Set the Date and Time" on page 15.
E42	Internal communications error	Disconnect the battery and wait 5 minutes. Reconnect the battery and then set the date and time, see "Set the Date and Time" on page 15.
E20 - E50	General internal malfunction	Contact Technical Service.

Blood Pressure Error Codes		
Code	Description	Corrective Action
C02	Auto-zero failure	Check for air obstruction, limit patient movement.
C03	Inflation too rapid	Check for kinked cuff tubing, pressure hose, or other air obstruction.
C04	Excessive inflation time	Check for air leaks.
C05	Excessive noise	Check patient condition and cuff placement, limit patient movement.
C06	Measurement was outside of device's measurement range	Check patient condition.
E10	Cuff overpressure condition	Check patient condition.

SureTemp Plus Temperature Error Codes		
Code	Description	Corrective Action
C20	Broken/missing probe	Replace probe.
P	Loss of tissue contact	Ensure proper probe positioning.

SureTemp Plus Temperature Error Codes		
Code	Description	Corrective Action
E0.2, E0.3	Ambient temperature out of range	Adjust temperature or device location.
C22	10-minute diagnostic limit exceeded	Check patient. Read Directions for Use manual. Verify that the device is not used for monitoring purposes.

SpO₂ Error Codes		
Code	Description	Corrective Action
E7	Internal malfunction	Contact Technical Service.
C9	10-minute diagnostic limit exceeded	Check patient. Press Select button to clear error code. Verify that the device is not used for monitoring purposes.
C6	SpO ₂ heart rate out of range	Check patient condition.
C8	Bad sensor	Replace sensor.

Braun Temperature Error Codes		
Code	Description	Corrective Action
C32	Communication Error	Contact Technical Service.

WiFi Error Codes		
Code	Description	Corrective Action
C30	Cannot find server	Check Internal Configuration Settings
C31	Communication timeout	Confirm wireless local area network availability with facility's IT group.

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Possible Causes and Corrective Actions

SYMPTOM: Inaccurate Blood Pressure Readings

Note: Differences of up to 10 mmHg are considered normal and occur for a number of reasons including intra-patient BP variability, observer hearing differences, and auscultatory deflation rate.

Possible Cause	Explanation and Corrective Action
Incorrect cuff size	Use Welch Allyn approved cuffs only. <ul style="list-style-type: none"> • Use reference markings on cuff. • Measure patient's arm circumference midway between elbow and shoulder (see "Chart for Determining Cuff Size" on page 23 to select correct cuff size).
Patient's arm position	Ensure patient's arm is at heart level.
Arm movement during blood pressure cycle	Keep arm still during blood pressure cycle. <ul style="list-style-type: none"> • Movement may cause inaccuracies from artifact.
Blood pressure taken over clothing	Take blood pressure on a bare arm.
Arrhythmia	Check for regularity of heart rate (palpate pulse or check device). <ul style="list-style-type: none"> • Moderate to severe heart rate irregularities may make blood pressure difficult to measure accurately.
Incorrect reference	Use the correct Korotkoff sound to determine diastolic blood pressure. <ul style="list-style-type: none"> • Many listeners incorrectly equate diastolic blood pressure with the disappearance of sound only (phase 5). Spot Vital Signs Ultra was developed using the American Heart Association recommendations, which state that phase 5 be used unless sound continues to 0 mmHg, in which case the change in the quality of sound (phase 4) is to be used. Deflate cuff no faster than 3 mmHg per second. <ul style="list-style-type: none"> • One of the major sources of error in auscultatory blood pressure measurement is deflating the cuff too quickly. The American Heart Association recommends deflation no faster than 3 mmHg per second. Only use a sphygmomanometer that is calibrated. <ul style="list-style-type: none"> • An uncalibrated sphygmomanometer may result in inaccurate blood pressure measurements.
Change in blood pressure between auscultatory reading and Spot Vital Signs Ultra reading	Check blood pressure immediately before Spot Vital Signs Ultra reading. Blood pressure is dynamic and changing. It is normal for blood pressure to fluctuate 5 to 10 mmHg.
Poor auscultatory sound recognition by observer	Use high-quality stethoscope. Have a different observer check patient's blood pressure.

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SYMPTOM: Cuff Inflation and Deflation with No Blood Pressure Reading Displayed (or Error Code in Display)

Possible Cause	Corrective Action
Leak in pneumatic system	Ensure all cuff attachments are tight. Carefully check for leaks in the blood pressure cuff, tubing, and pressure hose attached to the device.
Arm movement during cycle	Keep arm still during blood pressure cycle. Movement may cause inaccuracies from artifact, long cycle times, and error message.
Cuff tubing or pressure hose movement artifact	Do not contact cuff tubing or pressure hose during blood pressure cycle. Movement may cause inaccuracies from artifact.

SYMPTOM: No Cuff Inflation

Possible Cause	Corrective Action
Connections between device and cuff loose	Check all connections (do not overtighten).

SYMPTOM: Cuff Pops Off

Possible Cause	Corrective Action
Inappropriate cuff size	Determine cuff size with the cuff markings or see "Chart for Determining Cuff Size" on page 23. If cuff continues to pop off, notify biomedical department or Welch Allyn Technical Support.
Cuff not applied securely	Smooth hook and loop securely before inflating cuff.
Cuff applied inside out	Re-apply cuff. Make sure Welch Allyn label is facing away from arm.

SYMPTOM: Cuff Deflating Too Slowly

Possible Cause	Corrective Action
Patient movement	Have patient sit still. Do not have arm tight against chest wall, as respiration may affect speed and accuracy of blood pressure measurement.
Arrhythmia	Check for regularity of heart rate (palpate pulse or check device). Moderate to severe heart rate irregularities may make blood pressure difficult to measure accurately.
Small leak in pneumatic system	Check cuff tubing and pressure hose for leaks.

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SYMPTOM: Temperature Malfunction

Possible Cause	Explanation	Corrective Action
Error code displayed	Broken probe	Replace probe. Consult Service Manual. Notify biomedical department or Welch Allyn Technical Support.
Low temperature readings	Improper probe placement	Place probe in most posterior sublingual pocket when in Oral Mode. Ensure the thermometer is in the correct mode.
No temperature displayed	Probe not replaced	Replace probe in holder prior to taking another temperature. Is the thermometer plugged into the Spot Vital Signs Ultra correctly?

SYMPTOM: SpO₂ Malfunction

Possible Cause	Explanation	Corrective Action
Sensor in place but no SpO ₂ on display	Improperly attached sensor Cable incorrectly plugged into device Using a Nellcor (light blue) sensor for previous generation technology	Insert the patient's finger completely into sensor. Verify BP and SpO ₂ measurements are not taken on the same extremity. Ensure sensor cable is correctly plugged into device. Replace with a new (blue) Nellcor sensor for current technology.
Inaccurate SpO ₂ reading	Incorrect sensor	Ensure that correct manufacturer's sensor is in use. Use only Nellcor or Masimo sensors.

SYMPTOM: Device Does Not Turn On

Possible Cause	Corrective Action
Low battery	Check connections between device and transformer, and transformer and wall receptacle.
Device not powering up	Unplug device from wall receptacle and check for breaks in cord. If connections are secure, check electrical outlet. Charging indicator is on if connections are good and the device is plugged into a working outlet. Notify biomedical department or Welch Allyn Technical Support.

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Maintenance

Welch Allyn will make available, upon request, circuit diagrams and other information that will assist appropriately qualified technical personnel in repair of this device. Please reference "422207 Service Manual" on page 50.

Cleaning

Spot Vital Signs Ultra

Wipe Spot Vital Signs Ultra clean with a cloth slightly dampened with warm water and a mild detergent solution. Never immerse Spot Ultra in any type of fluid.

1. Occasionally clean the device, as necessary, with either 70% isopropyl alcohol, 10% chlorine bleach solution, quaternary ammonium, PDI Sani-System Cloths, or mild detergent in water.



Prevent water or other fluids from entering any connectors. If this occurs, dry the connectors with warm air. Check all measurement functions.

2. Every 3 months, inspect the temperature probe, SpO₂ cord, and accessories for fraying or other damage. Replace as necessary.



Do not sterilize or autoclave Spot Vital Signs Ultra.

Blood Pressure Cuff

Clean the Durable One-Piece Blood Pressure Cuff with a damp cloth, or wash in water with soap or detergent. Before washing the cuff, remove the tube fittings, close off tubes with plugs (available as accessory 5082-163), and place the hook and loop fasteners in the closed position. After washing, allow the cuff to air dry. Re-assemble the tube fittings.

Disinfection: You may use glutaraldehyde-type liquid disinfectants on the Durable One-Piece Cuff. Prolonged use of these disinfectants at full strength may cause discoloration of the white cuff markings.

Sterilization: Do not use steam or heat to sterilize the cuff or pressure hose. If necessary, use gas sterilization.

Do not clean, disinfect, or sterilize the Disposable One-Piece Cuffs.

Do not press with a hot iron.

Cables and Pressure Hose

Wipe the cables and pressure hose with a damp cloth moistened in a mild detergent solution. Do not immerse hose.

SureTemp Plus Temperature Probe

Clean on a routine basis according to each facility's policy. Disinfect the device whenever contamination occurs.

Wipe the probe regularly with a cloth dampened with warm water and a mild detergent solution.

As needed, clean the probe with a 70% isopropyl alcohol solution, a 10% chlorine bleach solution, a nonstaining disinfectant such as CaviCide,[®] or its equivalent.



DO NOT immerse or soak the thermometer or probe in any type of fluid.



DO NOT use steam, heat, or gas sterilization on the probe. DO NOT autoclave the probe.

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SureTemp Plus Removable Probe Well

1. Remove the probe well from the device and unplug the latching probe connector to prevent the device from consuming battery power while you are cleaning the probe well.
2. To clean the inner surface of the probe well, swab the surface with a cloth dampened with a mild detergent solution, 70% isopropyl alcohol, 10% chlorine bleach solution, or a nonstaining disinfectant such as CaviCide[®] or its equivalent.
3. To clean the probe well's outer surface, swab the surface with one of the solutions mentioned above. Immerse the probe well in mild detergent solution as necessary for cleaning.



DO NOT use hard or sharp objects to clean the probe well. This could damage the probe well and cause the device to not function properly.



DO NOT use steam, heat, or gas sterilization on the probe well.
DO NOT autoclave the probe well.

4. Thoroughly dry all surfaces before re-assembling the instrument.
5. Re-connect the latching probe connector to the back of Spot Vital Signs Ultra. Ensure that the connector snaps into place.
6. Re-install the probe well, making sure it snaps into place.
7. Insert the probe into the probe well.

Braun Thermometer

Review the enclosed Braun PRO 4000 Operator's Manual.

Nellcor SpO₂ Sensor

Clean the reusable SpO₂ sensor with a 70% isopropyl alcohol solution and sterilize it using ethylene oxide (EtO), cold cycle. Do not immerse the sensor.

Masimo SpO₂ Sensor

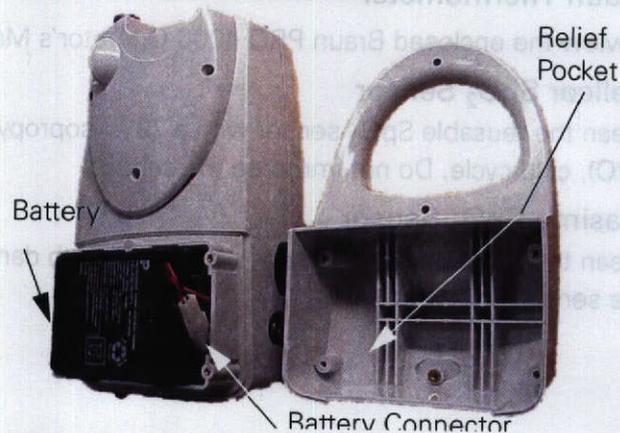
Clean the reusable SpO₂ sensor with a soft cloth dampened with a mild soap and water. Do not immerse the sensor.

Battery Removal and Replacement

Spot Vital Signs Ultra

If necessary, replace the internal battery after heavy use. When the battery no longer charges, remove and replace with a battery with the same part number. To replace the battery:

1. Insure the AC power transformer cord is disconnected from the Spot Vital Signs Ultra and that the device is turned off.
2. Use a phillips-head screwdriver to remove the 4 screws holding the battery door. Remove the battery door and expose the battery.
3. Tip the Spot Vital Signs Ultra and slide the battery out. Disconnect the in-line connector and discard the old battery per local regulations. Re-connect new battery to device connector as quickly as possible to prevent loss of power to the device and subsequent loss of clock time.
4. Attach the battery connector to the new battery as shown:
5. Slide the new battery into the battery compartment as far as it will go. Do not push the connector down into the case or lay it flat next to the battery. The relief pocket in the battery door purposely provides sufficient clearance for the battery connector.
6. Replace the battery door, tightening each of the 4 screws.
7. Connect the AC power transformer to the Spot Vital Signs Ultra and allow the new battery to charge for approximately 16 hours. It is possible to use the Spot Vital Signs Ultra during this charging period.
8. If an E38 error code is displayed when the device is owered on, refer to section "Set the Date and Time" on page 15.



The battery is a non-spillable lead-acid battery. In the USA, call 1-800-SAV-LEAD for instructions on how to recycle. For International users, contact your local authorities on recycling.

Braun PRO 4000

Welch Allyn supplies two 1.5V type AA (LR6) batteries with the Braun PRO 4000. For best performance, we recommend Duracell® Ultra alkaline batteries. Insert new batteries when the battery symbol appears on the display.

1. Open the battery compartment.
2. Remove the batteries and replace with new batteries, making sure the poles are in the right direction.
3. Slide the battery door back in until it snaps into place.

To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.

Blood Pressure Calibration Check

The Spot Vital Signs Ultra is manufactured to the highest industry standards for quality and accuracy. The device is manufactured using calibrated pressure standards traceable to NIST (National Institute of Standards and Technology). Welch Allyn recommends the BioMedical Department check the blood pressure calibration for the Spot Vital Signs Ultra on an annual basis using the following procedure.

1. Place the unit into the Internal Configuration Mode (see "Enter Internal Configuration Mode" on page 14).
2. Press the Navigation button to highlight "Test Settings" on the display and press the Select button.
3. Press the Navigation button to highlight "Calibration" on the display and press the Select button.
4. Press the Select button to close the valve.
5. To check the calibration, connect Spot Vital Signs Ultra to the test equipment (an inflation source, Digital or Analog pressure meter, 500 cc volume) and inflate the unit manually to 300 mmHg.
6. Drop the pressure to 250 mmHg, wait 15 seconds for stabilization, and take a reading.
7. Repeat for 150 mmHg, 50 mmHg, and 0 mmHg (all measuring downscale).
8. If the calibration at any point is outside of ± 3 mmHg, use the Spot Vital Signs Ultra Repair Software to re-calibrate the unit. The use of the Repair Software is the only way to change the pressure calibration constants that would be embedded into the unit from the ATE.

Temperature Calibration Check

Use either a Temperature Calibration Key (see "Supplies and Accessories" on page 47) or a Braun BB3200 IR Calibrator to check the thermometer accuracy. There is no way to change the calibration of the temperature. If the thermometer is out of calibration, contact Technical Service.

SpO₂ Calibration Check

Use either a Nellcor SpO₂ simulator or the Masimo SpO₂ simulator (depending on your SpO₂ module) to check the accuracy. There is no way to change the calibration of the SpO₂ module. If the SpO₂ is out of calibration, Contact Technical Service.

Specifications

Performance Specifications

This section describes normal ranges for Spot Vital Signs Ultra.

Patient Population

Spot Vital Signs Ultra is designed for use with adult and pediatric patients. Welch Allyn defines a pediatric patient as 29 days old or older.

THE SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATES.

Welch Allyn defines neonates as children 28 days or less of age, born at term (37 weeks of gestation or more), otherwise up to 44 gestational weeks. This is the definition from the AAMI SP10:2002 Standard.

Cuff Pressure Range

0 mmHg to 300 mmHg

Systolic Range

60 to 250 mmHg

Diastolic Range

30 to 160 mmHg

Blood Pressure Accuracy

Blood pressure accuracy meets or exceeds SP10:2002 AAMI standards for non-invasive blood pressure accuracy (AAMI standard: ± 5 mmHg mean error, 8 mmHg standard deviation). Blood pressure accuracy is validated for pressure measurement using the upper arm only.

Blood Pressure Determination Time

Typical: 15 seconds Maximum: 150 seconds

Mean Arterial Pressure Range

40 to 190 mmHg

Pulse Rate Range (using SpO₂ determination)

25 to 245 bpm

Pulse Rate Range (using Blood Pressure determination)

35 to 199 bpm

Pulse Rate Accuracy (using SpO₂ determination)

Without Motion: 25 to 245 bpm ± 3 digits***

With Motion: normal physiologic range (55 to 125 bpm) ± 5 digits

Low Perfusion: 25 to 245 bpm ± 3 digits***

*** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

Pulse Rate Accuracy (using Blood Pressure determination)

$\pm 5.0\%$

Overpressure Cutoff

315 mmHg ± 15 mmHg

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Temperature Ranges

SureTemp Plus

Normal Mode: 94.0° to 109.4° F (34.5° to 43.0° C)

Monitor Mode: 80.0° to 110° F (26.7° to 43.0° C)

Braun PRO 4000

68° to 108° F / 20° to 42.2° C

Temperature Calibration Accuracy

± 0.2°F (± 0.1°C)

Temperature Determination Time

Oral: 4 to 6 seconds

Adult Axillary: 12 to 15 seconds (age 18 years and older)

Pediatric Axillary: 10 to 13 seconds (age 17 years and younger)

Rectal: 10 to 13 seconds

Oxygen Saturation Range (SpO₂%)

40 to 100% oxygen saturation

Pulse Oximetry Accuracy

Without Motion: Adults: 70 to 100% ± 2 digits*

With Motion: Adults: 70 to 100% ± 3 digits**

Low Perfusion: 70 to 100% ± 2 digits***

<70% unspecified by the OEM

Biocompatibility testing has been conducted on Nellcor sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

* Adult specifications are shown for OxiMax MAX-A sensors. Sensor type will vary the saturation accuracy. Refer to the following Sensor Accuracy Guide.

** Applicability: OxiMax MAX-A, MAX-AL, MAX-P, and MAX-I sensors.

*** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO₂ range. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ± "X" digits. This variation equals ± one standard deviation (± 1 SD), which encompasses 68% of the population.

Mechanical

Dimensions

Height: 25 cm

Length: 15 cm

Depth: 10 cm

Weight

6.5 lbs

Mounting

Self-supporting on rubber feet

Custom mobile stand

Custom wall mount

Spot Vital Signs Ultra

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

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Portability

May be hand-carried when held by the rear handle.

Electrical

Power Requirements

Patient-Rated isolation transformer is connected to AC mains:

North American Version: 120VAC, 60Hz. 0.20A Input, 8VDC, 0.75A Output

International Version: 240VAC, 50Hz 0.10A Input, 8VDC, 0.75A Output

Australian Version: 240VAC, 50Hz, 13VA Input, 8VDC, 0.75A Output

Battery

Sealed lead acid, with external charger.

A fully charged battery supports 120 typical blood pressure determinations taken at 7-minute intervals. The battery is 90 to 100% charged after 12 hours of charging. The battery automatically charges when Spot Vital Signs Ultra is powered through the AC power transformer. An operator can use the device while the battery is charging; however, the battery charges faster when the instrument is not in operation.

