Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)

FOLDER: K082819 - 597 pages

COMPANY: MIRAMAR LABS, INC. (MIRALABS)

PRODUCT: SYSTEM, ABLATION, MICROWAVE AND ACCESSORIES (NEY)

SUMMARY: Product: DERMATOLOGIC TREATMENT SYSTEM (DTS) G2

DATE REQUESTED: Sep 1, 2015

DATE PRINTED: Sep 1, 2015

Note: Printed

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K082819

510(k) Summary

MAR 20 2009

General Information

Classification	Class II
Trade Name	DTS G2 System
Submitter	Miramar Labs, Inc. 199 Jefferson Drive Menlo Park, CA 94025 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Kathy O'Shaughnessy, PhD VP, Clinical and Regulatory Affairs

Intended Use

The DTS G2 System is indicated for use for coagulation of soft tissue.

Predicate Devices

K072870 Foundry Newco X Microwave Tissue Coagulation System

Device Description

The DTS G2 System is designed to interact using a surface contact applicator. The system consists of an applicator; external microwave generator with integrated vacuum pump; and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, integrated vacuum pump, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator. The distal end has a sterile, disposable applicator head that contacts the patient.

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

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Materials

All materials used in the manufacture of the DTS G2 System are suitable for this use and have been used in numerous previously cleared products.

Testing

Product and animal testing was conducted to evaluate conformance to product specification and equivalence to predicate devices.

The results showed the system met specification.

Summary of Substantial Equivalence

The DTS G2 System is equivalent to the predicate product. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

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
9200 Corporate Boulevard
Rockville MD 20850

Miramar Labs, Inc.
% Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
199 Jefferson Drive
Menlo Park, California 94025

MAR 20 2009

Re: K082819
Trade/Device Name: DTS G2 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: February 27, 2009
Received: March 2, 2009

Dear Dr. O'Shaughnessy:

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. 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.

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

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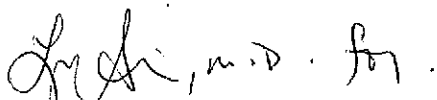
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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K082819

Indications for Use

510(k) Number (if known):	K082819
Device Name:	DTS G2 System
Indications for Use:	The DTS G2 System is indicated for use for coagulation of soft tissue.

X		
Prescription Use (Per 21 CFR 801 Subpart D)	OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082819

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Miramar Labs, Inc.
% Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
199 Jefferson Drive
Menlo Park, California 94025

MAR 20 2009

Re: K082819
Trade/Device Name: DTS G2 System
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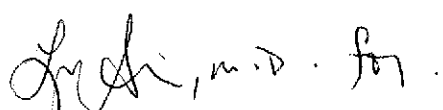
Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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Device Name:	DTS G2 System
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082819

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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
9200 Corporate Boulevard
Rockville, Maryland 20850

March 03, 2009

MIRAMAR LABS, INC.
199 JEFFERSON DR.
MENLO PARK, CALIFORNIA 94025
UNITED STATES
ATTN: KATHY O'SHAUGHNESSY

510k Number: K082819

Product: DERMATOLOGIC TREATMENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 02, 2009

MIRAMAR LABS, INC.
199 JEFFERSON DR.
MENLO PARK, CALIFORNIA 94025
UNITED STATES
ATTN: KATHY O'SHAUGHNESSY

510k Number: K082819
Product: DERMATOLOGIC TREATMENT SYSTEM

Extended Until: 03/02/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

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

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FDA CDRH DMC
FEB 2 2009
Received

January 30, 2009

Document Mail Center, HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Submission - DTS G2 System (**K082819**)
Request for extension

Dear Madam or Sir,

We are requesting an additional 30 day extension on this 510(k) submission (to March 2, 2009) to respond to the additional information request sent to us by Dr. Long Chen on December 2, 2008. We have been in discussions with Dr. Chen and other reviewers and are still assembling the necessary information to respond.

If you have any further questions, feel free to contact me.