Environmental

Operating Temperature

50° to 104°F (10° to 40°C)

Storage/Transport Temperature

Device with SureTemp Plus

-13° to 131°F (-25° to 55°C)

Device with Braun PRO 4000

50° to 104°F (10° to 40°C)

Relative Humidity

15 to 95% (non-condensing)

Operating Altitude

-557 to 16,000 ft. (-170 to 4877 m)

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Supplies and Accessories

Blood Pressure

Durable One-Piece Blood Pressure Cuff (1 per pack)

5082-203-4 Small Child
5082-204-4 Child
5082-205-4 Small Adult
5082-206-4 Adult
5082-207-4 Large Adult
5082-208-4 Thigh

Disposable One-Piece Blood Pressure Cuffs (5 per box)

5082-93-4 Small Child Cuff
5082-94-4 Child Cuff
5082-95-4 Small Adult Cuff
5082-96-4 Adult Cuff
5082-97-4 Large Adult Cuff
5082-98-4 Thigh Cuff

Miscellaneous

XXXX-XX Straight Pressure Hose (8ft.) (2.4M)
XXXX-XX Straight Pressure Hose (5ft) (1.5M)
XXXX-XX Calibration T-Connector

Temperature

02893-000 SureTemp Plus Oral Probe and Well (4 feet/1.2M)
02893-100 SureTemp Plus Oral Probe and Well (9 feet/2.7M)
02892-000 SureTemp Plus Rectal Probe and Well (4 feet/1.2M)
02892-100 SureTemp Plus Rectal Probe and Well (9 feet/2.7M)
02891-0000 SureTemp Plus Oral Well
02891-1000 SureTemp Plus Rectal Well
06138-000 Temperature Calibration Key
05031-101 Disposable SureTemp Plus Probe Covers (1,000 covers, packaged 25/box)
05031-105 Disposable SureTemp Plus Probe Covers (5,000 covers, packaged 25/box)
05031-110 Disposable SureTemp Plus Probe Covers (10,000 covers, packaged 25/box)

04000-200 Braun PRO 4000 Thermoscan Thermometer
05074-800 Disposable Braun Probe Covers (800 covers, packaged 20/box)
05074-005 Disposable Braun Probe Covers (5,000 covers, packaged 20/box)

Nellcor Pulse Oximetry

OxiMax Adhesive Sensors: Single-patient use

Description	Weight Range	Quantity	Catalog #
MAX-A Adhesive Sensor, adult	>66 lbs (30 kg)	Case of 24	MAX-A
MAX-P Adhesive Sensor, pediatric	22 to 110 lbs (10 to 50 kg)	Case of 24	MAX-P
MAX-I Adhesive Sensor, infant	6.5 to 44 lbs (3 to 20 kg)	Case of 24	MAX-I
MAX-R Adhesive Sensor, adult nasal	>110 lbs (50 kg)	Case of 24	MAX-R

OxiMax OxiCliq® Sensors: Reusable cable with adhesive sensor bandage

Description	Weight Range	Quantity	Catalog #
OxiCliq Sensor Cable (3 ft / 91cm)	N/A	1	OC-3
OxiCliq P, pediatric	22 to 110 lbs (10 to 50 kg)	Case of 24	OxiCliq-P

OxiMax Reusable Sensors

Description	Weight Range	Quantity	Catalog #
Durasensor® DS-100A finger-clip sensor, adult	>88 lbs (40 kg)	1	DS-100-A
Oxiband® OXI-A/N, adult/neonatal*	< 6.5 lbs or > 88 lbs (<3 kg or >40 kg)	1	OXI-A/N
Oxiband OXI-P/I, pediatric/infant	6.5 lbs to 88 lbs (3 to 40 kg)	1	OXI-P/I
Dura-Y® D-YS, multisite sensor	>2.2 lbs (1 kg)	1	D-YS
D-YSE ear clip for Dura-Y sensor	>66 lbs (30 kg)	1	D-YSE
PediCheck™ D-YSPD pediatric spot-check sensor	6.5lbs to 88 lbs (3 to 40 kg)	1	D-YSPD

OxiMax Sensor Cables

Description	Weight Range	Quantity	Catalog #
DEC-4 OxiMax 4-ft/1.2M sensor extension cable	N/A	1	DEC-4
DEC-8 OxiMax 8-ft/2.4M sensor extension cable	N/A	1	DEC-8

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Masimo Pulse Oximetry Accessories

Adhesive Sensors: Single-patient use

Description	Weight Range	Quantity	Catalog #
Finger clip probe - adult	>66 lbs (30 kg)	20	LNOP Adt
Finger clip probe - pediatric	22 to 110 lbs (10 to 50 kg)	20	LNOP Pdt
Neonatal preterm sensor	<2.2 lbs (1 kg)	20	LNOP Neo
SofTouch neonatal preterm sensor	<2.2 lbs (1 kg)	20	LNOP NeoPt

Reusable Sensors

Description	Weight Range	Quantity	Catalog #
Finger clip probe - adult	>66 lbs (30 kg)	1	LNOP DCI

Sensor Cables

Description	Weight Range	Quantity	Catalog #
4-foot cable with sensor connector	NA	1	PC 04
8-foot cable with sensor connector	NA	1	PC 08
12-foot cable with sensor connector	NA	1	PC 12

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Mounting

- 4200-60 Complete Mobile Stand Device includes:
Storage Basket
Pole and Base Assembly
Transformer Mounting Kit
- 4200-62 Complete Wall Mount Device includes:
Storage Basket
Wall Mount Bracket
Transformer Mounting Kit
- 4200-70 Anti-Theft Kit

Miscellaneous

- 422015 Lead Acid Battery
422200 Directions for Use
422206 Quick Reference Card
422207 Service Manual
XXXXX Training Video
XXXXX Carrying Case
5200-101A AC Power Transformer (desktop transformer, line cord not included)
-120V, 60Hz
5200-103A AC Power Transformer (desktop transformer, line cord not included)
-240V, 50Hz
5200-103Z AC Power Transformer (Australian version, desktop transformer with line cord included)
- 240V, 50Hz
5200-110 Line Cord (United States/Canadian/Japanese version)
5200-111 Line Cord (European version)
5200-112 Line Cord (United Kingdom version)
XXXX-XXX Printer with Mounting Bracket
XXXX-XXX Printer Paper
XXXX-XXX Bar Code Scanner with Mounting Bracket

Extended Warranties

- 4500-0T0 BP with Oral Thermometer
4500-0E0 BP with Ear Thermometer
4500-NT0 BP with Nellcor SpO₂ and Oral Thermometer
4500-NE0 BP with Nellcor SpO₂ and Ear Thermometer
4500-MT0 BP with Masimo SpO₂ and Oral Thermometer
4500-ME0 BP with Masimo SpO₂ and Ear Thermometer
4500-0TC BP with Oral Thermometer and Connectivity
4500-0EC BP with Ear Thermometer and Connectivity
4500-NTC BP, Nellcor SpO₂, Oral Thermometer, and Connectivity
4500-NEC BP, Nellcor SpO₂, Ear Thermometer, and Connectivity
4500-MTC BP, Masimo SpO₂, Oral Thermometer, and Connectivity
4500-MEC BP, Masimo SpO₂, Ear Thermometer, and Connectivity

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Warranty and Service

Warranty

Welch Allyn warrants Spot Vital Signs Ultra, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return Spot Vital Signs Ultra to Welch Allyn or an authorized distributor, agent, or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

IMPORTANT - Return the Instrument Registration Card

Remember to submit the instrument registration/warranty card for warranty validation. Complete the information and mail the pre-addressed card to Welch Allyn.

Accessories

The Nellcor or Masimo finger sensor is covered by a one-year warranty against original defects in material or workmanship.

The Durable One-Piece Cuff is covered by a three-year warranty against original defects in material or workmanship.

The battery is covered by a two-year warranty against original defects in material or workmanship.

The SureTemp Plus probes and wells meet Welch Allyn's specifications for the product at the time of purchase and are warranted to be free from original defects in material and workmanship under normal use and service for a period equal to one year from the date of first shipment of such product to the customer by or on behalf of the distributor. Probe covers are intended for single-use only.

The Braun PRO 4000 is covered by a two-year warranty against original defects in material or workmanship.

The printer is covered by a one-year warranty against original defects in material or workmanship.

The bar code scanner is covered by a one-year warranty against original defects in material or workmanship.

Service Policy

All repairs on products under warranty must be performed or approved by a Welch Allyn Service Center. Unauthorized repairs will void the warranty. Products out of warranty should be repaired by qualified electronics personnel or a Welch Allyn Service Center.

Technical Assistance

If you have an equipment problem that you cannot resolve, you may call the Welch Allyn Service Center nearest you for assistance. Technical service support is available by telephone on normal business days at the phone numbers listed on page 52.

If you are advised to return a product to Welch Allyn for repair or routine maintenance, schedule the repair with the service center nearest you.

Before returning a product for repair you must obtain authorization from Welch Allyn. An RMA (Return Merchandise Authorization) number will be given to you by our service personnel. Be sure to note this number on the outside of your shipping box. Returns without an RMA number will not be accepted for delivery.

Welch Allyn Service Centers

For Service or Repair

USA

Welch Allyn Inc.
Technical Service Centers
4341 State Street Road
Skaneateles Falls, NY 13153
Tel: 800-535-6663
Fax: 315-685-3361

Welch Allyn GmbH

Technical Service Centers
Zollerstrasse 2-4
D-72417 Jungingen
Germany
Tel: 00 49 7477 927186
Fax: 00 49 7477 927193

Welch Allyn Ltd. Singapore

300 Beach Road #25-08
The Concourse
Singapore 199555
Tel: 011 656 291 0882
Fax: 011 656 291 5780

Welch Allyn China

Room 708 Central Plaza
No. 227 Huang Pi Bei Road
Huang Pu District
Shanghai, 200003
China
Tel: 011-86-21-63279631
Fax: 011-82-61-6327-9632

CANADA

Welch Allyn Canada Limited
Technical Service Centers
160 Matheson Blvd., East
Mississauga, Ontario CANADA L4Z 1V4
Tel: 905-890-0004 or 800-561-8797
Fax: 905-890-0008

Welch Allyn Australia Pty. Ltd.

Technical Service Centers
The Metro Centre Unit 5
38-46 South Street
Rydalmere NSW 2116 Australia
Tel: 011 612 9638-3000
Fax: 011 612 9638-3500

Welch Allyn UK Ltd.

Cublington Road
Aston Abbots
Buckinghamshire England HP22 4ND
Tel: 011 0207 365 6780
Fax: 011 0207 365 9694

Latin America

MD International
Technical Service Centers
7324 S.W. 48th Street
Miami, FL 33155
USA
Tel: 305-669-9003
Fax: 305-669-8951

Service Manual/Spare Parts

A service manual is available by request to qualified electronics personnel. The service manual is a comprehensive guide to troubleshooting, service, and repair of Spot Vital Signs Ultra.

Also included with the service manual is a complete spare parts list. Order spare parts from your local Welch Allyn Service Center.

Service Loaners

Service loaners are provided, on request, when repair service is provided by a Welch Allyn Service Center. Loaners for products repaired while under the original warranty, or while under extended warranty or service contract, are provided free of charge and are shipped within 48 hours of notification of need. Shipment charges are paid by Welch Allyn.

For service repairs outside of warranty or contract, loaners are available for a nominal daily charge and shipment is subject to availability. Loaners are shipped pre-paid; however, this charge is added to the service charges.

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Welch Allyn®

Welch Allyn, Inc.
4341 State Street Road
PO Box 220
Skaneateles Falls, NY 13153-0220
U.S.A.
Telephone: 800-535-6663 or
315-685-4100
Fax: 315-685-3361

Part No. 422200

Printed in U.S.A.

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

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Frank Lacy
Subject: 510(k) Number K040490/S002
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this a prescription device?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Special 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO

Truthful and Accurate Statement Requested Enclosed
 A 510(k) summary OR A 510(k) statement
 The required certification and summary for class III devices N/A
 The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs): N/A
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

74 DXN (Class #)

Review: [Signature] CEMB 08/17/04
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] for 802 8/17/04
(Division Director) (Date)

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: K 040490/52
Frank Looy
 Division/Branch: DCD/CEMB
 Device Name: Welch Allyn Spot Ultra Vital Signs Device
 Product To Which Compared (510(K) Number If Known): K002530 and K024005

YES NO

1.	Is Product A Device	<input checked="" type="checkbox"/>	If NO = Stop
2.	Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>	If NO = Stop
3.	Same Indication Statement?	<input checked="" type="checkbox"/>	If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	If YES = Stop NE
5.	Same Technological Characteristics?	<input checked="" type="checkbox"/>	If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?	<input checked="" type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	If YES = Stop NE
9.	Accepted Scientific Methods Exist?	<input type="checkbox"/>	If NO = Stop NE
10.	Performance Data Available?	<input type="checkbox"/>	If NO = Request Data
11.	Data Demonstrate Equivalence?	<input type="checkbox"/>	Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

1. Intended Use:

See review

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See review

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

See review

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

DATE: August 16, 2004

FROM: Frank Lacy
ODE/DCD/CEMB, HFZ-450

SUBJECT: K040490/S2– **Abbreviated 510(k)**
Welch Allyn Spot Ultra Vital Signs Device
Welch Allyn, Inc.
4341 State Street Road
Skaneateles NY 13153

CONTACT: David Klementowski
Sr. Manager Regulatory Affairs

Tel: (315) 685-4133
Fax: (315) 685-2532
Email: klementowskiD@welchallyn.com

To: The Record

BACKGROUND

The sponsor, Welch Allyn, Inc., has submitted an original premarket notification (510(k)) to seek market clearance for the Welch Allyn Spot Ultra Vital Signs Device, and has identified this application as an **Abbreviated 510(k)** submission.

The predicate device cited is the Welch Allyn Spot Vital Signs Device also manufactured by Welch Allyn, Inc., cleared under 510(k) submissions K002530 and K024005.

The first review of this 510(k) application was conducted by Felipe Aguel, Ph.D. I have been asked to continue this review based on a time conflict between the due date and plans for Dr. Aguel to be out of the office. A consult has been obtained by Mike Husband, in DAGID/ARDB, for the SpO2 module. Upon marketing clearance, the proposed device would be classified under 21 CFR §870.1130, as Class II with panel and product code of 74 DXN.

INTENDED USE

As taken from the indications for use statement (page 53 of submission), the proposed device is indicated for prescription use to automatically measure systolic and diastolic pressure, mean arterial pressure, pulse rate, temperature, and pulse oximetry (SpO2) of adult and pediatric patients. The proposed device also allows manual entry of height, weight, respiration, and pain level and calculates body mass index following height and weight entry.

The indications for use statement is different from that identified in submission K002530 in that the indications for use statement of the predicate device explicitly includes the following contraindications:

- The Welch Allyn Spot Check Device should not be used on patients who are linked to heart lung machines
- The Welch Allyn Spot Check Device is not designed for use of axillary temperature option in children above three years of age.
- The Welch Allyn Spot Check Device is not intended to monitor patients' vital signs.
- The Welch Allyn Spot Check Device is not defibrillator proof.

SUMMARY

- | | | |
|---|---|---|
| Is the device life-supporting or life-sustaining? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device an implant (short-term or long-term)? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device sterile? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device for single use? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device for prescription use? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the device for home use or portable? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the device a combination product? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is the device a kit? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Is this device software driven? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |
| What is the estimated level of concern? | <input type="checkbox"/> Major | <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Minor |
| Is the device electrically operated? | <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> No |

DEVICE DESCRIPTION

The proposed device is a one-time vital signs measurement device without continuous monitoring capability, timed cycle intervals, or any programmable alarm features. It includes blood pressure, pulse rate, and temperature measurement features and optionally an SpO2 measurement feature. Other optional features include custom wall mount, external printer, bar code scanner, and 802.11b wireless communications. Measured data is displayed on a large LCD and may be printed by an optional thermal printer. The device is not intended for monitoring of patients, for use with neonates, or for use in environments that are not supervised by a health care practitioner. A rechargeable battery powers the device.

The following are the basic specifications for the device:

- Pressure measurement range: Systolic: 60-250 mmHg, Diastolic: 30-160mmHg
- Pulse measurement range: 25-245 bpm using SpO2 determination, 35-199 bpm using BP determination
- SpO2 measurement range: 40-100%
- Temperature measurement range: SureTemp oral, axillary or rectal probe: 80.0 – 109.4°F; Braun 4000 ear IR probe 68.0 –108.0 °F.

**Page 2 – Third Review of Abbreviated 510(k)
K040490/S2 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

- Accuracy: ± 3 mmHg for pressure; $\pm 3\%$ for SpO₂ for measurement range of 70-100%, unspecified for <70%, $\pm 5\%$ for pulse using blood pressure determination, ± 3 bpm using SpO₂ determination. Temperature, as per ASTM E1112 (2000).

In order to demonstrate substantial equivalence to the predicate device, the sponsor certifies compliance to the following standards:

- IEC 60601-1 (1990) + A1 (1993) + A2 (1995): Medical electrical equipment Part1: General requirements for safety.
- IEC 60601-1-2 (2001): Medical electrical equipment. Part 1: General requirements for safety – 2. Collateral standard: electromagnetic compatibility – requirements and testing.
- IEC 60601-1-4 (1996): Medical electrical equipment. Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems.
- AAMI SP10 (2002): Standard for electronic or automated sphygmomanometers.
 - Except section 4.2.4.1 because the proposed device is battery powered
 - Except section 4.3.3 because the proposed device and accessories do not utilize anything that is conductive
- ASTM1112-86 (200): Standard Specification for Electronic Thermometer or Intermittent Determination of Patient Temperature
 - Except section 4.4.1 because the proposed device utilizes a digital display
 - Except section 4.6.1 because this will be tested in IEC 60601-1 above.
- EN 865 (1997) Pulse Oximeters – Particular Requirements

Note: a refuse to accept letter was considered, for the original application, based on the fact that submissions relying on non-recognized standards should include supporting data for those standards. However, because these standards were accepted for a predicate device, this option was not pursued. The predicate device submission where these standards were accepted (K002530) contained minor modifications and elimination of software features. It was therefore appropriate to accept the standards since the modifications did not affect the function of the device covered by the non-recognized standards.

SUBSTANTIAL EQUIVALENCE

Description of Change - comparison to predicate

The significant differences between the proposed device and the predicate device are summarized below:

- The predicate device intended for use by health care professionals; the proposed device is indicated for over the counter use.

Page 3 – Third Review of Abbreviated 510(k)

K040490/S2 – Welch Allyn, Inc.

Welch Allyn Spot Ultra Vital Signs Device

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- The cuff material has changed; the outside of the cuff is made of nylon, and the inside of the cuff, the part that comes in contact with the patient, is made of polyester.

Predicate Comparison Chart

Device Characteristic	Predicate device (K002530 and K024005)	Proposed device
Name	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Indication for use	Measurement of BP, pulse rate, temperature and oxygen saturation of adult and pediatric patients. Not to be used on patients on heart-lung machines, not defibrillator proof, not intended to monitor patients' vital signs.	Automatically measure systolic and diastolic pressure, mean arterial pressure, pulse rate, temperature, and SpO2 of adult and pediatric patients. Prescription Use only.
Performance Standards	IEC60601-1 (1990) + A1 + A2 IEC60601-1-2 (1993) IEC60601-1-4 (1996) AAMI SP10 (1992) ASTM 1112-86 (1991) EN865 (1997)	Same IEC60601-1-2 (2001) Same AAMI SP10 (2002) ASTM 1112-86 (2000) Same
Temperature Sensors / OEM Modules	SureTemp	Same Braun 4000 IR
SpO2 Sensors / OEM Modules	Nellcor MP506	Same Massimo OEM SpO2 model NCT-11
Method/algorithm	Oscillometric for BP Pulse Oximetry for SpO2 rectal, oral, axillary thermistor probe	Same Same Same plus ear IR probe

According to the consultant's review, it remains unclear whether the only changes in the device are the OEM modules with which the device will work and the optional accessories available.

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MATERIALS/BIOCOMPATIBILITY

During the original review, the sponsor makes no mention of the biocompatibility of the device. Hence, the issue has been raised in a previous deficiency letter regarding the biocompatibility.

STERILIZATION

The sponsor does not claim that the proposed device is sterile. Sterility is not an issue.

LABELING

Labeling, promotional literature, and the user's manual are provided as section VI and attachments 3 and 4, respectively. However, in the original application, the labeling lacked information specified in the AAMI SP10 standard as well as information regarding the accuracy and specifications of the different sensors. Revised labeling has been provided for our consideration.

PERFORMANCE TESTING

The sponsor does not provide performance testing for the proposed device, but instead supplies a statement of conformance to the performance standards mentioned above. Because some of these standards are not FDA-recognized, supporting data has been requested in the deficiencies mentioned above.

Electrical Safety – EN 60601-1 (1990)

On page 15 of the submission, the sponsor presents a Statement of Conformance to EN60601-1 (1990) + A1 (1993) + A2 (1995).

Electromagnetic Compatibility – EN 60601-1-2 (1993)

On page 15 of the submission, the sponsor presents a Statement of Conformance to EN60601-2 (2001).

Environmental Testing

On page 15 of the submission, the sponsor presents a Statement of Conformance to ANSI/AAMI SP10 (2002), ASTM1112-86 (2000), and EN 865(1997). Because some of these are not FDA-recognized standards, data and test reports may be necessary.

SOFTWARE

In the original submission, the manufacturer includes a software description in section IV on page 25 of the submission, and identifies the level of concern for each software module as

**Page 5 – Third Review of Abbreviated 510(k)
K040490/S2 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

(2)

minor. The sponsor does not include the following items identified in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Although the sponsor has identified the level of concern as minor, failure of the software in the device could cause non-serious injury to the patient. Therefore, the documentation should be consistent with a Moderate level of concern.

REGULATORY INFORMATION

The sponsor has provided a truth and accuracy statement as required by 21 CFR §807.87, a 510(k) summary in accordance with 21 CFR 807.92, and an indications for use statement.

PREVIOUS QUESTIONS AND SUMMARY RESPONSES

1. You have stated in your comparison table on page 10 of the supplemental information that the Masimo OEM Model hardware used is the MS-11. Your software requirements specifications indicate that the Masimo NCT-11 is to be used. Please clarify this.

Summary Response: adequate; an oversight and has corrected the software requirements specifications, see consult review by Michael Husband

(b)(4)

3. You have provided cleaning instructions for the SpO2 sensors on page 41 of your user manual. Please provide test data that demonstrates that each reusable component will function within specifications after repeated cleaning. Please demonstrate this with all procedures mentioned in the labeling. If you are unable to complete these tests with any of the cleaning procedures described in the labeling, please remove these procedures. Please provide data that demonstrates that the device functions within its specified parameters after thirty cycles of cleaning as recommended by British Standard 6850 as a minimum simulation of reuse.

Response: adequate; sponsor has indicated that the cleaning validation is identical to the predicate device; I don't concur with the consultant's recommendation as the term identical is acceptable to this reviewer; see review by consult Michael Husband

4. We would also recommend that a declaration of conformity to IEC 60601-1 is not sufficient to determine mechanical safety. We would recommend that you also provide a summary of the testing performed, summary of the requirements met, and the pass/fail criteria; otherwise provide a signed declaration of conformity to an appropriate FDA consensus program standard.

Summary Response: adequate; provided a summary of the testing to be performed and requirements to be met for mechanical safety; see consultant

(b) (4)

6. Also, in our last letter, we asked that you please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 29, 1998. A copy of the guidance can be retrieved at our webpage www.fda.gov/cdrh/ode/57.html. While numerous parts of the software information, have been provided for our review, a complete software analysis could not be conducted because you have provided incomplete documentation as well as a statement in the correspondence, on page 28, that the device is still in the design and development phase and has not entered into the

**Page 7 – Third Review of Abbreviated 510(k)
K040490/S2 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

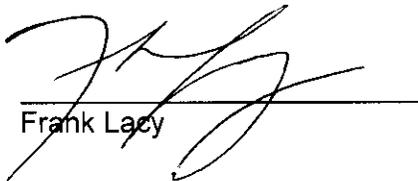
14

verification and validation phase. A partial response is not acceptable so please provide a complete response for our consideration.

Summary Response: adequate; provided a statement of "I will" conformance to IEC 60601-1-4:1996: Medical Electrical Equipment – Part 1: General requirements for safety; 4. Collateral Standard: Programmable electrical medical systems; manufacturer indicates that they will test and NOT market the device (will not introduce into interstate commerce) until the device is said to be in compliance with the aforementioned standard; I don't concur with the consultant's recommendation as the agency has previously cleared devices with this promising statement; see review by consult Michael Husband

RECOMMENDATION

Based on the responses mentioned above, I believe that the proposed device is substantially equivalent to the predicate devices. I recommend that the file be found substantially equivalent and that the sponsor receive a K-1 or Substantially Equivalent letter indicating our findings.



Frank Lacy

August 16, 2004
Date

VE Moller 08/17/04

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Firmware Version	1.02	0.12
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	Intelligent Target inflation, (which can return a BP reading) or 160 mmHg (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-1992
Heart Rate	+/- 5% (BP Determination)	+/- 5% or 3 BPM (BP Determination)

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 typical, 165 max.	15 to 30 typical, 150 max.
Mean Arterial Pressure	Calculated	Calculated
Overall System (General Characteristics)		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR wireless Capable Communication	Wireless (802.11b) Capable Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-25 to 55 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

	Nellcor Puritan Bennett N-550 Pulse Oximeter	Welch Allyn Spot Ultra Vital Signs Device
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model HW Used	MP506	MP506
Firmware Version	1.9.0.1	1.9.0.1
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified
Heart Rate	+/- 3 digits (w/o motion) +/- 5 digits (w/motion) Low Perfusion: +/- 3 digits	+/- 3 digits (w/o motion) +/- 5 digits (w/motion) Low Perfusion: +/- 3 digits
	Masimo Corporation SET RAD-5 Pulse Oximeter	Welch Allyn Spot Ultra Vital Signs Device
Massimo OEM SpO2		
Spo2 Measurement	Yes	Yes
OEM Model HW Used	MS-11	MS-11
Firmware version	4.1.0.0	4.1.0.0
Measurement Range		
SpO2	1-100%	1-100%
Heart Rate	25-240 bpm	25-240 bpm
Measurement Accuracy		
SpO2 (Adult, Pediatric)	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified
Heart Rate	+/- 3 digits (w/o motion) +/- 5 digits (w/ motion) Low Perfusion: +/- 3 digits	+/- 3 digits (w/o motion) +/- 5 digits (w/ motion) Low Perfusion: +/- 3 digits

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	Welch Allyn SureTemp Plus Thermometer	Welch Allyn Spot Ultra Vital Signs Device
SureTemp® OEM Temperature		
Temperature	Via thermistor technology	Same (Hardware, Firmware + Algorithm are identical).
Firmware version	1.1	1.1
Measurement Range	80°F (26.6°C) to 110 °F (43.0°C)	80.0° F to 110° F (26.6°-43.0°C)
Measurement Accuracy	+/- 0.2 F (0.1 C) (Monitor Mode)	+/- 0.2 F (0.1 C) (Monitor Mode)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
	Braun GmbH Thermoscan Pro 4000	Welch Allyn Spot Ultra Vital Signs
Braun 4000 IR Thermometer		
Temperature	Taken using IR technology	Taken using IR Technology (Housings, Hardware, Algorithm + Firmware are identical)
Measurement Range	68° to 108° F (20° C to 42.2° C)	68° to 108° F (20° C to 42.2° C)
Measurement Accuracy	+/- 2° C (35.5° to 42.0°C)	+/- 2° C (35.5° to 42.0°C)
Display Resolution	0.1° C or 0.1° F	0.1° C or 0.1° F

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K040490/52

Standard Organization No:

or

Standard Identification No:

or

CDRH Internal Reference No:

IEC 60601-1 (1990)

Declaration of Conformity Elements:

Any Adaptations Applied	yes	<input type="radio"/> no
Any Requirements Not Applicable	<input checked="" type="radio"/> yes	<input type="radio"/> no
Any Deviations Applied	yes	<input checked="" type="radio"/> no
Any Differences in Device Tested and Finished Product	yes	<input checked="" type="radio"/> no
*Is There a Third Party or Test Lab Involved	<input checked="" type="radio"/> yes	<input type="radio"/> no

Was there another standard used in the review of this submission? yes no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Standards Data Form for Abbreviated 510(k)s

510(k) Number:

K040490/52

Standard Organization No:

or

Standard Identification No:

or

CDRH Internal Reference No:

IEC 60601-1-2 (2001)

Declaration of Conformity Elements:

Any Adaptations Applied	yes	<input checked="" type="radio"/> no
Any Requirements Not Applicable	<input checked="" type="radio"/> yes	no
Any Deviations Applied	yes	<input checked="" type="radio"/> no
Any Differences in Device Tested and Finished Product	yes	<input checked="" type="radio"/> no
*Is There a Third Party or Test Lab Involved	<input checked="" type="radio"/> yes	no

Was there another standard used in the review of this submission? yes no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

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Standards Data Form for Abbreviated 510(k)s

510(k) Number:

K040490/52

Standard Organization No:

or

Standard Identification No:

or

CDRH Internal Reference No:

IEC 60601-1-4 (1996)

Declaration of Conformity Elements:

Any Adaptations Applied	yes	<input checked="" type="radio"/> no
Any Requirements Not Applicable	<input checked="" type="radio"/> yes	no
Any Deviations Applied	yes	<input checked="" type="radio"/> no
Any Differences in Device Tested and Finished Product	yes	<input checked="" type="radio"/> no
*Is There a Third Party or Test Lab Involved	<input checked="" type="radio"/> yes	no

Was there another standard used in the review of this submission? yes no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

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Standards Data Form for Abbreviated 510(k)s

510(k) Number:

K040490/S2

Standard Organization No:

or

Standard Identification No:

or

CDRH Internal Reference No:

ANSI/AAMI SP10 (1992)

Declaration of Conformity Elements:

Any Adaptations Applied	yes	<input checked="" type="radio"/> no
Any Requirements Not Applicable	<input checked="" type="radio"/> yes	no
Any Deviations Applied	yes	<input checked="" type="radio"/> no
Any Differences in Device Tested and Finished Product	yes	<input checked="" type="radio"/> no
*Is There a Third Party or Test Lab Involved	<input checked="" type="radio"/> yes	no

Was there another standard used in the review of this submission? yes no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Consult Review

K040490/S2

Date: August 3, 2004

To: Frank Lacy

From: Michael Husband

Company Name: Welch Allyn, Inc.

Device Name: Welch Allyn Spot Ultra Vital Signs Device.

Office: HFZ-480

Division: DAGID/ARDB

Device Description

The device is a one-time vital signs measurement device. The device is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature, and oxygen saturation for adult and pediatric patients. The device does not have continuous monitoring capability with timed cycle intervals or any programmable alarm features. The device has the following indications for use:

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO₂) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon order of a physician or licensed health care provider.

Consult Request

The Cardiac Electrophysiology and Monitoring Branch requested a consult review on the responses to Question 1,2,3,4, and 6 to the deficiency letter sent to the sponsor on June 21, 2004. The selected deficiencies and the sponsor's response are included below:

1. You have stated in your comparison table on page 10 of the supplemental information that the Masimo OEM Model hardware used is the MS-11. Your software requirements specifications indicate that the Masimo NCT-11 is to be used. Please clarify this.
Response: The sponsor has stated that this is an oversight and has corrected the software requirements specifications. Response Adequate.
2. You have not provided any performance testing information for the new MS-11 SpO₂

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Records Processed under FOIA Request 2016-6537; Released by CDRH on 8/17/2016 module. Please provide summary test information that shows your device functions within the specifications you have listed on page 10 of supplemental information. Please include test objectives, test methods and set up, acceptance criteria, and results.

Response: The sponsor has indicated that the SpO2 module is identical in all respects to the predicate device K033296. The sponsor has also provided a verification protocol for the SpO2 module. Response Adequate.

3. You have provided cleaning instructions for the SpO2 sensors on page 41 of your user manual. Please provide test data that demonstrates that each reusable component will function within specifications after repeated cleaning. Please demonstrate this with all procedures mentioned in the labeling. If you are unable to complete these tests with any of the cleaning procedures described in the labeling, please remove these procedures. Please provide data that demonstrates that the device functions within its specified parameters after thirty cycles of cleaning as recommended by British Standard 6850 as a minimum simulation of reuse.

Response: The sponsor has indicated that the cleaning validation is identical to the predicate device. However, validation of the subject device has not been provided. The sponsor has indicated that they will be validating the device with non-staining disinfectant as part of their verification protocol. The sponsor has not provided test set up, test procedures, or acceptance criteria for any of these tests. Response Inadequate.

4. We would also recommend that a declaration of conformity to IEC 60601-1 is not sufficient to determine mechanical safety. We would recommend that you also provide a summary of the testing performed, summary of the requirements met, and the pass/fail criteria; otherwise provide a signed declaration of conformity to an appropriate FDA consensus program standard.

Response: The sponsor has provided a summary of the testing to be performed and requirements to be met in regards to mechanical safety. Response Adequate.

6. Also, in our last letter, we asked that you please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 29, 1998. A copy of the guidance can be retrieved at our webpage www.fda.gov/cdrh/ode/57.html. While numerous parts of the software information, have been provided for our review, a complete software analysis could not be conducted because you have provided incomplete documentation as well as a statement in the correspondence, on page 28, that the device is still in the design and development phase and has not entered into the verification and validation phase. A partial response is not acceptable so please provide a complete response for our consideration.

Response: The sponsor has provided a verification plan with a list of test to be performed. These tests do not include test set up, test procedure, or acceptance criteria. Response Inadequate.

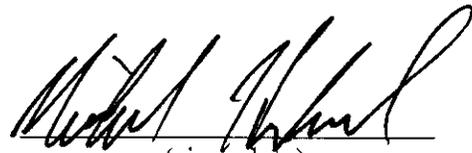
The sponsor was contacted via phone on August 3, 2004 and asked if the probes used with the SpO2 module were identical to the predicate device and that the cleaning procedure was identical to the predicate device. The sponsor confirmed this and has sent an email as written verification. The email is attached.

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Records Processed under FOIA Request 2016-6537; Released by CDRH on 8/17/2016
It is recommended that test set up, test procedure, and acceptance criteria are provided for the Verification Plan provided as well as for the cleaning and disinfection procedures for the device not covered in the Verification Plan.

Recommendation

I recommend that the **SpO2 portion** of the device be found substantially equivalent to the predicate device.


(sign, date)

26

Husband, Michael J

From: klaczykc@welchallyn.com
Sent: Tuesday, August 03, 2004 12:12 PM
To: mjh@cdrh.fda.gov
Cc: BelloJ@welchallyn.com; BuchananJ@welchallyn.com
Subject: K040490 - Request for Clarification Regarding SpO2 Probes and Their Cleaning

Per our telephone conversation of Tuesday, August 2, 2004, I respectfully submit the following clarification:

The SpO2 probes indicated for use with the subject device are identical in every respect to those used with the Massimo predicate per K033296 as they are sourced directly from Massimo. This is also true of the probes sourced from Nellcor Puritan Bennett per predicate reference K021090.

This being the case, the performance specifications and cleaning procedures are identical for the probes indicated for use with the subject device as with the referenced predicate devices.

Regards,
Chris Klaczyk
Sr. Regulatory Engineer
Welch Allyn
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220
TEL (315) 685-3694
FAX (315) 685-2532
klaczykc@mail.welchallyn.com

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8/3/2004

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

Consult Request Memorandum

Date: July 29, 2004
To: Michael Husband, ODE/DAGID/ARDB
From: Frank Lacy, Electrical Engineer, ODE/DCD/CEMB
RE: K040490/S2

CONSULT DUE TO LEAD REVIEWER: Friday, August 13, 2004

FILE DUE OUT OF ODE: 60 day total – Tuesday, September 21, 2004

Please **review responses to** Q1, Q2, Q3, Q4, and Q6 on the SpO2 utility and other concerns for this device.

Please provide your written review, comments, and any questions to me by Friday, August 13, 2004. If you are unable to complete the review in the requested timeframe, please let me know ASAP and we can discuss how to obtain alternate input for this file.

Thank you in advance for your assistance on this file.

Thanks,
Frank Lacy
(301) 443-8517 ext. 157

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, 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Felipe Aguel

Subject: K040490

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
Requires additional information (other than refuse to accept).
Accepted for review.
Is substantially equivalent to marketed devices.
NOT substantially equivalent to marketed devices.
Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is the device subject to Section 522 Postmarket Surveillance?
Is this device subject to the Tracking Regulation?
Was clinical data necessary to support the review of this 510(k)?
Is this a prescription device?
Was this 510(k) reviewed by a Third Party?
Special 510(k)
Abbreviated 510(k)

This 510(k) contains:

- Truthful and Accurate Statement
A 510(k) summary OR A 510(k) statement
The required certification and summary for class III devices
The Indication for Use form

Combination Product Category: N/A

- Material of Biological Origin
Animal Source
Human Tissue
Human Cell
Human Extraction Material
Product
Product
Product

The submitter requests under 21 CFR 807.95 (doesn't apply for SE's):

- No Confidentiality
Confidentiality for 90 days
Continued Confidentiality exceeding 90 days

Predicate Product Code with Class: 74 DXN Class II (two)
Additional Product Code(s) with panel (optional): 74 DQA, FLL

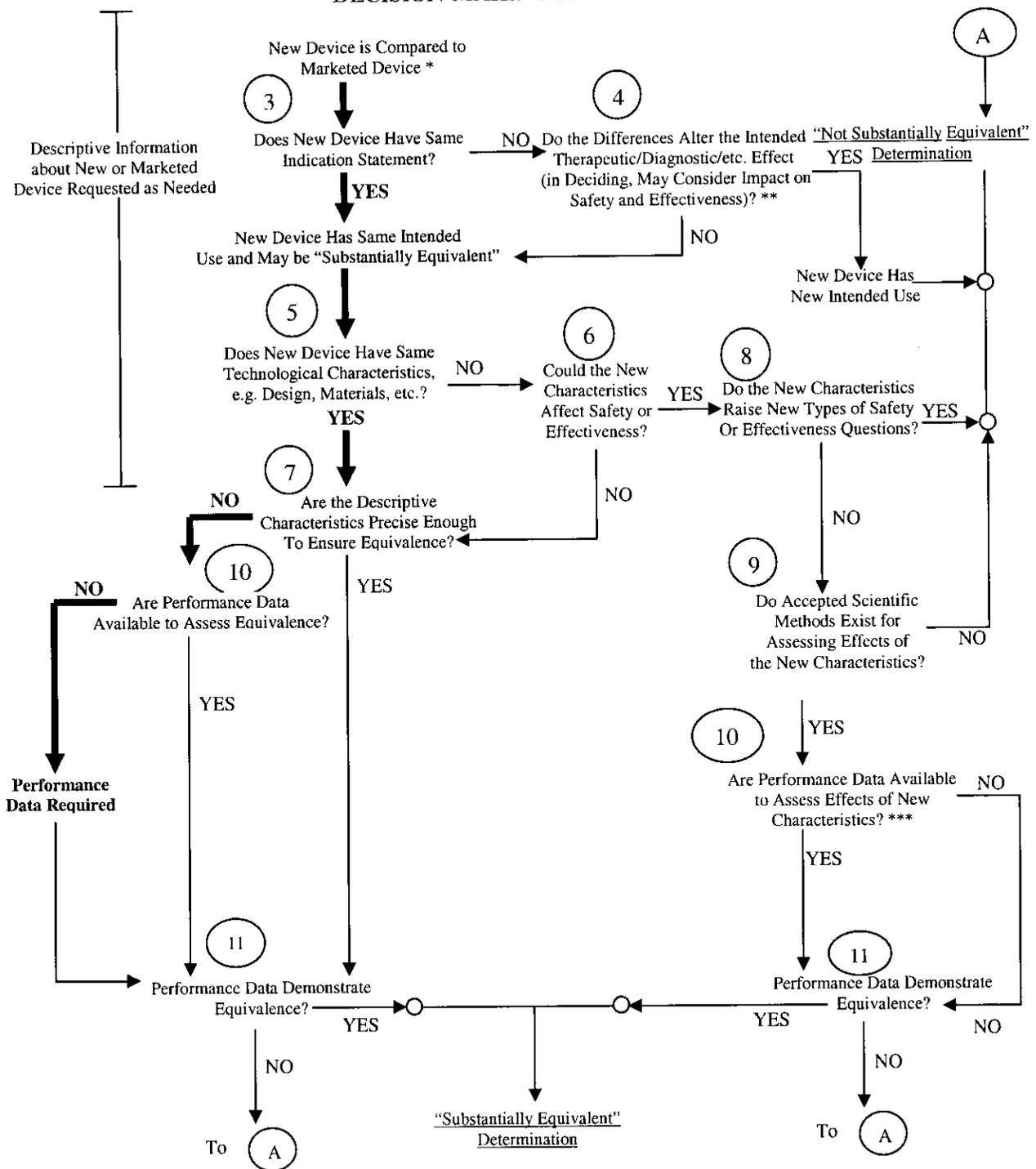
Review: [Signature] (Branch Chief)
CEMB (Branch Code)
09/21/04 (Date)

Final Review:

(Division Director) (Date)

Revised: 6/5/98, 4/2/03, 10/7/03 FA

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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

DATE: April 21, 2004

FROM: Felipe Aguel, Staff Fellow
DCD/CEMB, HFZ-450

SUBJECT: K040490 – **Abbreviated 510(k)**
Welch Allyn Spot Ultra Vital Signs Device
Welch Allyn, Inc.
4341 State Street Road
Skaneateles NY 13153

CONTACT: David Klementowski
Sr. Manager Regulatory Affairs

Tel: (315) 685-4133
Fax: (315) 685-2532
Email: klementowskiD@welchallyn.com

To: The Record

BACKGROUND

The sponsor, Welch Allyn, Inc., has submitted an original premarket notification (510(k)) to seek market clearance for the Welch Allyn Spot Ultra Vital Signs Device, and has identified this application as an **Abbreviated 510(k)** submission.

The predicate device cited is the Welch Allyn Spot Vital Signs Device also manufactured by Welch Allyn, Inc., cleared under 510(k) submissions K002530 and K024005.

This is my first review of this 510(k) application. Upon marketing clearance, the proposed device would be classified under 21 CFR §870.1130, as Class II with panel and product code of 74 DXN.

INTENDED USE

As taken from the indications for use statement (page 53 of submission), the proposed device is indicated for prescription use to automatically measure systolic and diastolic pressure, mean arterial pressure, pulse rate, temperature, and pulse oximetry (SpO2) of adult and pediatric patients. The proposed device also allows manual entry of height, weight, respiration, and pain level and calculates body mass index following height and weight entry.

The indications for use statement is different from that identified in submission K002530 in that the indications for use statement of the predicate device explicitly includes the following contraindications:

- The Welch Allyn Spot Check Device should not be used on patients who are linked to heart lung machines

- The Welch Allyn Spot Check Device is not designed for use of axillary temperature option in children above three years of age.
- The Welch Allyn Spot Check Device is not intended to monitor patients' vital signs.
- The Welch Allyn Spot Check Device is not defibrillator proof.

SUMMARY

Is the device life-supporting or life-sustaining?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device an implant (short-term or long-term)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device sterile?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device for single use?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device for prescription use?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is the device for home use or portable?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is the device a combination product?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device a kit?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is this device software driven?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
What is the estimated level of concern?	<input type="checkbox"/> Major	<input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Minor
Is the device electrically operated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

DEVICE DESCRIPTION

The proposed device is a one-time vital signs measurement device without continuous monitoring capability, timed cycle intervals, or any programmable alarm features. It includes blood pressure, pulse rate, and temperature measurement features and optionally an SpO2 measurement feature. Other optional features include custom wall mount, external printer, bar code scanner, and 802.11b wireless communications. Measured data is displayed on a large LCD and may be printed by an optional thermal printer. The device is not intended for monitoring of patients, for use with neonates, or for use in environments that are not supervised by a health care practitioner. A rechargeable battery powers the device.

The following are the basic specifications for the device:

- Pressure measurement range: Systolic: 60-250 mmHg, Diastolic: 30-160mmHg
- Pulse measurement range: 25-245 bpm using SpO2 determination, 35-199 bpm using BP determination
- SpO2 measurement range: 40-100%
- Temperature measurement range: SureTemp oral, axillary or rectal probe: 80.0 – 109.4°F; Braun 4000 ear IR probe 68.0 – 108.0 °F.

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- Accuracy: ± 3 mmHg for pressure; $\pm 3\%$ for SpO₂ for measurement range of 70-100%, unspecified for <70%, $\pm 5\%$ for pulse using blood pressure determination, ± 3 bpm using SpO₂ determination. Temperature, as per ASTM E1112 (2000).

In order to demonstrate substantial equivalence to the predicate device, the sponsor certifies compliance to the following standards:

- IEC 60601-1 (1990) + A1 (1993) + A2 (1995): Medical electrical equipment Part1: General requirements for safety.
- IEC 60601-1-2 (2001).: Medical electrical equipment. Part 1: General requirements for safety – 2. Collateral standard: electromagnetic compatibility – requirements and testing.
- IEC 60601-1-4 (1996): Medical electrical equipment. Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems.
- AAMI SP10 (2002): Standard for electronic or automated sphygmomanometers.
 - Except section 4.2.4.1 because the proposed device is battery powered
 - Except section 4.3.3 because the proposed device and accessories do not utilize anything that is conductive
- ASTM1112-86 (200): Standard Specification for Electronic Thermometer or Intermittent Determination of Patient Temperature
 - Except section 4.4.1 because the proposed device utilizes a digital display
 - Except section 4.6.1 because this will be tested in IEC 60601-1 above.
- EN 865 (1997) Pulse Oximeters – Particular Requirements

Note: a refuse to accept letter was considered based on the fact that submissions relying on non-recognized standards should include supporting data for those standards. However, because these standards were accepted for a predicate device, this option was not pursued. The predicate device submission where these standards were accepted (K002530) contained minor modifications and elimination of software features. It was therefore appropriate to accept the standards since the modifications did not affect the function of the device covered by the non-recognized standards.