Regards,

Kathy O'Shaughnessy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs

Email: kathyo@miramarlabs.com
Phone: 650-326-2656 x152
Cell: 650-269-4770

KS

miramarlabs
199 Jefferson Drive
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

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
9200 Corporate Boulevard
Rockville, Maryland 20850

January 05, 2009

MIRAMAR LABS, INC.
199 JEFFERSON DR.
MENLO PARK, CALIFORNIA 94025
UNITED STATES
ATTN: KATHY O'SHAUGHNESSY

510k Number: K082819
Product: DERMATOLOGIC TREATMENT SYSTEM

Extended Until: 02/02/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

December 31, 2008

FDA CDRH DMC
JAN 2 2009
Received

Document Mail Center, HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Submission - DTS G2 System (**K082819**)
Request for extension

Dear Madam or Sir,

We are requesting a 30 day extension beyond January 1, 2009 to respond to the additional information request sent to us by Dr. Long Chen on December 2, 2008. We have been in discussions with Dr. Chen regarding one of his questions and are still assembling the necessary information to respond. With the holidays we have not been able to complete to response.

If you have any further questions, feel free to contact me.

Regards,

K. OShaughnessy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs

Email: kathyo@miramarlabs.com
Phone: 650-326-2656 x152
Cell: 650-269-4770

K19

39

miramarlabs
199 Jefferson Drive
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

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

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COPY

FDA CDRH DMC

JAN 2 2009

Received

December 31, 2008

Document Mail Center, HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850

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Regards,

K. OShaughnessy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs

Email: kathyo@miramarlabs.com
Phone: 650-326-2656 x152
Cell: 650-269-4770

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

miramarlabs
399 Lathrop Way, Suite 200
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

40

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 03, 2008

510k Number: K082819
Product: DERMATOLOGIC TREATMENT SYSTEM

MIRAMAR LABS, INC.
199 JEFFERSON DR.
MENLO PARK, CALIFORNIA 94025
UNITED STATES
ATTN: KATHY O'SHAUGHNESSY

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (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 deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

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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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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

October 20, 2008

510k Number: K082819
Product: DERMATOLOGIC TREATMENT SYSTEM

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Sincerely yours,

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

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 25, 2008

MIRAMAR LABS, INC.
199 JEFFERSON DR.
MENLO PARK, CA 94025
ATTN: KATHY O'SHAUGHNESSY

510(k) Number: K082819
Received: 25-SEP-2008
Product: DERMATOLOGIC TREATMENT SYSTEM (DTS) G2

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(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 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued

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a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review:
1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process.
2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

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

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K082819

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) CCI [redacted]3
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MIRAMAR LABS INC.
199 JEFFERSON DR.
Menlo Park CA 94025
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4) [redacted]

2. CONTACT NAME
Steve Kim

2.1 E-MAIL ADDRESS
skim@miramarlabs.com

2.2 TELEPHONE NUMBER (Include Area code)
650-3262656 134

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
null-null

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/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted] 15-Sep-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

K7

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
09/23/2008	(b) (4) [redacted]	

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Miramar Labs, Inc.	Establishment Registration Number *(if known)*: pending		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (650) 326-2656		
Street Address: 199 Jefferson Drive	FAX Number *(including area code)*: (650) 326-3108		
City: Menlo Park	State / Province: CA	ZIP/Postal Code: 94025	Country: USA
Contact Name: Kathy O'Shaughnessy			
Contact Title: VP, Clinical and Regulatory	Contact E-mail Address: kathyo@miramarlabs.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

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

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

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

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

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

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

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NEY	2	GEI	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072870	1	Microwave Tissue Coagulation System	1	Foundry Newco X, Inc.
2	K013639	2	ThermaCool TC System	2	Thermage, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Tissue coagulation system

	Trade or Proprietary or Model Name for This Device		Model Number
1	Dermatologic Treatment System (DTS) G2	1	
2		2	
3		3	
4		4	
5		5	

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

1 K072870	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

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

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NEY	878.4400	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

General and Plastic Surgery

Indications *(from labeling)*

The Dermatologic Treatment System (DTS) G2 is intended for dermatologic and general surgery hemostasis and coagulation of soft tissue.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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

FDA Document Number *(if known)*

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

☑ Original ☐ Add ☐ Delete

Facility Establishment Identifer (FEI) Number: Pending

☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Miramar Labs, Inc.	Establishment Registration Number: pending
Division Name *(if applicable)*	Phone Number *(including area code)*: (650) 326-2656
Street Address: 199 Jefferson Drive	FAX Number *(including area code)*: (650) 326-3108