Deficiency 1.

You provide a signed statement of conformance to recognized and non-recognized standards on page 15 of the submission. Among the standards to which you certify conformance is ANSI/AAMI SP10 (2002). The FDA does not recognize the 2002 version of the ANSI/AAMI SP10 standard. The latest revision of the standard that is FDA recognized is the 1992 version. Please use the ANSI/AAMI SP-10 (1992) standard and not the ANSI/AAMI SP-10 (2002) standard to demonstrate substantial equivalence of the blood pressure measurement component of the proposed device. You can provide either:

Page 3 – First Review of Abbreviated 510(k)
K040490 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device

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- the bench top and clinical data to demonstrate the safety and effectiveness of the blood pressure measurement module of the proposed device, or
- a signed statement of conformance to the 1992 version of ANSI/AAMI SP-10.

Deficiency 2.

You provide a signed statement of conformance to recognized and non-recognized standards on page 15 of the submission. Among the standards to which you certify conformance is EN865 (1997). The FDA does not recognize the EN865 (1997) standard. You may still use the standard to establish substantial equivalence to legally marketed devices if you provide detailed protocols, data, and conclusions of the tests specified in the standard. Additional data may be requested if the protocols specified in the standard are not sufficient to demonstrate safety and effectiveness of the proposed device. Please refer to the FDA Draft Guidance Document on Non-Invasive Pulse Oximeter, which is available at <http://www.fda.gov/cdrh/ode/guidance/997.pdf>, and to deficiencies 3 and 4 below.

SUBSTANTIAL EQUIVALENCE

Description of Change - comparison to predicate

The significant differences between the proposed device and the predicate device are summarized below:

- The predicate device intended for use by health care professionals; the proposed device is indicated for over the counter use.
- The cuff material has changed; the outside of the cuff is made of nylon, and the inside of the cuff, the part that comes in contact with the patient, is made of polyester.

Predicate Comparison Chart

Device Characteristic	Predicate device (K002530 and K024005)	Proposed device
Name	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device

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Device Characteristic	Predicate device (K002530 and K024005)	Proposed device
Indication for use	Measurement of BP, pulse rate, temperature and oxygen saturation of adult and pediatric patients. Not to be used on patients on heart-lung machines, not defibrillator proof, not intended to monitor patients' vital signs.	Automatically measure systolic and diastolic pressure, mean arterial pressure, pulse rate, temperature, and SpO2 of adult and pediatric patients. Prescription Use only.
Performance Standards	IEC60601-1 (1990) + A1 + A2 IEC60601-1-2 (1993) IEC60601-1-4 (1996) AAMI SP10 (1992) ASTM 1112-86 (1991) EN865 (1997)	<i>Same</i> IEC60601-1-2 (2001) <i>Same</i> AAMI SP10 (2002) ASTM 1112-86 (2000) <i>Same</i>
Temperature Sensors / OEM Modules	SureTemp	<i>Same</i> Braun 4000 IR
SpO2 Sensors / OEM Modules	Nelcor MP506	<i>Same</i> Massimo OEM SpO2 model NCT-11
Method/algorithm	Oscillometric for BP Pulse Oximetry for SpO2 rectal, oral, axillary thermistor probe	<i>Same</i> <i>Same</i> <i>Same</i> plus ear IR probe

It remains unclear whether the only changes in the device are the OEM modules with which the device will work and the optional accessories available.

Deficiency 3.

(b)(4)

3) to include a comparison of the hardware, firmware, and algorithms in the predicate and proposed devices.

Deficiency 4.

(b)(4)

If the data and protocols of the non-recognized standards cited in deficiency 2 (i.e. EN865 (1997)) conform to the above list, providing detailed test reports including protocols, data, and conclusions may suffice to address deficiency 4.

MATERIALS/BIOCOMPATIBILITY

The sponsor makes no mention of the biocompatibility of the device.

Deficiency 5.

You do not provide a reasonable assurance that the proposed device is biocompatible. We recommend that you provide biocompatibility data for the proposed device in accordance with ISO10993, "Biological Evaluation of Medical Devices", for medical devices that are in contact with skin for less than 24 hours to support the safety of these materials. For devices that are skin contacting, FDA recommends the following tests: cytotoxicity, intracutaneous reactivity or irritation, and sensitization. Alternatively, if the patient-contacting materials are identical to those in the predicate device, please provide supporting information including the vendor, material formulation, and manufacturing processes of patient-contacting components. As a second alternative, you can provide the 510(k) number(s) of legally marketed devices that utilize the identical OEM sensors to be used with the proposed device. Because this is an abbreviated 510(k) submission, another alternative is to certify conformance to the appropriate section(s) of the FDA-recognized ISO10993 standard prior to marketing the proposed device.

STERILIZATION

The sponsor does not claim that the proposed device is sterile. Sterility is not an issue.

LABELING

Labeling, promotional literature, and the user's manual are provided as section VI and attachments 3 and 4, respectively. However, there the labeling lacks information specified in the AAMI SP10 standard as well as information regarding the accuracy and specifications of the different sensors.

Deficiency 6.

In section VI and attachments 3 and 4 of the submission, you provide the device labeling. However, it appears that not all of the labeling specifications of the AAMI SP-10 (1992) standard are included. Please include all of the labeling specified in the AAMI SP-10 (1992) standard. Furthermore, your labeling should include the sensor specifications (i.e. SpO2, blood pressure, temperature, and pulse rate accuracy claims, etc.). Please note that this accuracy specification should be for each sensor and should be consistent with the results of the clinical validation study.

**Page 7 – First Review of Abbreviated 510(k)
K040490 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

PERFORMANCE TESTING

The sponsor does not provide performance testing for the proposed device, but instead supplies a statement of conformance to the performance standards mentioned above. Because some of these standards are not FDA-recognized, supporting data has been requested in the deficiencies mentioned above.

Electrical Safety – EN 60601-1 (1990)

On page 15 of the submission, the sponsor presents a Statement of Conformance to EN60601-1 (1990) + A1 (1993) + A2 (1995).

Electromagnetic Compatibility – EN 60601-1-2 (1993)

On page 15 of the submission, the sponsor presents a Statement of Conformance to EN60601-2 (2001).

Environmental Testing

On page 15 of the submission, the sponsor presents a Statement of Conformance to ANSI/AAMI SP10 (2002), ASTM1112-86 (2000), and EN 865(1997). Because these are not FDA-recognized standards, data and test reports may be necessary. See deficiencies 1-3 above.

SOFTWARE

The submission includes a software description in section IV on page 25 of the submission, and identifies the level of concern for each software module as minor. The sponsor does not include the following items identified in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Although the sponsor has identified the level of concern as minor, failure of the software in the device could cause non-serious injury to the patient. Therefore, the documentation should be consistent with a Moderate level of concern.

Deficiency 7.

(b)(4)

**Page 8 – First Review of Abbreviated 510(k)
K040490 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

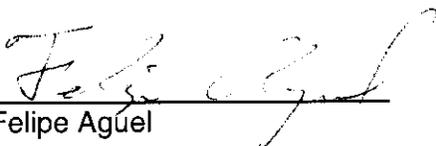
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REGULATORY INFORMATION

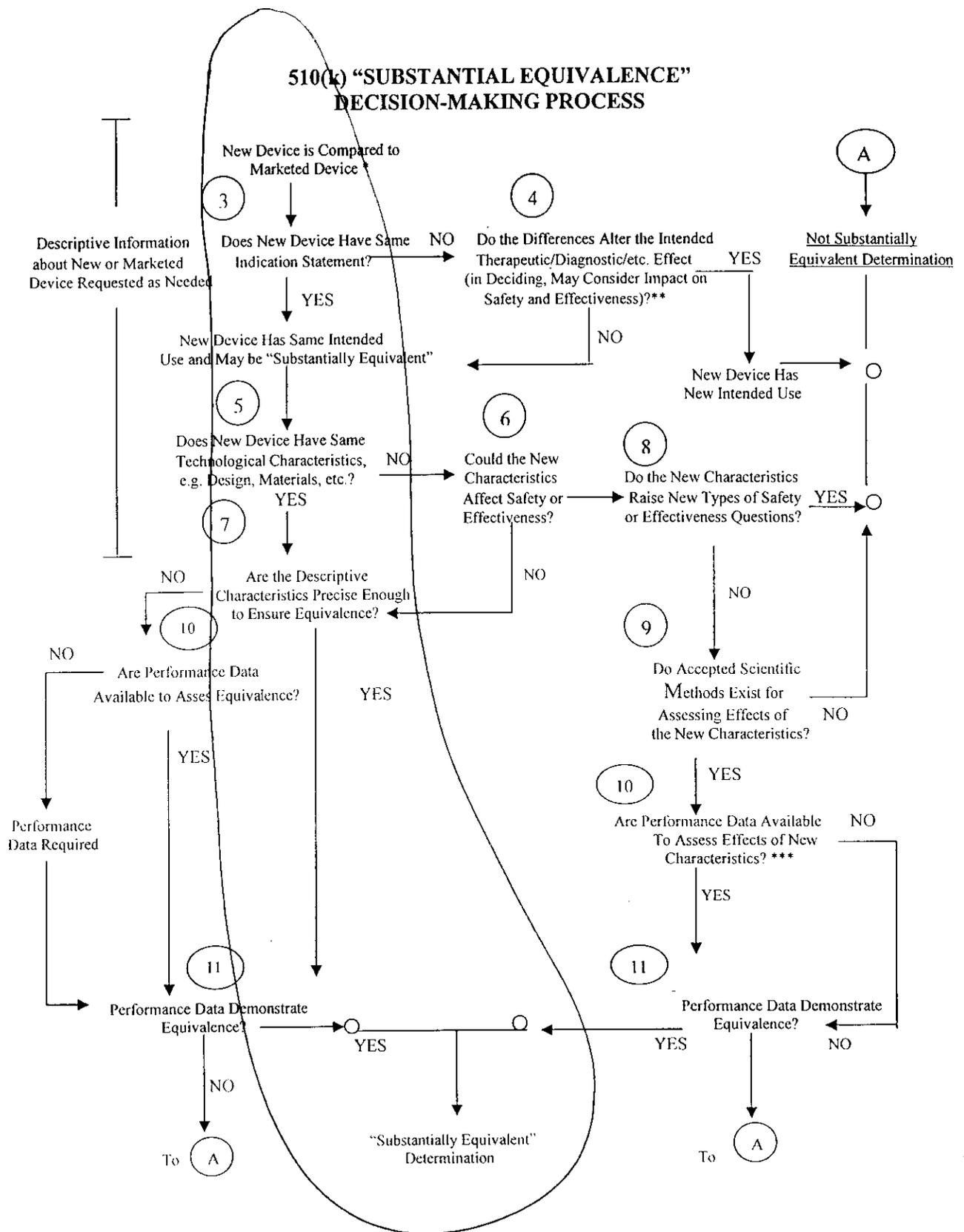
The sponsor has provided a truth and accuracy statement as required by 21 CFR §807.87, a 510(k) summary in accordance with 21 CFR 807.92, and an indications for use statement.

RECOMMENDATION

Based on the deficiencies mentioned above, I cannot determine whether the proposed device is substantially equivalent to the predicate device. I recommend that the file be placed on hold for additional information, and that the sponsor receive a K-3 "Additional Information" letter describing the deficiencies mentioned above.


Felipe Aguel

April 21, 2004
Date



* 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.

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 13, 2004

WELCH ALLYN, INC.
MEDICAL
4341 STATE ST. RD.
SKANEATELES FALLS, NY 13153

510(k) Number: K040490
Product: WELCH ALLYN SPOT
ULTRA VITAL
SIGNS DEVICE

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K040490/S'

17 May 2004

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: Premarket Notification K040490

Document Control Clerk:

In response to questions received on 21 April 2004, I have assembled the enclosed addendum to the Abbreviated 510(k) K040490.

If you would please add this to the above mentioned Premarket Notification Submission.

If you have any questions regarding this submission, please telephone (315) 685-4100 ext. 4133.

Sincerely yours,



David Klementowski
Corporate Regulatory Affairs Manager
Welch Allyn Inc.

RECEIVED
2004 MAY 13 A 9:56
FDA/CDRH/OCE/PMO

slc3

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Section I – Revised Statement of Conformance

FDA Question/Statement #1:

The FDA does not recognize the 2002 version of the ANSI/AAMI SP10 standard. The latest revision of the standard that is FDA recognized is the 1992 version. Please use the ANSI/AAMI SP10: 1992 standard and not the ANSI/AAMI SP10: 2002 standard to demonstrate substantial equivalence of the blood pressure component of the proposed device.

Welch Allyn Response:

Welch Allyn, Inc. understands and hereby revises its “Statement of Conformance” to state compliance to the ANSI/AAMI SP10: 1992 Standard:

III. Statement of Conformance to Recognized and non-Recognized Standards

The following mentioned product will be tested in typical configuration (BP, SpO₂, and Temperature) by a third party testing facility (ITS Cortland, NY), and will be found to be in compliance with the requirements of the standards listed below before Welch Allyn begins the sale of this device.

Equipment:

Type of Product - Non-invasive Blood Pressure Device

Model Number – 45XXX

Produced By:

Company Name: Welch Allyn, Inc.

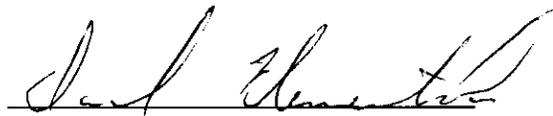
Company Address: 4341 State Street Road,
Skaneateles, New York 13153

Applied Standards:

- 1) **IEC 60601-1 (1990)** - Medical electrical equipment. Part 1: General requirements for safety. *Compliance to the standard.*
- 2) **IEC 60601-1, Amendment 1 (1993)** - Medical electrical equipment. Part 1: General requirements for safety. *Compliance to the standard.*
- 3) **IEC 60601-1, Amendment 2 (1995)** - Medical electrical equipment. Part 1: General requirements for safety. *Compliance to the standard.*
- 4) **IEC 60601-1-2 (2001)** - Medical electrical equipment. Part 1. General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and testing (Compliance with CISPR 55011, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-7, IEC 61000-4-8, IEC 61000-4-9, IEC 61000-4-10, IEC 61000-4-11 will be tested). *Compliance to the standard.*

- 5) **IEC 60601-1-4 (1996)** - Medical electrical equipment. Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems. *Compliance to the standard.*
- 6) **AAMI SP10 (1992)** - Standard for electronic or automated sphygmomanometers. *Compliance to all sections except for the following:*
- a) Sections 4.2.4.1 - Rational: The Spot Ultra Vital Signs Device is battery-powered device and only uses AC to charge the battery. AC alone will not run the Device. Therefore this section is not applicable.
 - b) Section 4.3.3 - Rational: The Spot Ultra Vital Signs Device and it accessories does not utilize anything that is conductive. There for this section is not applicable.
- 1) **ASTM1112-86 (2000)** - Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature. *Compliance to all sections except for the following:*
- a) Section 4.4.1 - Rational: The Spot Ultra Vital Signs Device utilizes a digital display. Therefore this section is not applicable.
 - b) Section 4.6.1 - Rational: This will be tested in IEC 60601-1.

Evidence of compliance to the above mentioned standards shall be on file at Welch Allyn, Inc. 4341 State Street Road, Skaneateles, NY 13153 on or before the release of the product for sale. Estimated launch date for the device listed above is December 2004.



12 - May - 2004
Date

Section II – Update Regarding EN 865: 1997

FDA Question/Statement #2:

Among the standards to which you certify conformance is EN 865:1997. The FDA does not recognize the EN 865:1997 standard. You may still use the standard to establish substantial equivalence to legally marketed devices if you provide detail protocols, data, and conclusions of the tests specified in the standard. Additional data may be requested if the protocols specified in the standard are not sufficient to demonstrate safety and effectiveness of the proposed device.

Welch Allyn Response:

Welch Allyn, Inc., is removing its statement regarding conformance to the EN 865:1997 standard. A new “Statement of Conformance to Recognized Standards is being enclosed with this response.

Section V – Update regarding Biocompatibility

FDA Question/Statement #5:

You do not provide reasonable assurance that the proposed device is biocompatible. We recommend that you provided biocompatible data for the proposed device in accordance with ISO 10993, “Biological Evaluation of Medical Devices,” for medical devices that are in contact with the skin for less than 24 hours to support the safety of these materials.

Welch Allyn Response:

As seen in the updated General Section, 510(k) Summary, and the tabular comparison of the predicates to Spot Ultra, Welch Allyn is using the same previously cleared device OEMs in the Spot Ultra Vital Signs. These devices are:

- 1) Braun Thermoscan Pro 4000, 510(k) # K031928
- 2) Nellcor OxiMax N-550 Pulse Oximeter, 510(k) # K021090
- 3) Masimo SET RAD-5 Pulse Oximeter, 510(k) # K033296
- 4) Welch Allyn SureTemp Plus Electronic Thermometer, 510(k) # K030580

Similarly, the biocompatibility of the OEMs listed above and the skin contact material of the Spot Vital Signs (510(k) #'s K002530 and K022163) are identical for Spot Ultra Vital Signs.

Section VI – Update regarding labeling

FDA Question/Statement #6:

In Section VI and attachments 3 and 4 of the submission you provide the device labeling. However, it appears that not all of the labeling specifications of the AAMI SP10: 1992 standard are included. Please include all the labeling specified in the AAMI SP10: 1992 standard. Furthermore, your labeling should include the sensor specifications (i.e. SpO₂, blood pressure, temperature, and pulse rate accuracy claims, etc.). Please note that this accuracy specification should be for each sensor and should be consistent with the results of clinical validation testing.

Welch Allyn Response:

Updates to the Spot Ultra Vital Signs Operator's Manual specification section can be found in Attachment 1 of this submission. The specifications are identical to the OEMs that have FDA 510(k) clearance and are listed in section III.

Welch Allyn has completed a review of AAMI SP10: 1992 regarding labeling and the following is the results:

Section 4.1.2.1 – The Spot Ultra Vital Signs is to be used under the supervision of a physician; an Operator's Manual was created and included in the first submission. The manual satisfies section 4.1.2.1 of the AAMI standard.

Section 4.1.2.2 – The Spot Ultra Vital Signs is not intended for over-the-counter sale. Therefore, this section does not apply to the device. However, the label section has been updated with the box label that will appear on the container for Spot Ultra.

Section 4.1.3a – On page 3 of the Operator's Manual is the section on Safety Warnings and Precautions. This is indicated in the Table of Content just in side of the Operator's Manual. This section satisfies section 4.1.3a of the standard.

Section 4.1.3b – On page 7 of the Operator's Manual that was included in the first submission is the section on Contents Checklist which represents the unpack requirement. The Set-up and Check requirements can be found on pages 8-13 of the Operator's Manual that was included in the first submission. On page 52 of the Operator's Manual that was included in the first submission is the list of Service Centers for the customer depending on what part of the world they are located.

Section 4.1.3c – On page 23 and running through page 34 of the Operator's Manual that was included in the first submission, are the standard operating instructions for the use of the Spot Ultra Vital Signs. Routine care and maintenance instruction along with re-calibration instruction are found on pages 40-43 of the Operator's Manual that was included in the first submission.

Section 4.1.3d – A statement will need to be added to the Operator’s Manual to satisfy section 4.1.3d of the AAMI Standard. See Attachment 1 for the new statement that will be included.

Section 4.1.3e – A statement will need to be added to the Operator’s Manual to satisfy section 4.1.3e of the AAMI Standard. See Attachment 1 for the new statement that will be included.

Section 4.1.3f – On page 52 of the Operator’s Manual that was included in the first submission is the list of Service Centers. The users will be required to send devices to these sites for repair if there is an issue with the Spot Ultra Vital Signs. This satisfies the requirement of section 4.1.3f

Section 4.1.3g – On page 5 of the Operator’s Manual that was included in the first submission, the first bullet point satisfies the requirement of section 4.1.3g.

Section 4.1.3h – On page 44 of the Operator’s Manual that was included in the first submission, the heart rate range is given. It is labeled as Pulse Rate Range.

Section 4.1.3i – On page 43 of the Operator’s Manual that was included in the first submission is the statement of when to check for calibration. This satisfies the requirement called out in section 4.1.3i.

Section 4.1.3j – On Page 6 in the Blood Pressure Cautions section of the Operator’s Manual that was included in the first submission is the statement regarding positioning of the patient’s arm and the effect thereof. A statement of physiological conditions needs to be added to the Operator’s Manual. See Attachment 1 for the new statement that will be included in the Operator’s Manual.

Section 4.1.3k – Storage Ranges are indicated on page 46 of the Operator’s Manual that was included in the first submission. A statement will need to be added to the Operator’s Manual regarding the non-use of the device outside of the storage ranges. See Attachment 1 for the new statement that will be included.

Section 4.1.3l – Product warranty information is found on page 51 of the Operator’s Manual that was included in the first submission. This satisfies the requirements of 4.1.3l.

Section 4.1.4.1 – The last bullet point on Page 4 of the Operator’s Manual that was included with the first submission is that statement that satisfies the requirement of 4.1.4.1.

Section 4.1.4.2 – The label of the AC Adapter is included in Attachment 1 of this submission that satisfies the requirements of section 4.1.4.2.

Section 4.1.4.3 - The label of the battery is included in Attachment 1 of this submission that satisfies the requirements of section 4.1.4.3.

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Section III – Update to General Information, 510(k) Summary and Comparison Table
FDA Question/Statement #3:

You tabulate a specification and technological comparison between the predicate and the proposed device that included information regarding different OEM modules and sensors, as well as general information comparing the overall system performance. However you do not provide a comparison of the hardware, firmware, and algorithms of the two devices. Please expand the table of the submission to include a comparison of the hardware, firmware and algorithms in the predicate and proposed device.

Welch Allyn Response:

The General Information section I. “Predicate Devices” and the 510(k) Summary section labeled “Predicate Devices” are now updated with the 510(k) clearance numbers of the OEMs that will be used in Spot Ultra Vital Signs beside that of the Spot Vital Signs. The new sections to read as follows:

I. General Information Update:

I. Predicate Devices

Welch Allyn Spot Vital Signs Device

Welch Allyn

510(k) Document Control Number *K002530 and K022163*

Braun Thermoscan PRO 4000

Braun GmbH

510(k) Document Control Number *K031928*

OxiMax N-550 Pulse Oximeter

Nellcor Puritan Bennett, Incorporated

510(k) Document Control Number *K021090*

Masimo SET RAD-5 Pulse Oximeter

Masimo Corporation

510(k) Document Control Number *K033296*

Welch Allyn SureTemp Plus Electronic Thermometer

Welch Allyn

510(k) Document Control Number *K030580*

II. 510(k) Summary Update:

Predicate Device: Welch Allyn Spot Vital Signs
Welch Allyn, Inc.
510(k) Document Control Number *K002530 and K022163*

Braun Thermoscan PRO 4000
Braun GmbH
510(k) Document Control Number *K031928*

OxiMax N-550 Pulse Oximeter
Nellcor Puritan Bennett, Inc.
510(k) Document Control Number *K021090*

Masimo SET RAD-5 Pulse Oximeter
Masimo Corporation
510(k) Document Control Number *K033296*

Welch Allyn SureTemp Plus Electronic
Thermometer
Welch Allyn, Inc.
510(k) Document Control Number *K030580*

With the update to the predicate devices in K040490's General Section and 510(k) Summary, the following is the update to the comparison table for the device and its predicates.

Note 1: A mistake was made in the statement of the 510(k) number for the Welch Allyn Spot Vital Signs. That 510(k) number is K022163 and is hereby corrected. The K024005 number is Welch Allyn's Vital Signs Monitor 510(k) clearance number.

Note 2: The Masimo SpO2 OEM has changed since the first submission. Welch Allyn has decided to go with the MS-11 OEM, which is present in the SET RAD-5, cleared under 510(k) number K033296 and not the NCT-11 and is reflected in the table below.

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
<u>Blood Pressure</u>		
BP Determination Method	Oscillometric	Oscillometric
Firmware Version	1.02	0.12
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	Intelligent Target inflation, (which can return a BP reading) or 160 mmHg (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
<u>Measurement Range</u>		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
<u>Measurement Accuracy</u>		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-1992
Heart Rate	+/- 5% (BP Determination)	+/- 5% or 3 BPM (BP Determination)

K040490 Spot Ultra Response

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 typical, 165 max.	15 to 30 typical, 150 max.
Mean Arterial Pressure	Calculated	Calculated
Overall System (General Characteristics)		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR wireless Capable Communication	Wireless (802.11b) Capable Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-25 to 55 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

K040490 Spot Ultra Response

	Nellcor Puritan Bennett N-550 Pulse Oximeter	Welch Allyn Spot Ultra Vital Signs Device
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model HW Used	MP506	MP506
Firmware Version	1.9.0.1	1.9.0.1
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified
Heart Rate	+/- 3 digits (w/o motion) +/- 5 digits (w/motion) Low Perfusion: +/- 3 digits	+/- 3 digits (w/o motion) +/- 5 digits (w/motion) Low Perfusion: +/- 3 digits
	Masimo Corporation SET RAD-5 Pulse Oximeter	Welch Allyn Spot Ultra Vital Signs Device
Massimo OEM SpO2		
Spo2 Measurement	Yes	Yes
OEM Model HW Used	MS-11	MS-11
Firmware version	4.1.0.0	4.1.0.0
Measurement Range		
SpO2	1-100%	1-100%
Heart Rate	25-240 bpm	25-240 bpm
Measurement Accuracy		
SpO2 (Adult, Pediatric)	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified
Heart Rate	+/- 3 digits (w/o motion) +/- 5 digits (w/ motion) Low Perfusion: +/- 3 digits	+/- 3 digits (w/o motion) +/- 5 digits (w/ motion) Low Perfusion: +/- 3 digits

K040490 Spot Ultra Response

	Welch Allyn SureTemp Plus Thermometer	Welch Allyn Spot Ultra Vital Signs Device
SureTemp® OEM Temperature		
Temperature	Via thermistor technology	Same (Hardware, Firmware + Algorithm are identical).
Firmware version	1.1	1.1
Measurement Range	80°F (26.6°C) to 110 °F (43.0°C)	80.0° F to 110° F (26.6°-43.0°C)
Measurement Accuracy	+/- 0.2 F (0.1 C) (Monitor Mode)	+/- 0.2 F (0.1 C) (Monitor Mode)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
	Braun GmbH Thermoscan Pro 4000	Welch Allyn Spot Ultra Vital Signs
Braun 4000 IR Thermometer		
Temperature	Taken using IR technology	Taken using IR Technology (Housings, Hardware, Algorithm + Firmware are identical)
Measurement Range	68° to 108° F (20° C to 42.2° C)	68° to 108° F (20° C to 42.2° C)
Measurement Accuracy	+/- 2° C (35.5° to 42.0°C)	+/- 2° C (35.5° to 42.0°C)
Display Resolution	0.1° C or 0.1° F	0.1° C or 0.1° F

Section IV – Update regarding hardware, firmware, algorithms

FDA Question/Statement #4:

It is unclear if the hardware, firmware, and algorithms used in the proposed device are the same as those in the predicate device. If they are not identical to the predicate device, then clinical validation is recommended.

Welch Allyn Response:

As seen in the updated General Section, 510(k) Summary, and the tabular comparison of the predicates to Spot Ultra, Welch Allyn is using the same previously cleared device OEMs in the Spot Ultra Vital Signs. These devices are:

- 1) Braun Thermoscan Pro 4000, 510(k) # K031928
- 2) Nellcor OxiMax N-550 Pulse Oximeter, 510(k) # K021090
- 3) Masimo SET RAD-5 Pulse Oximeter, 510(k) # K033296
- 4) Welch Allyn SureTemp Plus Electronic Thermometer, 510(k) # K030580

Hardware, firmware and the algorithms of these device OEMs are identical for the Spot Ultra Vital Signs.

Section VII – Software Documentation

FDA Question/Statement #7

In Section IV and beginning on page 25 of the submission, you provide a software description identifying the level of concern for each software module. However, the software description you have provided for your device is inadequate. Please provide the requested information found in Table 1 of the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” dated 29 May 1998.

Welch Allyn Response:

Documents required from Table 1 of the Guidance document mentioned above are listed in the table below:

Requirement and/or Document	Refer To
Level of concern	Attachment 2
Software Description	Attachment 2
Hazard Analysis	Attachment 2
SRS	Attachment 3
A chart depicting the partitioning of the SW system into functional subsystems, listing of the functional models and a description of how each fulfills the requirements	Attachment 2
SW Design Specification Document	Attachment 4
Traceability Matrix for the SW	Attachment 5
Summary of software life cycle, including a summary of the configuration management and maintenance activities	Attachment 6
Description of VV&T activities at the unit, integration and system level. System level test protocol including pass/fail criteria and test results	Attachment 7
Revision log history	Attachment 8
List of errors and bugs, which remain in the device and an explanation how they were determined to not impact safety or effectiveness, including operator usage and human factors	Attachment 9
Version number and date.	Attachment 8

Attachment I

The following are the specification that will be included in the Spot Ultra Operator's Manual for the OEMs devices.

Nellcor SpO2 Accuracy

- Without Motion - Adults: 70 to 100% + 2 digits*
- With Motion - Adults: 70 to 100% + 3 digits**
- Low Perfusion: 70 to 100% + 2 digits***
- <70% unspecified by the OEM

Biocompatibility testing has been conducted on Nellcor sensors in compliance with ISO10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

- * Adult specifications are shown for *OxiMax* MAX-A sensors. Saturation accuracy will vary by sensor type. Refer to the following Sensor Accuracy Grid.
- **Applicability: *OxiMax* MAX-A, MAX-AL, MAX-P, and MAX-I sensors.
- *** Specification applies to monitor performance and was validated with Biotek and Nellcor simulators.

Nellcor Sensor Accuracy Guide

Sensor Models	SpO2 Range 70% - 100%
OXIMAX Sensor Models Single Patient Use	
MAX-A,* MAX-AL*	+/- 2
MAX-P*	+/- 2
MAX-I*	+/- 2
MAX-R**	+/- 3.5
OxiCliq Sensor Models Single Patient Use	
OxiCliq A	+/- 2.5
OxiCliq P	+/- 2.5
Reusable Sensor Models	
D-YS (Infant to Adult)	+/- 3
D-YS & D-YSE	+/- 3.5
DS-100A	+/- 3
OXI-A/N (Adult)	+/- 3
OXI-P/I	+/- 3

* The accuracy specification under motion conditions is +/- 3. For a definition of motion, contact Nellcor Technical Services or your local Nellcor representative.

**The accuracy specification has been determined between saturations of 80% - 100%.

Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified

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saturation SpO₂ range. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry. All accuracies are expressed as + "X" digits. This variation equals + one standard deviation (+ 1 SD), which encompasses 68% of the population.

Masimo SpO₂ Specifications

Performance Measurement Range

SpO₂: 1-100%
 Pulse Rate 25-240 beats per minute (bpm)
 Pulse Amplitude Index: 0.02% - 20%

Accuracy

Saturation 70% to 100%

No Motion

Adults, Pediatrics +/- 2 digits
 Neonate +/- 3 digits

Motion

Adults, Pediatrics +/- 3 digits
 Neonate +/- 3 digits

Low Perfusion

Adults, Pediatrics +/- 2 digits
 Neonate +/- 3 digits

Pulse Rate Accuracy

Pulse Rate: 25-240 bpm

No Motion

Adults, Pediatrics, Neonate +/- 3 digits

Motion

Adults, Pediatrics, Neonate +/- 5 digits

Low Perfusion

Adults, Pediatrics, Neonate +/- 3 digits

Resolution

Saturation (%SpO₂) 1%
 Pulse Rate (bpm) 1 bpm

Masimo Sensor Accuracy Guide

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy	
		No Motion	Motion	No Motion	Motion
LNOP Adt	> 30 kg	+/-2%	+/-3%	+/-3 bpm	+/-5 bpm
LNOP Pdt	10 - 50 kg	+/-2%	+/-3%	+/-3 bpm	+/-5 bpm
LNOP Neo	<10 kg	+/-3%	+/-3%	+/-3 bpm	+/-5 bpm
LNOP NeoPt	< 1 kg	+/-3%	+/-3%	+/-3 bpm	+/-5 bpm
LNOP DC-I	>30 kg	+/-2%	+/-3%	+/-3 bpm	+/-5 bpm

Sensor Accuracy

Accuracy specified when used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules using PC series patient cables, during no motion. Numbers represent +/- 1 standard deviation. Plus or minus one standard deviation represents 68% of the population. SpO₂ accuracy from 70% to 100%. Pulse rate accuracy from 25 to 240bpm.

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Temperature Specifications

Temperature Ranges

SureTemp Plus

80.0° to 110° F (26.7° to 43.0° C)

Braun Pro 4000

68° to 108° F (20° to 42.2° C)

Temperature Accuracy

SureTemp Plus Calibration Accuracy

±0.2° F (0.1° C) (Monitor Mode)

Braun Accuracy for Displayed Temperature Ranges

±0.2° C (95.9° to 107.6° F) (35.5° to 42° C)

±0.3° C (outside this temperature range)

Braun Display Resolution

0.1°C or °F

SureTemp Plus Determination Time

Oral: 4 to 6 seconds

Adult Axillary: 12 to 15 seconds (age 18 years and older)

Pediatric Axillary: 10 to 13 seconds (age 17 years and younger)

Rectal: 10 to 13 seconds

CAUTIONS

To satisfy section 4.1.3k; the following statements will be added to the General Cautions section of the DFU:

It is recommended that the device be used within stated temperature ranges, as seen on page 46 of the Directions for Use manual. Using the device outside these temperature ranges will cause the unit to not meet its performance specifications.

To satisfy sections 4.1.3e, j, d and b; the following statements will be added to the Blood Pressure Cautions section of the DFU:

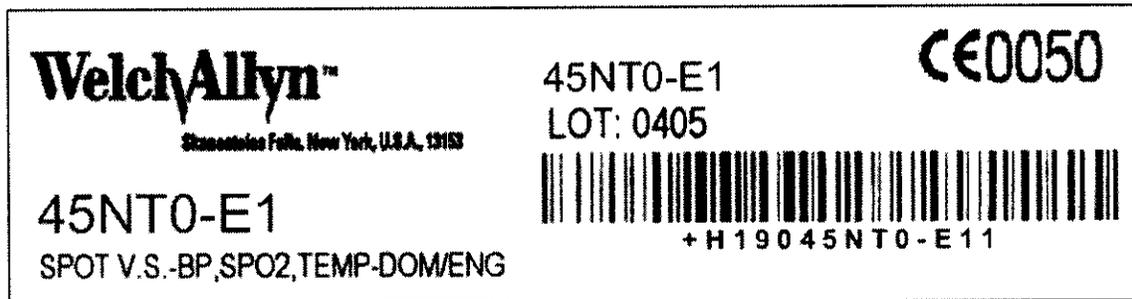
Blood pressure measurements determined with this device are equivalent to those obtained by trained observer using the cuff/stethoscope auscultation method and by intraarterial blood pressure measurement within the limits prescribed by the American National Standard, Electronic or automated sphygmomanometer.

A blood pressure recording can be affected by the position of the subject and his or her physiologic condition.

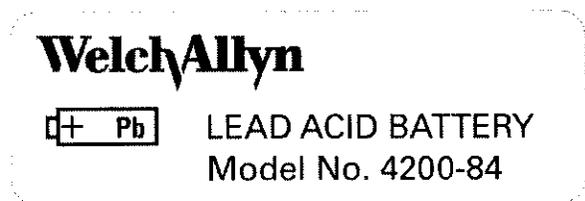
The device uses the oscillometric method of measurement. The fifth Korotkoff sound was used to determine overall efficacy. Clinical reports are available by contacting Welch Allyn Customer Service.

Additional Labels for the Spot Ultra Device:

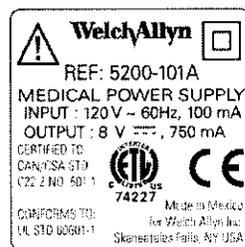
To satisfy section 4.1.2.2 the Boxing label is provided:



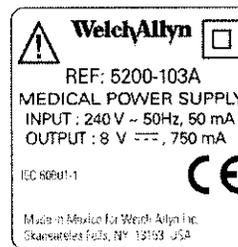
To satisfy section 4.1.4.3 Battery Label that will reside on the inside of the battery compartment:



To satisfy section 4.1.4.2 the following are the labels for the transformers:



421279



421279-1

Attachment 2 – Software Risk Assessment

The following attached document satisfies the requirements of document 1, 2, 3, and 5 in the list from the FDA Guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” dated 29 May 1998.



**Spot Ultra Vital Signs
Software Risk Assessment**

Version 2.0

Date: 30 April 2004

Document Number: (b)(4)

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Approvals:
Project Leader: _____ Date: _____

Lead Software Engineer: _____ Date: _____

Quality Engineer: _____ Date: _____

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Revision History

Revision	Date	Author	Description
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(b) (4), (b) (6)

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(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

(b)(4) Software Risk Assessment

Records Processed Under FOIA Request #016-6537, Released by CDRH on 6/17/2016

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Firmware Version	1.02	0.12
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	Intelligent Target inflation, (which can return a BP reading) or 160 mmHg (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-1992
Heart Rate	+/- 5% (BP Determination)	+/- 5% or 3 BPM (BP Determination)

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K040490 Spot Ultra Response

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 typical, 165 max.	15 to 30 typical, 150 max.
Mean Arterial Pressure	Calculated	Calculated
Overall System (General Characteristics)		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR wireless Capable Communication	Wireless (802.11b) Capable Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-25 to 55 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

K040490 Spot Ultra Response

	Nellcor Puritan Bennett N-550 Pulse Oximeter	Welch Allyn Spot Ultra Vital Signs Device
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model HW Used	MP506	MP506
Firmware Version	1.9.0.1	1.9.0.1
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified
Heart Rate	+/- 3 digits (w/o motion) +/- 5 digits (w/motion) Low Perfusion: +/- 3 digits	+/- 3 digits (w/o motion) +/- 5 digits (w/motion) Low Perfusion: +/- 3 digits
	Masimo Corporation SET RAD-5 Pulse Oximeter	Welch Allyn Spot Ultra Vital Signs Device
Massimo OEM SpO2		
Spo2 Measurement	Yes	Yes
OEM Model HW Used	MS-11	MS-11
Firmware version	4.1.0.0	4.1.0.0
Measurement Range		
SpO2	1-100%	1-100%
Heart Rate	25-240 bpm	25-240 bpm
Measurement Accuracy		
SpO2 (Adult, Pediatric)	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified	70-100% +/- 2 digits (w/o motion) 70-100% +/- 3 digits (w/ motion) Low Perfusion: 70-100% +/- 2 digits <70% unspecified
Heart Rate	+/- 3 digits (w/o motion) +/- 5 digits (w/ motion) Low Perfusion: +/- 3 digits	+/- 3 digits (w/o motion) +/- 5 digits (w/ motion) Low Perfusion: +/- 3 digits

K040490 Spot Ultra Response

	Welch Allyn SureTemp Plus Thermometer	Welch Allyn Spot Ultra Vital Signs Device
SureTemp® OEM Temperature		
Temperature	Via thermistor technology	Same (Hardware, Firmware + Algorithm are identical).
Firmware version	1.1	1.1
Measurement Range	80°F (26.6°C) to 110 °F (43.0°C)	80.0° F to 110° F (26.6°-43.0°C)
Measurement Accuracy	+/- 0.2 F (0.1 C) (Monitor Mode)	+/- 0.2 F (0.1 C) (Monitor Mode)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
	Braun GmbH Thermoscan Pro 4000	Welch Allyn Spot Ultra Vital Signs
Braun 4000 IR Thermometer		
Temperature	Taken using IR technology	Taken using IR Technology (Housings, Hardware, Algorithm + Firmware are identical)
Measurement Range	68° to 108° F (20° C to 42.2° C)	68° to 108° F (20° C to 42.2° C)
Measurement Accuracy	+/- 2° C (35.5° to 42.0°C)	+/- 2° C (35.5° to 42.0°C)
Display Resolution	0.1° C or 0.1° F	0.1° C or 0.1° F

Lacy, Frank

From: Husband, Michael J
Sent: Wednesday, June 09, 2004 11:51 AM
To: Lacy, Frank
Cc: Aguel, Felipe
Subject: K040490

Frank,

I was assigned a consult review on K040490. The original reviewer was Dr. Aguel. Attached is my review memo. I will drop a signed hard copy by your office.



k040490.doc (59
KB)

Thank you,

Michael Husband
Anesthesiology and Respiratory Branch
301-827-9612

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, 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.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Consult Review

K040490

Date: June 9, 2004

To: Frank Lacy

From: Michael Husband

Company Name: Welch Allyn, Inc.

Device Name: Welch Allyn Spot Ultra Vital Signs Device.

Office: HFZ-480

Division: DAGID/ARDB

Device Description

The device is a one-time vital signs measurement device. The device is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature, and oxygen saturation for adult and pediatric patients. The device does not have continuous monitoring capability with timed cycle intervals or any programmable alarm features. The device has the following indications for use:

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO₂) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon order of a physician or licensed health care provider.

Consult Request

The Cardiac Electrophysiology and Monitoring Branch requested a consult review on the SpO₂ modules used in the device. The following deficiency regarding the SpO₂ portion of the device was sent to the sponsor on April 21, 2004.

It is unclear if the hardware, firmware, and algorithms used in the proposed device are the same as those in the predicate device. If they are not identical to the predicate device, then clinical validation is recommended. Furthermore, clinical validation is recommended when the device is used in conjunction with the Massimo OEM SpO₂ and Braun 4000 IR thermometer, since these are have not been cleared for use nor validated with the device. The following suggestions should be included in your testing protocol for the pulse oximeter module:

Data from laboratory testing with human subjects should be provided to validate the functional

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(b)(4) Software Risk Assessment

If the data and protocols of the non-recognized standards cited in deficiency 2 (i.e. EN865 (1997)) conform to the above list, providing detailed test reports including protocols, data, and conclusions may suffice to address deficiency 4.

The sponsor has responded by revising the SpO2 modules used in their device. The sponsor has stated that the Nellcor OxiMax N-550 Pulse Oximeter (K021090) and the Masimo SET RAD-5 Pulse Oximeter (K030580) will be used with their device.

The following is our review of the supplemental information provided by the sponsor:

Intended Use

Both of the pulse oximeters provided are cleared for adult and pediatric use. There are no new issues of safety and efficacy with the intended use in regard to the SpO2 sensors.

Materials/Biocompatibility

The sensors used are identical to the sensors previously cleared in the above referenced 510(k) numbers. There are no new issues of safety and efficacy with the biocompatibility in regard to

Design/Specifications

The sensors used are identical to the sensors previously cleared in the above referenced 510(k) numbers. There are no new issues of safety and efficacy with the design and specifications in regard to the SpO2 sensors.

Sterilization/Reuse

The SpO2 devices are provided non-sterile. Cleaning instructions for the SpO2 sensors can be found on page 41 of the user manual in the original submission. No validation information for this process has been provided by the sponsor.

Labeling

Revised labeling can be found in Attachment 1 of the supplemental information. The revised labeling details the specifications for the above SpO2 sensors. There are no new issues of safety and efficacy with the labeling of the device in regard to the SpO2 sensors.

Performance Testing

The sensors used are identical to the sensors previously cleared in the above referenced 510(k) numbers. However, these sensors are not identical to those used in the sponsor's previous devices.

Clinical Testing

Since the SpO2 modules described by the sponsor have been previously cleared, no clinical testing is necessary.

Software

The software requirements specification still references the Masimo NCT-11. The sponsor should update this document to reflect the use of the MS-11 OEM model used. No verification and Validation protocols or testing are present for the software of the device. The sponsor has stated that they are still in the process of completing verification and validation.

Environmental Testing

No electrical safety, electromagnetic compatibility, or mechanical testing is present for the device. The sponsor has provided a statement of conformity to IEC 60601-1.

It is still unclear which SpO2 modules the sponsor is using with their device. I recommend the following issues be presented to the sponsor regarding the SpO2 modules:

(b)(4)Software Risk Assessment

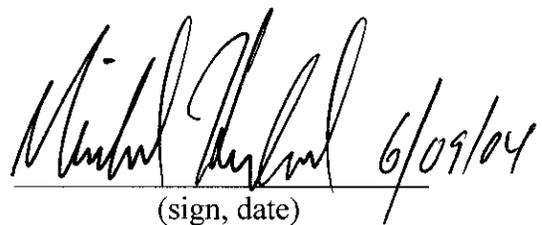
3. You have not provided any validation and verification for the SpO2 software for your device. Please provide this information in accordance to the guidance found at <http://www.fda.gov/cdrh/ode/software.pdf>.
4. You have provided cleaning instructions for the SpO2 sensors on page 41 of your user manual. Please provide test data that demonstrates that each reusable component will function within specifications after repeated cleaning. Please demonstrate this with all procedures mentioned in the labeling. If you are unable to complete these tests with any of the cleaning procedures described in the labeling, please remove these procedures. Please provide data that demonstrates that the device functions within its specified parameters after thirty cycles of cleaning as recommended by British Standard 6850 as a minimum simulation of reuse.

We would also recommend that a declaration of conformity to IEC 60601-1 is not sufficient to determine EMC/electrical/mechanical safety. We would recommend that the sponsor also provide the following additional information:

- a. Please provide a summary of the testing performed.
- b. Please provide a summary of the requirements that were met.
- c. Please provide the pass/fail criteria used for each test, if the criteria are not stated in the standard.
- d. Please provide a description of the performance of the device during each immunity test (i.e. degradation observed).
- e. Please provide a summary outlining the differences between the EN standard test methods and criteria as compared to those outlined in the FDA Reviewer Guidance found at <http://www.fda.gov/cdrh/ode/638.pdf>.

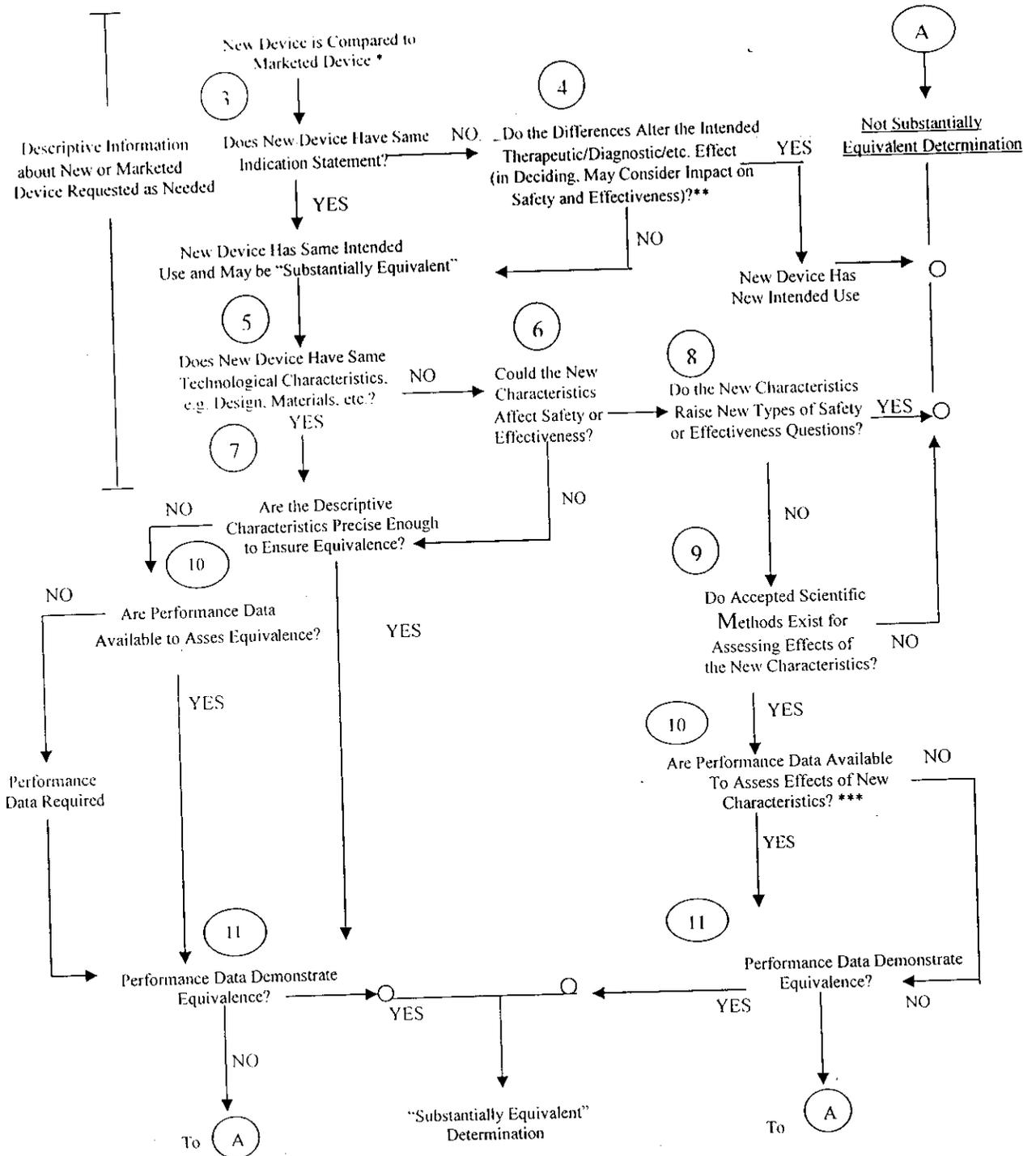
Recommendation

I recommend the device be put on hold pending the above information.

A handwritten signature in black ink, followed by the date 6/09/04. The signature is written in a cursive style. Below the signature and date, the text "(sign, date)" is printed in a smaller font.

(sign, date)

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.

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(b)(4) Software Requirements

Records Processed under FOIA Request 2016-6131. Released by CDRH on 3/17/2016

(b)(4) Software Requirements

Records Processed under FOIA Request 2016-6131. Released by CDRH on 3/17/2016

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(b)(4) Software Requirements

Records Processed under FOIA Request 2016-6131. Released by CDRH on 3/17/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/1/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/17/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/17/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/17/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/17/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/1/2016

(b)(4) Verification Plan

Record Processed under FOIA Request 2016-06537; Released by CDRH on 3/17/2016



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 19 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Avenue
Irvine, California 92614-5826

Re: K033296
Trade/Device Name: Masimo SET RAD-5 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 23, 2004
Received: January 26, 2004

Dear Mr. Cronin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

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Page 2 – Mr. James J. Cronin

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K033296

Device Name: Masimo SET Rad 5 Pulse Oximeter

Indications For Use:

The Masimo SET® Rad5 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). The Masimo SET® Rad 5 Pulse Oximeter is indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

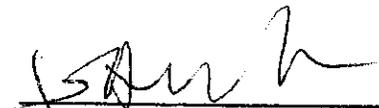
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033296

0080

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Welch Allyn Spot Check Device Pre-market Notification

K002530

II. 510(k) Summary

NOV 14 2000

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
95 Old Shoals Road
Arden, NC 28704

Contact Person: Joseph D. Buchanan
Senior Quality Assurance Engineer

Date Prepared: 14 August 2000

Proprietary Name: Welch Allyn Spot Check Device

Common Name: Vital Signs Measurement Device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure System

Predicate Device: Welch Allyn Vital Signs Monitor
Welch Allyn, Inc.
510(k) Document Control Number *K951193*

Description of the Device:

The Welch Allyn Spot Check Device is not a monitor, but a one time vital signs measurement device. This product will not have continuous monitoring capability with timed cycle intervals, memory, or any various programmable alarm features. The device is intended to provide the physician, physician's assistant, or nurse, facing high patient traffic or multiple tasks, a cost effective method to determine a one-time vital signs reading on the spot. The base unit will have non-invasive blood pressure (BP) measurement. Options will also be offered such as SureTemp[®] thermometry, Nellcor[®] pulse oximetry (SpO₂), mounting bracket, and rolling stand. The device may be interfaced with an external printer via an infrared port.

The Welch Allyn Spot Check Device is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO₂) for adult and pediatric patients. The Welch Allyn Spot Check Device also calculates Mean Arterial Pressure (MAP). All blood pressure, pulse, temperature and SpO₂ values are displayed on a large, easy-to-read LCD display, and may be printed via an external thermal printer, as desired. The rechargeable battery and wide variety of

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Welch Allyn Spot Check Device Pre-market Notification

mounting accessories make the Welch Allyn Spot Check Device convenient for many locations.

The Welch Allyn Spot Check Device is intended for use in a wide variety of health care settings. This includes hospital departments, alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes. ***The Welch Allyn Spot Check Device is not intended for the monitoring of patients.*** The Welch Allyn Spot Check Device is not intended for use in environments which are not supervised by a health care practitioner.

Indications/Contraindications For Use of the Device:

The Welch Allyn Spot Check Device Check Device is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO₂) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece Cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.

The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.

The Welch Allyn Spot Check Device is not intended to monitor patients vital signs.

The Welch Allyn Spot Check Device is not defibrillator proof.

Technological Characteristics:

The Welch Allyn Spot Check Device Check Vital Signs Device utilizes the same BP Algorithm, the same temperature technology and algorithm, and the same pulse oximetry OEM as the Welch Allyn Vital Signs Monitor. The following table summarizes the similarities between the Welch Allyn Spot Check Device and the Welch Allyn Vital Signs Monitor.

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Check Device and the Welch Allyn Vital Signs Monitor.

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Welch Allyn Spot Check Device Pre-market Notification

	Welch Allyn Spot Check Device	Welch Allyn Vital Signs Monitor.
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate	40-200 bpm	40-200 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-1992
Heart Rate	+/- 5% (BP Determination) +/- 3% (SpO2 Determination)	+/- 5% (BP Determination) +/- 3% (SpO2 Determination)
BP Time Intervals (Min.)	NA	Manual, Stat, 1, 3, 4, 5, 10, 15, 30, 45, 60, 90 min.
Measurement time (sec.)	20-45 typical, 165 max.	20-45 typical, 165 max.
Mean Arterial Pressure	Calculated	Calculated
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model Used	MP205	MP205
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	40-200 bpm
Measurement Accuracy		
SpO2	70-100% +/- 3% <70% unspecified	70-100% +/- 3% <70% unspecified
Heart Rate	+/- 3 bpm	+/- 3 bpm
Alarm Adjustable Ranges		
SpO2 Low	NA	70-100%
SureTemp® OEM Temperature		
Temperature	Yes	Yes
Measurement Range	86F (30C) to 109.4F (43.0C)	84F (28.9C) to 108F (42.2C)
Measurement Accuracy	per ASTM E1112-86 (1991)	per ASTM E1112-86 (1991)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
Overall System		

Welch Allyn Spot Check Device Pre-market Notification

Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR Capable Communication	RS232 Communications
Display Type	Custom LCD	7 Segment LED PCB
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	LED illuminates when low battery voltage is detected.
Number of readings stored in memory	No readings are stored	Last 99 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	200 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	6.5 inches (16.5 cm)
Length	5.72 inches (14.53 cm)	8.6 inches (21.8 cm)
Depth	4.73 inches (12.01 cm)	5.0 inches (12.7 cm)
Weight	4.25 lbs	6 lbs
Operating Temperature	10 to 40 C (except temperature which is 16 to 40 C)	10 to 40 C (except temperature which is 16 to 40 C)
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170m (557 ft) to +4877 (16,000 ft)	-170m (557 ft) to +4877 (16,000 ft)
Storage Temperature	-20 to 50 C	-20 to 50 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2000

Joseph D. Buchanan
Senior Quality Engineer
Welch Allyn, Inc.
95 Old Shoals Road
Arden, NC 28704-9739

Re: K002530
Trade Name: Welch Allyn Spot Check Device
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: August 14, 2000
Received: August 16, 2000

Dear Mr. Buchanan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

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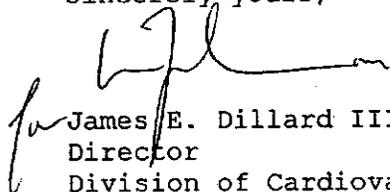
Page 2 - Joseph D. Buchanan

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Welch Allyn Spot Check Device Pre-market Notification

VII. Indications for Use Statement

510(k) Number: ~~Unknown~~ K002530

Device Name: Welch Allyn Spot Check Device

Indications for use: The Spot Check Device is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO₂) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.

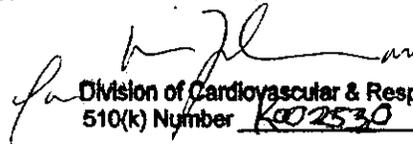
The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.

The Welch Allyn Spot Check Device is not intended to monitor patients vital signs.

The Welch Allyn Spot Check Device is not defibrillator proof.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K002530

Prescription Use _____ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

K022163

Welch Allyn Spot Vital Signs Pre-market Notification

SEP 17 2002

V. 510(k) Summary

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153

Contact Person: David Klementowski
Corporate Regulatory Affairs Manager

Date Prepared: 20 May 2002

Proprietary Name: Welch Allyn Spot Vital Sign Monitor with MP506

Common Name: Vital Signs measurement device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure
Measurement System

Predicate Devices: Welch Allyn Spot Vital Signs
Welch Allyn, Inc.
510(k) Document Control Number *K002530*

OxiMax Pulse Oximetry System w/N-595 Pulse Oximeter
Nellcor Puritan Bennett, Incorporated
510(k) Document Control Number *K012891*

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Welch Allyn Spot Vital Signs Pre-market Notification

Description of the Device:

The Welch Allyn Spot Vital Signs is not a monitor, but a one-time vital signs measurement device. This product will not have continuous monitoring capability with timed cycle intervals, memory, or any various programmable alarm features. The device is intended to provide the physician, physician's assistant, or nurse, facing high patient traffic or multiple tasks, a cost effective method to determine a one-time vital signs reading on the spot. The base unit will have non-invasive blood pressure (BP) measurement. Options will also be offered such as SureTemp[®] thermometry, Nellcor[®] pulse oximetry (SpO₂), mounting bracket, and rolling stand. The device may be interfaced with an external printer via an infrared port.

The Welch Allyn Spot Vital Signs is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO₂) for adult and pediatric patients. The Welch Allyn Spot Vital Signs also calculates Mean Arterial Pressure (MAP). All blood pressure, pulse, temperature and SpO₂ values are displayed on a large, easy-to-read LCD display, and may be printed via an external thermal printer, as desired. The rechargeable battery and wide variety of mounting accessories make the Welch Allyn Spot Vital Signs convenient for many locations.

Intended Use

The Welch Allyn Spot Check Device is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO₂) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece Cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.

The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.

The Welch Allyn Spot Check Device is not intended to monitor patient's vital signs.

The Welch Allyn Spot Check Device is not defibrillator proof.

Welch Allyn Spot Vital Signs Pre-market Notification

Action Taken to Comply with Section 514 of the Act

The agency has recognized the following standards:

- a) EN60601-1
- b) EN60601-1-1
- c) EN60601-1-2
- d) EN60601-1-4
- e) AAMI SP10
- f) ASTM 1112-86
- g) EN 865

The Welch Allyn Spot Vital Sign with MP506 Pulse Oximeter OEM module meets the requirements called out in these standards. Evidence of compliance is on file at Welch Allyn and is available for review upon demand.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2002

Mr. David Klementowski
Corporate Regulatory Affairs Manager
Welch Allyn, Incorporated
4341 State Street Road
Skaneateles Falls, New York 13153-0220

Re: K022163

Trade/Device Name: Welch Allyn Spot Vital Sign Monitor with MP506
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 13, 2002
Received: August 20, 2002

Dear Mr. Klementowski:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

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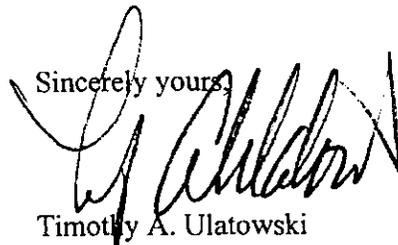
Page 2 – Mr. Klementowski

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Welch Allyn Spot Vital Signs Pre-market Notification

III. Indications for Use Statement

510(k) Number: Unknown K022163

Device Name: Welch Allyn Spot Vital Signs

Indications for use: The Welch Allyn Spot Vital Signs is intended for measurement of blood pressure, pulse rate, temperature and oxygen saturation (SpO₂) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

** The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn small cuff (5200-03) and the small One Piece cuff (5200-13) are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.*

** The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.*

** The Welch Allyn Spot Check Device is not designed for use of axillary temperature option above three years of age in children.*

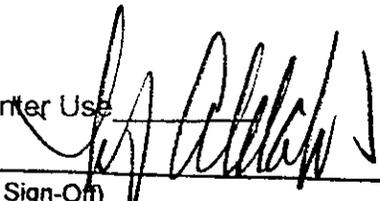
** The Welch Allyn Spot Check Device is not intended to monitor patient's vital signs.*

** The Welch Allyn Spot Check Device is not defibrillator proof.*

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Or Over-The-Counter Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022163

K030580

Welch Allyn, Inc.

510(k) Premarket Notification SureTemp® Plus

Section 11: 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR § 807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

Submitted By

MAY 06 2003

Debra L. Jackson, RAC
Senior Manager, Quality Assurance & Regulatory Affairs
Welch Allyn, San Diego
7420 Carroll Road
San Diego, California 92121

Telephone: (315) 685-4133
Contact: Dave Klementowski
Date Prepared: February 21, 2003

Device Name

Common or usual name: Thermometer, Electronic Thermometer,
Predictive Thermometer

Classification

Class: II
Panel: 80
Procode: FLL - clinical electronic thermometer

Predicate Devices

The SureTemp® Plus clinical electronic thermometer consists of an elongated metal heat-conductive probe connected to the thermometer's main body through a coiled cord. The probe contains a thermistor that conveys temperature information to the main body for calculation of patient temperature.

Prior to use, a plastic probe cover must cover the probe. This cover must not be a significant barrier to the transfer of heat from the patient to the probe body (and thermistor). In addition, the disposable nature of the probe cover prevents microbiological cross-contamination among patients which might occur with a re-useable probe. Calculation of patient temperature may (in the normal or predictive mode) utilize algorithms that enable accurate temperature prediction within 4 to 15 seconds of probe placement (times vary based on the temperature mode selected).

There are two model designations for the SureTemp® Plus and they are the Model 692 and 690. The Model 690 is the lower cost version of the Model 692 and does not include the backlit display and security features or pulse timer.

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Device Description

The SureTemp® Plus clinical electronic thermometer consists of an elongated metal heat-conductive probe connected to the thermometer's main body through a coiled cord. The probe contains a thermistor that conveys temperature information to the main body for calculation of patient temperature.

Prior to use, a plastic probe cover must cover the probe. This cover must not be a significant barrier to the transfer of heat from the patient to the probe body (and thermistor). In addition, the disposable nature of the probe cover prevents microbiological cross-contamination among patients which might occur with a re-useable probe. Calculation of patient temperature may (in the normal or predictive mode) utilize algorithms that enable accurate temperature prediction within 4 to 15 seconds of probe placement (times vary based on the temperature mode selected).

There are two model designations for the SureTemp® Plus and they are the Model 692 and 690. The Model 690 is the lower cost version of the Model 692 and does not include the backlit display and security features or pulse timer.

Intended Use

The Welch Allyn SureTemp® Plus thermometer enables the health care professional to make an accurate prediction of a febrile, afebrile or hypothermic patient's oral temperature in approximately 4-6 seconds (in Normal mode). Pediatric Axillary (age 17 and younger) temperatures can be obtained in approximately 10-13 seconds. Adult Axillary temperatures (in Normal mode) can be obtained in approximately 12-15 seconds. Rectal temperatures (in Normal mode) can be obtained in approximately 10-13 seconds. Normal (predictive) mode is available for oral, rectal, and axillary use.

In the Monitor mode, the instrument provides the capability of accurate, long-term monitoring of actual oral, rectal or axillary temperature, and of following the temperature whether constant, increasing, or decreasing.

The SureTemp is a clinical grade thermometer intended for use by healthcare practitioners only; typically in a hospital, clinic, long-term care, or mobile health care environment. It is not intended for home use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 06 2003

Ms. Debra L. Jackson
Senior Manager, QA/RA
Welch Allyn, Incorporated
7420 Carroll Road
San Diego, California 92121

Re: K030580
Trade/Device Name: SureTemp® Plus
Regulation Number: 880.2910
Regulation Name: Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 21, 2002
Received: February 24, 2003

Dear Ms. Jackson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Page 2 – Ms. Jackson

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K030580

DEVICE NAME: SureTemp[®] Plus

INDICATIONS FOR USE:

The Welch Allyn SureTemp[®] Plus thermometer is intended to be used by healthcare professionals, to provide an accurate prediction of patient temperature using the oral, axillary or rectal body sites in 4 to 15 seconds, or to provide an actual temperature reading in the continuous monitor mode in about 3 minutes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

Patricia Ciccone

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030580

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MAY 08 2002

K021090

tyco

Healthcare

Nellcor

4280 Hacienda Drive
Pleasanton, CA 94588

Tele: 925 463-4000
Fax: 925 463-4020

510(k) Summary

Submitted by: Nellcor Puritan Bennett, Incorporated
(a business unit of Mallinckrodt Inc.,
a division of Tyco Healthcare Group, LP)
4280 Hacienda Drive
Pleasanton, CA 94588

Company Contact: Gina To
Senior Regulatory Affairs Project Manager
(925) 463-4427
(925) 463-4020 – FAX

Date Summary Prepared: April 3, 2002

Trade Name: OxiMAX N-550 Pulse Oximeter

Common/Usual Name: Pulse Oximeter

Classification Name: Oximeter (74DQA) per 21 CFR §870.2700

Legally Marketed (Unmodified) Device: Nellcor Puritan Bennett, Inc., OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors (510(k) #K012891)

Device Description

The N-550 Pulse Oximeter is designed for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate by use of one of a range of compatible Nellcor Puritan Bennett OxiMAX oxygen transducers (sensors). The N-550 Pulse Oximeter displays digital values of SpO₂ and Pulse Rate, and individual LED's are used for status indicators. Pulse Amplitude is displayed by means of a "blip bar" presentation.

Intended Use

The N-550 Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The N-550 Pulse Oximeter is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. This device is for prescription use only.

N-550 Pulse Oximeter

510(k) Summary

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00239

Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The N-550 Pulse Oximeter has the same technological characteristics as the above referenced predicate device, the N-595 Pulse Oximeter. The only modifications relate to an ergonomic change from LCD to LED display and a change in oximeter module.

Tests Performed to Support Determination of Substantial Equivalence

Clinical and non-clinical tests were performed to support the determination of substantial equivalence. Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 - Institutional Review Boards.

Conclusions

The technological characteristics of the N-550 Pulse Oximeter and the results of non-clinical and clinical tests do not raise new questions of safety or effectiveness when compared to the legally marketed (unmodified) device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2002

Nellcor Puritan Bennett, Incorporated
c/o Ms. Gina To
4280 Hacienda Drive
Pleasanton, CA 94588

Re: K021090
OxiMAX N-550 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 24, 2002
Received: April 25, 2002

Dear Ms. To:

This letter corrects our substantially equivalent letter of May 8, 2002 regarding the indications for use of your device. Our letter incorrectly limited your device to use in military environments.

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 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). 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.

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

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Page 2 – Ms. Gina To

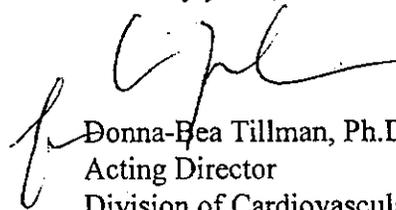
addition, FDA may publish further announcements concerning your device in the Federal Register.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021090

Device Name: OxiMAX N-550 Pulse Oximeter

Indications For Use:

The N-550 Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The N-550 Pulse Oximeter is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. This device is for prescription use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

~~X~~

(Optional Format 3-10-98)


Division of Cardiovascular & Respiratory Devices
510(k) Number K021090

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00009

510(k) SUMMARY

FEB 19 2004

K033296

Submitted by: Masimo Corporation
2852 Kelvin Ave
Irvine, CA 92614-5826
(714) 250-9688
FAX (714) 250-9686

Company Contact: James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance

Date Summary Prepared: December 5, 2003

Trade Name Masimo SET[®] Rad-5 Pulse Oximeter

Common Name Pulse Oximeter

Classification Name Oximeter (74DQA) (870.2700)

Substantially Equivalent Devices Masimo SET[®] Radical Pulse Oximeter with SatShare[™] and LNOP series of Sensors and Cables
510(k) Number - K031330

Features and Benefits

- Clinically proven Masimo SET[™] technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO₂, pulse rate, alarm, and perfusion index displays
- Signal IQ[™] for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 36 hours on 4 "AA" alkaline batteries
- Audible Alarm for sensor-off and low battery
- Alarms for Hi/Low saturation and Hi/Low pulse rate
- FastSat[™]
- Three sensitivity levels - Max, Normal and APOD[™]
- Adjustable alarm volume
- Adjustable averaging 2 to 16 seconds

Intended use

The Masimo SET[®] RAD-5 Pulse Oximeter is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, and mobile environments.

0020

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510(k) SUMMARY

Indications for use

The Rad-5 Handheld Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). The Rad-5 Handheld Pulse Oximeter is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Principles of Operation

The principles of operation of the Masimo SET[®] Rad-5 pulse oximeter are that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET[®] Rad-5 pulse oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO₂ saturation in an empirically derived equation into the Masimo SET[®] Rad-5 software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and non-motion conditions.

Method of Operation

The Masimo SET[®] Rad-5 pulse oximeter is turned on. An oximetry sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the Rad-5 pulse oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO₂ value. The practitioner can adjust the high and low alarm limits to their desired value, if required. The practitioner can then use the information that is continuously displayed on the monitor, and hear if an alarm limit is reached, to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

Power Source

The Masimo SET[®] Rad 5 pulse oximeter is powered by 4 AA batteries with an operating time of 36 hours⁵.

Specifications and Operating Ranges

Range		
	Saturation (% SpO ₂)	1% - 100%
	Pulse Rate (bpm)	25 - 240
	Perfusion	0.02% - 20%
Accuracy		
	Saturation (% SpO ₂) - During No Motion Conditions ¹	
	Adults, Pediatrics	70% - 100% ± 2 digits 0% - 69% unspecified
	Neonates	70% - 100% ± 3 digits 0% - 69% unspecified
	Saturation (% SpO ₂) - During Motion Conditions ^{2,3}	
	Adults, Pediatrics ²	70% - 100% ± 3 digits 0% - 69% unspecified
	Neonates ³	70% - 100% ± 3 digits

0021

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510(k) SUMMARY

0% - 69% unspecified

Pulse Rate (bpm) - During No Motion Conditions¹

Adults, Pediatric, Neonates 25 to 240 ± 3 digits

Pulse Rate (bpm) - During Motion Conditions^{2,3}

Adults, Pediatric, Neonates 25 to 240 ± 5 digits

Resolution

Saturation (% SpO₂) 1%

Pulse Rate (bpm) 1

Low Perfusion Performance⁴

> 0.02% Pulse Amplitude Saturation (% SpO₂) ± 2 digits

and % Transmission > 5% Pulse Rate ± 3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Power

Internally powered by 4 "AA" Alkaline batteries

Isolation

No external power or ground connection, internally powered only

Environmental

Operating Temperature 41°F to + 104°F (5°C to +40°C)

Storage Temperature -40°F to + 158°F (-40°C to +70°C)

Relative Humidity 5% to 95% noncondensing

Operating Altitude 500 mbar to 1060 mbar pressure

-1,000 ft to 18,000 ft (-304 m to 5,486 m)

Circuitry

Microprocessor controlled

Automatic self-test of oximeter when powered on

Automatic setting of parameters

Automatic alarm messages

Display

Type LED, 7-segment

Data Displayed Pulse Rate, SpO₂ %, Alarm status, alarm silenced status, Perfusion Index Bar, Signal IQ Bar, Battery Status, APOD, FastSat.

Audio indicators

Adjustable volume audible pulse: OFF and 33% to 100% in 3 steps

Adjustable volume audible alarm tone: levels and 33% to 100% in 3 steps

Alarm silence (120 seconds); all mute (continuous silence)

Pulse rate out-of-limits alarm

SpO₂ level out-of limits alarm

Sensor condition alarms

System failure and battery low alarms

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0022

510(k) SUMMARY

Physical characteristics

Dimensions: 6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight: 13oz. (0.32 kg)

Modes

Averaging mode: 2, 4, 8, 10, 12, and 16 seconds
Sensitivity: Normal, APOD, and MAX

- 1 The Masimo SET Technology with LNOP Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- 2 The Masimo SET Technology with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- 3 The Masimo SET Technology with LNOP Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- 4 The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- 5 This represents approximate run time at lowest indicator brightness, using a new, fully charged battery.

Environmental Testing

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed.

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET[®] Rad-5 Pulse Oximeters was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

The results of the bench testing showed that the Masimo SET[®] Rad-5 Pulse Oximeters returned the same saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits when compared to the simulators used.

Clinical tests performed that support a determination of substantial equivalence.

Clinical studies were performed using the Masimo SET[®] technology on healthy adult volunteer subjects during no motion and motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET[®] technology on neonates during no motion and motion conditions and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET[®] technology on healthy adult volunteer subjects who were subjected to low perfusion conditions and to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

0023

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510(k) SUMMARY

Clinical studies were performed using the Masimo SET[®] technology on neonates with low perfusion conditions and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 - Institutional Review Boards.

The results from the clinical studies show that the Masimo SET[®] technology saturation accuracy values for adults and pediatrics within ± 2 digits during no motion conditions and ± 3 digits during motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values within ± 3 digits during no motion conditions and ± 5 digits during motion conditions when compared to the ECG.

The specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on neonates with saturations down to 83% combined with clinical studies on adults to show that the Masimo SET[®] technology to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.

Conclusions

The results of the **environmental testing** demonstrated that the Masimo SET[®] Rad-5 Pulse Oximeter met the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **bench testing** demonstrates that the Masimo SET[®] Rad-5 Pulse Oximeters met its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET[®] technology meets its performance requirements during no motion and motion conditions and low perfusion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo SET[®] Rad-5 Pulse Oximeters is safe, effective.

0024

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 19 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Avenue
Irvine, California 92614-5826

Re: K033296
Trade/Device Name: Masimo SET RAD-5 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 23, 2004
Received: January 26, 2004

Dear Mr. Cronin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

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Page 2 – Mr. James J. Cronin

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K033296

Device Name: Masimo SET Rad 5 Pulse Oximeter

Indications For Use:

The Masimo SET® Rad5 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). The Masimo SET® Rad 5 Pulse Oximeter is indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

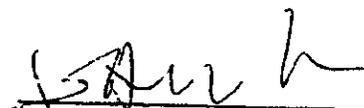
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033296

0080

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 25 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Welch Allyn, Inc.
c/o Mr. David Klementowski
Corporate Regulatory Affairs Manager
4341 State Street Road
Skaneateles, NY 13153

Re: K040490/S1
Welch Allyn Spot Ultra Vital Signs Device
Dated: May 17, 2004
Received: May 13, 2004

Dear Mr. Klementowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete our review, we require the following:

1. You have stated in your comparison table on page 10 of the supplemental information that the Masimo OEM Model hardware used is the MS-11. Your software requirements specifications indicate that the Masimo NCT-11 is to be used. Please clarify this.
2. You have not provided any performance testing information for the new MS-11 SpO2 module. Please provide summary test information that shows your device functions within the specifications you have listed on page 10 of supplemental information. Please include test objectives, test methods and set up, acceptance criteria, and results.
3. You have provided cleaning instructions for the SpO2 sensors on page 41 of your user manual. Please provide test data that demonstrates that each reusable component will function within specifications after repeated cleaning. Please demonstrate this with all procedures mentioned in the labeling. If you are unable to complete these tests with any of the cleaning procedures described in the labeling, please remove these procedures. Please provide data that demonstrates that the device functions within its specified parameters after thirty cycles of cleaning as recommended by British Standard 6850 as a minimum simulation of reuse.

Page 2 – Mr. David Klementowski

4. We would also recommend that a declaration of conformity to IEC 60601-1 is not sufficient to determine mechanical safety. We would recommend that you also provide a summary of the testing performed, summary of the requirements met, and the pass/fail criteria; otherwise provide a signed declaration of conformity to an appropriate FDA consensus program standard.
5. In our previous letter, dated April 21, 2004, we asked that you provide a reasonable assurance that the proposed device is biocompatible. The reason for this request is that we understand that the cuff material has changed (the outside of the cuff is made of nylon, and the inside of the cuff, the part that comes in contact with the patient, is made of polyester). There appears to be no specific mention of biocompatibility testing for the blood pressure cuff itself. Again, we recommend that you provide biocompatibility data for the proposed device in accordance with ISO10993, "Biological Evaluation of Medical Devices", for medical devices that are in contact with skin for less than 24 hours to support the safety of these materials. For devices that are skin contacting, FDA recommends the following tests: cytotoxicity, intracutaneous reactivity or irritation, and sensitization. Alternatively, if the patient-contacting materials are identical to those in the predicate device, please provide supporting information including the vendor, material formulation, and manufacturing processes of patient-contacting components. As a second alternative, you can provide the 510(k) number(s) of legally marketed devices that utilize the identical OEM sensors to be used with the proposed device. Because this is an abbreviated 510(k) submission, another alternative is to certify conformance to the appropriate section(s) of the FDA-recognized ISO10993 standard prior to marketing the proposed device. Please completely address the aforementioned concern.
6. Also, in our last letter, we asked that you please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 29, 1998. A copy of the guidance can be retrieved at our webpage www.fda.gov/cdrh/ode/57.html. While numerous parts of the software information, have been provided for our review, a complete software analysis could not be conducted because you have provided incomplete documentation as well as a statement in the correspondence, on page 28, that the device is still in the design and development phase and has not entered into the verification and validation phase. A partial response is not acceptable so please provide a complete response for our consideration.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence.

Page 3 – Mr. David Klementowski

Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

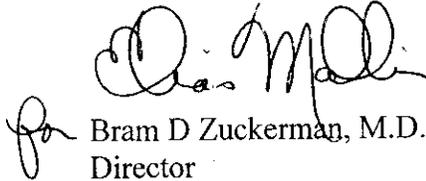
The requested information should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If the information 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Frank Lacy at (301) 443-8517, ext. 157. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Bram D Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Department of Health & Human Services

✓
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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-450	Lacy (K040490)	6/7/04			
450	Beck	6/21/04			
Z-486	Waller	06/24/04			

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Welch Allyn, Inc.
c/o Mr. David Klementowski
Corporate Regulatory Affairs Manager
4341 State Street Road
Skaneateles, NY 13153

Re: K040490/S1
Welch Allyn Spot Ultra Vital Signs Device
Dated: May 17, 2004
Received: May 13, 2004

Dear Mr. Klementowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete our review, we require the following:

1. You have stated in your comparison table on page 10 of the supplemental information that the Masimo OEM Model hardware used is the MS-11. Your software requirements specifications indicate that the Masimo NCT-11 is to be used. Please clarify this.
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3. You have provided cleaning instructions for the SpO2 sensors on page 41 of your user manual. Please provide test data that demonstrates that each reusable component will function within specifications after repeated cleaning. Please demonstrate this with all procedures mentioned in the labeling. If you are unable to complete these tests with any of the cleaning procedures described in the labeling, please remove these procedures. Please provide data that demonstrates that the device functions within its specified parameters after thirty cycles of cleaning as recommended by British Standard 6850 as a minimum simulation of reuse.

Page 2 -- Mr. David Klementowski

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6. Also, in our last letter, we asked that you please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 29, 1998. A copy of the guidance can be retrieved at our webpage www.fda.gov/cdrh/ode/57.html. While numerous parts of the software information, have been provided for our review, a complete software analysis could not be conducted because you have provided incomplete documentation as well as a statement in the correspondence, on page 28, that the device is still in the design and development phase and has not entered into the verification and validation phase. A partial response is not acceptable so please provide a complete response for our consideration.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence.

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Page 3 – Mr. David Klementowski

Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If the information 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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Sincerely yours,

Bram D Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Frank Lacy
Subject: 510(k) Number 1040490/S1
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this a prescription device?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NC
Special 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NC
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers <i>(done at time of SE)</i>	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NC

Truthful and Accurate Statement Requested Enclosed
 A 510(k) summary OR A 510(k) statement
 The required certification and summary for class III devices *N/A*
 The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: AI *2nd round* CEMB 06/24/04
 (Branch Chief) (Branch Code) (Date)

Final Review: _____ (Date)
 (Division Director)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

DATE: June 21, 2004

FROM: Frank Lacy
ODE/DCD/CEMB, HFZ-450

SUBJECT: K040490/S1– **Abbreviated 510(k)**
Welch Allyn Spot Ultra Vital Signs Device
Welch Allyn, Inc.
4341 State Street Road
Skaneateles NY 13153

CONTACT: David Klementowski
Sr. Manager Regulatory Affairs

Tel: (315) 685-4133
Fax: (315) 685-2532
Email: klementowskiD@welchallyn.com

To: The Record

Vemoli 06/24/04

BACKGROUND

The sponsor, Welch Allyn, Inc., has submitted an original premarket notification (510(k)) to seek market clearance for the Welch Allyn Spot Ultra Vital Signs Device, and has identified this application as an **Abbreviated 510(k)** submission.

The predicate device cited is the Welch Allyn Spot Vital Signs Device also manufactured by Welch Allyn, Inc., cleared under 510(k) submissions K002530 and K024005.

The first review of this 510(k) application was conducted by Felipe Aguel, Ph.D. I have been asked to continue this review based on a time conflict between the due date and plans for Dr. Aguel to be out of the office. A consult has been obtained by Mike Husband, in DAGID/ARDB, for the SpO2 module. Upon marketing clearance, the proposed device would be classified under 21 CFR §870.1130, as Class II with panel and product code of 74 DXN.

INTENDED USE

As taken from the indications for use statement (page 53 of submission), the proposed device is indicated for prescription use to automatically measure systolic and diastolic pressure, mean arterial pressure, pulse rate, temperature, and pulse oximetry (SpO2) of adult and pediatric patients. The proposed device also allows manual entry of height, weight, respiration, and pain level and calculates body mass index following height and weight entry.

The indications for use statement is different from that identified in submission K002530 in that the indications for use statement of the predicate device explicitly includes the following contraindications:

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- The Welch Allyn Spot Check Device should not be used on patients who are linked to heart lung machines
- The Welch Allyn Spot Check Device is not designed for use of axillary temperature option in children above three years of age.
- The Welch Allyn Spot Check Device is not intended to monitor patients' vital signs.
- The Welch Allyn Spot Check Device is not defibrillator proof.

SUMMARY

Is the device life-supporting or life-sustaining?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device an implant (short-term or long-term)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device sterile?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device for single use?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device for prescription use?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is the device for home use or portable?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is the device a combination product?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the device a kit?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is this device software driven?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
What is the estimated level of concern?	<input type="checkbox"/> Major	<input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Minor
Is the device electrically operated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

DEVICE DESCRIPTION

The proposed device is a one-time vital signs measurement device without continuous monitoring capability, timed cycle intervals, or any programmable alarm features. It includes blood pressure, pulse rate, and temperature measurement features and optionally an SpO2 measurement feature. Other optional features include custom wall mount, external printer, bar code scanner, and 802.11b wireless communications. Measured data is displayed on a large LCD and may be printed by an optional thermal printer. The device is not intended for monitoring of patients, for use with neonates, or for use in environments that are not supervised by a health care practitioner. A rechargeable battery powers the device.

The following are the basic specifications for the device:

- Pressure measurement range: Systolic: 60-250 mmHg, Diastolic: 30-160mmHg
- Pulse measurement range: 25-245 bpm using SpO2 determination, 35-199 bpm using BP determination
- SpO2 measurement range: 40-100%
- Temperature measurement range: SureTemp oral, axillary or rectal probe: 80.0 – 109.4°F; Braun 4000 ear IR probe 68.0 – 108.0 °F.

Page 2 – Second Review of Abbreviated 510(k)

K040490/S1 – Welch Allyn, Inc.

Welch Allyn Spot Ultra Vital Signs Device

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- Accuracy: ± 3 mmHg for pressure; $\pm 3\%$ for SpO₂ for measurement range of 70-100%, unspecified for <70%, $\pm 5\%$ for pulse using blood pressure determination, ± 3 bpm using SpO₂ determination. Temperature, as per ASTM E1112 (2000).

In order to demonstrate substantial equivalence to the predicate device, the sponsor certifies compliance to the following standards:

- IEC 60601-1 (1990) + A1 (1993) + A2 (1995): Medical electrical equipment Part1: General requirements for safety.
- IEC 60601-1-2 (2001): Medical electrical equipment. Part 1: General requirements for safety – 2. Collateral standard: electromagnetic compatibility – requirements and testing.
- IEC 60601-1-4 (1996): Medical electrical equipment. Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems.
- AAMI SP10 (2002): Standard for electronic or automated sphygmomanometers.
 - Except section 4.2.4.1 because the proposed device is battery powered
 - Except section 4.3.3 because the proposed device and accessories do not utilize anything that is conductive
- ASTM1112-86 (200): Standard Specification for Electronic Thermometer or Intermittent Determination of Patient Temperature
 - Except section 4.4.1 because the proposed device utilizes a digital display
 - Except section 4.6.1 because this will be tested in IEC 60601-1 above.
- EN 865 (1997) Pulse Oximeters – Particular Requirements

Note: a refuse to accept letter was considered, for the original application, based on the fact that submissions relying on non-recognized standards should include supporting data for those standards. However, because these standards were accepted for a predicate device, this option was not pursued. The predicate device submission where these standards were accepted (K002530) contained minor modifications and elimination of software features. It was therefore appropriate to accept the standards since the modifications did not affect the function of the device covered by the non-recognized standards.

Deficiency 1.

You provide a signed statement of conformance to recognized and non-recognized standards on page 15 of the submission. Among the standards to which you certify conformance is ANSI/AAMI SP10 (2002). The FDA does not recognize the 2002 version of the ANSI/AAMI SP10 standard. The latest revision of the standard that is FDA recognized is the 1992 version. Please use the ANSI/AAMI SP-10 (1992) standard and not the ANSI/AAMI SP-10 (2002) standard to demonstrate substantial equivalence of the blood pressure measurement component of the proposed device. You can provide either:

**Page 3 – Second Review of Abbreviated 510(k)
K040490/S1 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

CS6

- the bench top and clinical data to demonstrate the safety and effectiveness of the blood pressure measurement module of the proposed device, or
- a signed statement of conformance to the 1992 version of ANSI/AAMI SP-10.

Summary Response: adequate; provided a signed declaration of conformity to the 1992 version of ANSI/AAMI SP-10

Deficiency 2.

You provide a signed statement of conformance to recognized and non-recognized standards on page 15 of the submission. Among the standards to which you certify conformance is EN865 (1997). The FDA does not recognize the EN865 (1997) standard. You may still use the standard to establish substantial equivalence to legally marketed devices if you provide detailed protocols, data, and conclusions of the tests specified in the standard. Additional data may be requested if the protocols specified in the standard are not sufficient to demonstrate safety and effectiveness of the proposed device. Please refer to the FDA Draft Guidance Document on Non-Invasive Pulse Oximeter, which is available at <http://www.fda.gov/cdrh/ode/guidance/997.pdf>, and to deficiencies 3 and 4 below.

Summary Response: adequate; this standard is related to the pulse oximeter module of the device; removing conformance to such standard; see consultant review

SUBSTANTIAL EQUIVALENCE

Description of Change - comparison to predicate

The significant differences between the proposed device and the predicate device are summarized below:

- The predicate device intended for use by health care professionals; the proposed device is indicated for over the counter use.
- The cuff material has changed; the outside of the cuff is made of nylon, and the inside of the cuff, the part that comes in contact with the patient, is made of polyester.

Predicate Comparison Chart

Device Characteristic	Predicate device (K002530 and K024005)	Proposed device
Name	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device

**Page 4 – Second Review of Abbreviated 510(k)
K040490/S1 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

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Device Characteristic	Predicate device (K002530 and K024005)	Proposed device
Indication for use	Measurement of BP, pulse rate, temperature and oxygen saturation of adult and pediatric patients. Not to be used on patients on heart-lung machines, not defibrillator proof, not intended to monitor patients' vital signs.	Automatically measure systolic and diastolic pressure, mean arterial pressure, pulse rate, temperature, and SpO2 of adult and pediatric patients. Prescription Use only.
Performance Standards	IEC60601-1 (1990) + A1 + A2 IEC60601-1-2 (1993) IEC60601-1-4 (1996) AAMI SP10 (1992) ASTM 1112-86 (1991) EN865 (1997)	Same IEC60601-1-2 (2001) Same AAMI SP10 (2002) ASTM 1112-86 (2000) Same
Temperature Sensors / OEM Modules	SureTemp	Same Braun 4000 IR
SpO2 Sensors / OEM Modules	Nellcor MP506	Same Massimo OEM SpO2 model NCT-11
Method/algorithm	Oscillometric for BP Pulse Oximetry for SpO2 rectal, oral, axillary thermistor probe	Same Same Same plus ear IR probe

According to the consultant's review, it remains unclear whether the only changes in the device are the OEM modules with which the device will work and the optional accessories available.

Deficiency 3.

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**Page 5 – Second Review of Abbreviated 510(k)
K040490/S1 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

3) to include a comparison of the hardware, firmware, and algorithms in the predicate and proposed devices.

Summary Response: inadequate; see review memorandum from consultant

Deficiency 4.

(b)(4)

validated that your exclusion criteria are evaluated.

If the data and protocols of the non-recognized standards cited in deficiency 2 (i.e. EN865 (1997)) conform to the above list, providing detailed test reports including protocols, data, and conclusions may suffice to address deficiency 4.

Summary Response: inadequate; see review memorandum by consultant

MATERIALS/BIOCOMPATIBILITY

During the original review, the sponsor makes no mention of the biocompatibility of the device. Hence, the issue has been raised in a previous deficiency letter regarding the biocompatibility.

Deficiency 5.

You do not provide a reasonable assurance that the proposed device is biocompatible. We recommend that you provide biocompatibility data for the proposed device in accordance with ISO10993, "Biological Evaluation of Medical Devices", for medical devices that are in contact with skin for less than 24 hours to support the safety of these materials. For devices that are skin contacting, FDA recommends the following tests: cytotoxicity, intracutaneous reactivity or irritation, and sensitization. Alternatively, if the patient-contacting materials are identical to those in the predicate device, please provide supporting information including the vendor, material formulation, and manufacturing processes of patient-contacting components. As a second alternative, you can provide the 510(k) number(s) of legally marketed devices that utilize the identical OEM sensors to be used with the proposed device. Because this is an abbreviated 510(k) submission, another alternative is to certify conformance to the appropriate section(s) of the FDA-recognized ISO10993 standard prior to marketing the proposed device.

Summary Response: inadequate; remains unclear; one of the reasons for the applications is that the cuff material has changed; the outside of the cuff is made of nylon, and the inside of the cuff, the part that comes in contact with the patient, is made of polyester; there is no specific mention of biocompatibility testing for the blood pressure cuff itself

STERILIZATION

The sponsor does not claim that the proposed device is sterile. Sterility is not an issue.

LABELING

Labeling, promotional literature, and the user's manual are provided as section VI and attachments 3 and 4, respectively. However, in the original application, the labeling lacked information specified in the AAMI SP10 standard as well as information regarding the accuracy and specifications of the different sensors. Revised labeling has been provided for our consideration.

**Page 7 – Second Review of Abbreviated 510(k)
K040490/S1 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

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Deficiency 6.

In section VI and attachments 3 and 4 of the submission, you provide the device labeling. However, it appears that not all of the labeling specifications of the AAMI SP-10 (1992) standard are included. Please include all of the labeling specified in the AAMI SP-10 (1992) standard. Furthermore, your labeling should include the sensor specifications (i.e. SpO2, blood pressure, temperature, and pulse rate accuracy claims, etc.). Please note that this accuracy specification should be for each sensor and should be consistent with the results of the clinical validation study.

Summary Response: adequate; the manufacturer has completed a review of ANSI/AAMI SP-10:1992 labeling and provided complete labeling in accordance with the aforementioned standard

PERFORMANCE TESTING

The sponsor does not provide performance testing for the proposed device, but instead supplies a statement of conformance to the performance standards mentioned above. Because some of these standards are not FDA-recognized, supporting data has been requested in the deficiencies mentioned above.

Electrical Safety – EN 60601-1 (1990)

On page 15 of the submission, the sponsor presents a Statement of Conformance to EN60601-1 (1990) + A1 (1993) + A2 (1995).

Electromagnetic Compatibility – EN 60601-1-2 (1993)

On page 15 of the submission, the sponsor presents a Statement of Conformance to EN60601-2 (2001).

Environmental Testing

On page 15 of the submission, the sponsor presents a Statement of Conformance to ANSI/AAMI SP10 (2002), ASTM1112-86 (2000), and EN 865(1997). Because some of these are not FDA-recognized standards, data and test reports may be necessary. See earlier deficiencies 1-3 above.

SOFTWARE

In the original submission, the manufacturer includes a software description in section IV on page 25 of the submission, and identifies the level of concern for each software module as minor. The sponsor does not include the following items identified in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Although the sponsor has identified the level of concern as minor, failure of the software in the device could cause

**Page 8 – Second Review of Abbreviated 510(k)
K040490/S1 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

non-serious injury to the patient. Therefore, the documentation should be consistent with a Moderate level of concern.

Deficiency 7.

In section IV and beginning on page 25 of the submission, you provide a software description identifying the level of concern for each software module. However, the software description you have provided for your device is inadequate. Every software product should possess a basic level of reliability through analysis, design, implementation, system testing, quality assurance, and maintenance of the software product, which should all be well documented and controlled. Please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 29, 1998. A copy of the guidance can be retrieved at our webpage www.fda.gov/cdrh/ode/57.html. If the software in your device were to fail, it could cause non-serious injury to a patient. Therefore, your software is considered to be a Moderate level of concern.

Summary Response: inadequate; numerous parts of the software information, have been provided for our review; a complete software analysis, by this reviewer, cannot be conducted because the sponsor has provided incomplete documentation as well as a statement in the correspondence that the device is still in the design and development phase and has not entered into the verification and validation phase

REGULATORY INFORMATION

The sponsor has provided a truth and accuracy statement as required by 21 CFR §807.87, a 510(k) summary in accordance with 21 CFR 807.92, and an indications for use statement.

RECOMMENDATION

Based on the deficiencies mentioned above, I cannot determine whether the proposed device is substantially equivalent to the predicate device. I recommend that the file be placed on hold for additional information, and that the sponsor receive a K-3 "Additional Information" letter describing the deficiencies mentioned above. I believe that I have adequate information that I do not need to ask the totality of question number 5 from the consultants review; just mechanical safety aspect needs to be addressed.



Frank Lacy

June 17, 2004
Date

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K040490/S1 – Welch Allyn, Inc.
Welch Allyn Spot Ultra Vital Signs Device**

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(b)(4) Software Requirements

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Records Processed under FOIA Request 2016-0531; Released by CDRH on 8/7/2018

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(b)(4) Software Requirements Traceability Matrix

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(b)(4) Software Requirements Traceability Matrix

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(b)(4) Software Requirements Traceability Matrix

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K040490 Spot Ultra Response

Attachment 6 – Software Life Cycle

The following attached document represents the software life cycle at Welch Allyn. This document satisfies the requirement for document #8 in the list from the guidance document.

Summary: Spot Software Life Cycle Development Plan

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Figure 1 - SOFTWARE DEVELOPMENT FLOW CHART

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K040490 Spot Ultra Response

Attachment 7 – V V & T Test Activity

Due to the fact that the Spot Ultra Vital Signs is still in the design and development phase of our design control process and has not entered into the Verification and Validation phase, WA has not developed Test Protocols for the testing of the software. These protocols will be developed as Spot Ultra moves in to later phases of design control and will be completed and approved before launch of the device later in 2004.



K040490 Spot Ultra Response

Attachment 8 – Revision History Log

The following attached document represents the revision history log of the Spot Ultra Vital Signs software. This document satisfies the requirement for document #10 and 12 in the list from the guidance document.

version

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K040490 Spot Ultra Response

Attachment 9 – Errors List

Due to the fact that the Spot Ultra Vital Signs is still in the design and development phase of our design control process and has not entered into the Verification and Validation phase, WA has not developed an errors list that may have been found in testing of the software. This list and subsequent review and closer of errors will be developed as Spot Ultra moves in to later phases of design control and will be completed and approved before launch of the device later in 2004.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 26, 2004

WELCH ALLYN, INC.
MEDICAL
4341 STATE ST. RD.
SKANEATELES FALLS, NY 13153

510(k) Number: K040490
Product: WELCH ALLYN SPOT
ULTRA VITAL
SIGNS DEVICE

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Welch Allyn Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220
USA
Telephone: 315-685-4100
www.welchallyn.com

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K040490/S2



July 22, 2004

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference: K040490 – Request for Additional Information

Dear Sir or Madam:

This letter is in response to your request for additional information in the review of the referenced submission under section 510(k) of the Food, Drug and Cosmetics Act. First, you should know that your previous contact regarding this submission, Mr. David Klementowski, has retired from Welch Allyn, Inc. I am now the contact for this submission. My contact information is included below. As a back-up to myself, Mr. Joshua Kim may also be contacted as necessary regarding this submission. He can be reached by telephone at (315) 554-5289.

First, I would like to thank you for the guidance provided in your letter dated June 25, 2004. It is clear from the content and tone that your intent is not solely compliance, but also education. The letter has been shared with those involved in the preparation and submission of the original 510(k) and the supplementary information with the same goal. I expect that this response will satisfactorily address your remaining concerns regarding this submission. Our responses to the questions contained in your letter are presented on the pages that follow. I have repeated your question in italics before each response for your reference.

Question 1

You have stated in your comparison table on page 10 of the supplemental information that the Masimo OEM Model hardware used is the MS-11. Your software requirements specifications indicate that the Masimo NCT-11 is to be used. Please clarify this.

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Question 4

We would also recommend that a declaration of conformity to IEC 60601-1 is not sufficient to determine mechanical safety. We would recommend that you also provide a summary of the testing performed, summary of the requirements met, and the pass/fail criteria; otherwise provide a single declaration of conformity to an appropriate FDA consensus program standard.

As an active device with software, we did tend to focus more upon the electrical and software safety requirements. However, we also feel that the various recognized standards to which we are claiming compliance satisfactorily address the mechanical safety considerations for the various device functions.

IEC 60601-1 Section 4, *Protection against mechanical hazards*, addresses the following:

- Mechanical strength; applies. This will be addressed through the application of environmental stress tests and drop tests. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention items “g”, “h”, “i”, “j”, “k”, “l”, “p” and “r” listed on pages 4 and 5 of the document.
- Moving parts; applies only to the portable stand accessory, SpO2 sensor and blood pressure cuff. The stand is addressed under the stability in normal use portion of this standard. The cuff is addressed by application of section 4.3.1 of ANSI/AAMI SP10:2002. For the SpO2 sensor, we are applying the applicable requirements for mechanical safety defined in EN 865:1997 (we are aware that this is not presently a recognized consensus standard).
- Surfaces, corners and edges; applies. This will be addressed through visual examination and manipulation. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention items “q” on page 4 of the document.
- Stability in normal use; applies. Addressed by performance of standard tilt and drop testing. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention items i, j, k and w listed on pages 4 and 5 of the document. Note also that the stand is identical to that used for the Spot predicate cleared by 510(k) submissions K002530 and K022163 (summary attached).
- Expelled parts; applies. The only potential for expelled parts is if the tubing from the blood pressure cuff is not properly attached to the connectors. This is addressed on page 11 of the user manual, Attachment 4 of the original submission.
- Vibration and noise; applies. The only source of both noise and vibration is the cuff inflation pump. As the subject device uses the same pump as the Spot predicate cleared by 510(k) submissions K002530 and K022163 (summary attached), we are asserting that this satisfies this verification requirement for the subject device.
- Pneumatic and hydraulic power; applies. Cuff inflation and deflation is addressed by application of section 4.3.1 of ANSI/AAMI SP10:2002.
- Suspended masses; does not apply. The device has no suspended masses. The subject device, when mounted to the optional portable stand accessory, presents a moment of inertia that may affect stability in normal use. This risk is addressed under the stability in normal use section.

IEC 60601-1 Section 5, *Protection against hazards from unwanted or excessive radiation*, is addressed through functional test and labeling. For the SpO2 sensor, we are applying the applicable requirements for optical safety defined in EN 865:1997 (we are aware that this is not presently a recognized consensus standard). Labeling is addressed on page 5 of the user manual, Attachment 4 of the original submission for referral to the sensor user manual.

IEC 60601-1 Section 6, *Protection against hazards of ignition of flammable anesthetic mixtures*, is addressed through labeling. This is addressed on page 3 of the user manual, Attachment 4 of the original submission.

IEC 60601-1 Section 7, *Protection against excessive temperatures and other safety hazards*, addresses the following:

- Excessive temperatures; applies. This will be addressed through monitoring of the external case temperature. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention to item "l" on page 4 of the document.
- Fire prevention; applies. This is addressed through labeling relating to the environment of use. This is addressed on page 3 of the user manual, Attachment 4 of the original submission.
- Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility; applies, but only related to the ingress of cleaning liquids. Refer to the response provided to Question 3 above.
- Pressure vessels and parts subject to pressure; applies. Cuff inflation and deflation is addressed by application of section 4.3.1 of ANSI/AAMI SP10:2002.
- Human errors; applies. This will be addressed through visual examination and user interface testing. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention to items "a" and "q" on page 4 of the document.
- Electrostatic charges; applies. This is addressed through the application of IEC 60601-1-2.
- Biocompatibility; applies. This is addressed through history of use and the application of the appropriate ANSI/AAMI/ISO 10993 series standards.
- Interruption of the power supply; applies. This will be addressed through device functional testing. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention to items "n", "o" and "v" on pages 4 and 5 of the document.

ANSI/AAMI SP10 Section 4.3.1, *Devices incorporating automatic inflation systems*, addresses the following:

- Maximum cuff pressure; applies. This will be addressed through various device functional tests. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention to items "c", "m", "p" and "x" on pages 4 and 5 of the document.
- Release rate; applies. This will be addressed through various device functional tests. Reference attached document number 40700-201-1.0, *Spot Ultra Verification Plan (Rev 1.0)*, approved 22 Mar 04. I bring to your attention to items "c", "m", "p" and "x" on pages 4 and 5 of the document.

ASTM E1112 Section 4.6.2, *Material*, addresses the biocompatibility of the case and patient-contacting materials. These requirements are addressed through history of use and the application of the appropriate ANSI/AAMI/ISO 10993 series standards. Section 4.7, *Marking*, requirements are addressed through visual inspection. These requirements are also addressed through statements in the user manual.

All other potential mechanical safety risks are identified through application of risk analysis per ISO 14971:2000, *Medical devices - Application of risk management to medical devices*. I am supplying a revision to Section III of the submission to include a reference to ISO 14971:2000. The revised copy is attached to the end of this letter. The attachment replaces the versions supplied in the original submission and the supplementary information dated 17 May 2004.

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We believe that the foregoing information satisfactorily addresses your remaining questions pertaining to abbreviated 510(k) submission K040490. Should you have additional questions or require clarification of the information provided, please contact me directly at the telephone number provided below.

Regards,



Christopher Klaczyk
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Encl.

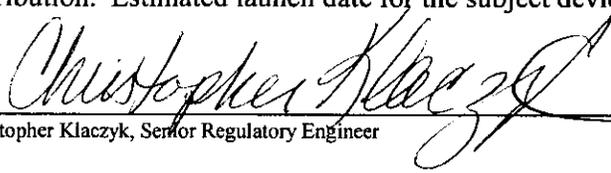
III. Statement of Conformance to Recognized Standards / Referenced Predicate Devices

The subject product will be tested in typical configuration (BP, SpO2 and Temperature) and will be found to be in compliance with the requirements of the listed standards before Welch Allyn, Inc. introduces the product into distribution.

Applied Standards/Guidance:

- 1) IEC 60601-1:1990; Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03. All elements will be applied as appropriate.
- 2) IEC 60601-1-1:2000; Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems. All elements will be applied as appropriate.
- 3) IEC 60601-1-2:2001; Medical Electrical Equipment - Part 1-2: General Requirements for Safety – 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests. All elements will be applied.
- 4) IEC 60601-1-4:1996; Medical Electrical Equipment - Part 1: General requirements for safety; 4. Collateral Standard: Programmable electrical medical systems. All elements will be applied.
- 5) ANSI/AAMI SP10:1992; Standard for electronic and automated sphygmomanometers. Compliance to all sections except for the following:
 - a. Section 4.2.4.1 – Rationale: The Spot Ultra Vital Signs Device is a battery-powered device and only uses AC to charge the battery. AC alone will not run the device. Therefore this section is not applicable.
 - b. Section 4.3.3 – Rationale: The Spot Ultra Vital Signs Device and its accessories do not have any exposed conductive materials. Therefore this section is not applicable.
- 6) ASTM E 1112-00; Electronic Thermometer for Intermittent Determination of Patient Temperature. All elements will be applied.
- 7) ANSI/AAMI/ISO 10993-1:1997; Biological evaluation of medical devices -- Part 1: Evaluation and testing. All elements will be applied as appropriate.
- 8) AAMI/ANSI/ISO 10993-5:1999; Biological evaluation of medical devices -- Part 5: Tests for cytotoxicity.
- 9) AAMI/ANSI/ISO 10993-10:1995; Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization -- Maximization sensitization test. Will apply section 5.2 for skin irritation tests and section 6.3 for maximization sensitization tests.
- 10) ISO 14971:2000; Medical devices - Application of risk management to medical devices. All elements will be applied.
- 11) General Principles of Software Validation; Final Guidance for Industry and FDA Staff; issued January 11, 2002. All elements will be applied.

Evidence of compliance to the above mentioned standards shall be on file at Welch Allyn, Inc., 4341 State Street Road, Skaneateles Falls, NY 13153 on or before the release of the product into distribution. Estimated launch date for the subject device is December 2004.


Christopher Klaczyk, Senior Regulatory Engineer

07/22/04
Date

Welch Allyn, Inc. Spot Ultra Vital Signs Pre-Market Notification

Referenced Predicate Devices:

- 1) K002530, Welch Allyn Spot Vital Signs Device, manufactured by Welch Allyn, Inc. (summary attached). This reference is used in support of the finished subject device.
- 2) K022163, Welch Allyn Spot Vital Signs Device, manufactured by Welch Allyn, Inc. (summary attached). This reference is used in support of the finished subject device.
- 3) K030580, Welch Allyn SureTemp Plus Electronic Thermometer, manufactured by Welch Allyn, Inc. (summary attached). This reference is used in support of the oral temperature product option.
- 4) K031928, Braun Thermoscan PRO 4000, manufactured by Braun GmbH (summary attached). This reference is used in support of the ear temperature product option.
- 5) K021090, OxiMax N-550 Pulse Oximeter, manufactured by Nellcor Puritan Bennett, Inc. (summary attached). This reference is used in support of the Nellcor SpO2 product option.
- 6) K033296, Masimo SET RAD-5 Pulse Oximeter, manufactured by Masimo Corporation (summary attached). This reference is used in support of the Masimo SpO2 product option.