City	State / Province	ZIP/Postal Code	Country
Menlo Park	CA	94025	USA

Contact Name	Contact Title	Contact E-mail Address
Kathy O'Shaughnessy	VP, Clinical and Regulatory Affairs	kathyo@miramarlabs.com

☑ Original ☐ Add ☐ Delete

Facility Establishment Identifer (FEI) Number:

☐ Manufacturer ☑ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Centurion Sterilization Services	Establishment Registration Number: 2032758
Division Name *(if applicable)*: Tri-State Hospital Supply Corp	Phone Number *(including area code)*: (517) 545-1150
Street Address: 3173 East 43rd Street	FAX Number *(including area code)*: ( )

City	State / Province	ZIP/Postal Code	Country
Yuma	AZ	85365	USA

Contact Name	Contact Title	Contact E-mail Address
Brenda Sparks	Director of Corporate Accounts	bsparks@tshsc.com

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifer (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )
Street Address:	FAX Number *(including area code)*: ( )

City	State / Province	ZIP/Postal Code	Country

Contact Name	Contact Title	Contact E-mail Address

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

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SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems	1988 + A1:1991 + A2:1995	
2	60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety: Electromagnetic Compatibility	2001 + A1:2004	
3	11135-1	AAMI / ANSI / ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2007	
4	10993-7	ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals	1995	
5					
6					
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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

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September 23, 2008

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

FDA CDRH DMC
SEP 25 2008
Received

Re: 510(k) Premarket Notification - Traditional Dermatologic Treatment System (DTS) G2 Miramar Labs, Inc.

Miramar Labs, Inc (formerly Foundry Newco X, Inc.) is submitting the enclosed application for a new device (the Dermatologic Treatment System (DTS) G2), indicated for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis. The indications for use and clinical applications are equivalent to current medical practice and existing legally marketed tissue coagulation products.

We consider our intent to market these devices as confidential commercial information and request that FDA consider it as such.

The submission and attachments are submitted in duplicate as required by regulation. A copy of a Premarket Submission Cover Sheet is enclosed for your convenience. If you have any questions regarding this 510(k) submission, please contact the undersigned at your earliest convenience.

Administrative Information

Proprietary Name: Dermatologic Treatment System (DTS) G2

Common Name: Tissue coagulation system

Classification Name and Reference: Electrosurgical, cutting & coagulation & accessories, 21 CFR §878.4400

Intended Use: The Dermatologic Treatment System (DTS) G2 is indicated for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis.

Proposed Regulatory Class: Class II

FDA Review Panel: General and Plastic Surgery

Device Product Code: NEY

miramarlabs
199 Jefferson Drive
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Design and Use of the Device

The Dermatologic Treatment System (DTS) G2 is a microwave device designed to coagulate soft tissue using a surface contact applicator. The system consists of an applicator; external microwave generator with integrated vacuum pump; and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

Table 3 –Design and Use of the Device

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

Thank you for your expeditious review of this application.

Sincerely,

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
(650) 326-2656 x152
kathyo@miramarlabs.com

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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List of Attachments:

A - Product Drawings

B - Instructions for Use and User Manuals

C - Predicate Information

D - Product Labels

E - Biocompatibility information

F - FDA Form 3674 - Certification of Compliance with ClinicalTrials.gov

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

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Indications for Use

510(k) Number (if known):

Device Name: Dermatologic Treatment System (DTS) G2

Indications for Use: The Dermatologic Treatment System (DTS) G2 is indicated for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis.

X		
Prescription Use (Per 21 CFR 801 Subpart D)	OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

510(k) Summary

General Information

Classification	Class II
Trade Name	Dermatologic Treatment System (DTS) G2
Submitter	Miramar Labs, Inc. 199 Jefferson Drive Menlo Park, CA 94025 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Kathy O'Shaughnessy, PhD VP, Clinical and Regulatory Affairs

Intended Use

The Dermatologic Treatment System (DTS) G2 is indicated for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis.

Predicate Devices

K013639	Thermage ThermoCool TC System
K072870	Foundry Newco X Microwave Tissue Coagulation System

Device Description

The Dermatologic Treatment System (DTS) G2 is designed to interact using a surface contact applicator. The system consists of an applicator; external microwave generator with integrated vacuum pump; and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator. The distal end has a sterile, disposable applicator head that contacts the patient.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Materials

All materials used in the manufacture of the DTS are suitable for this use and have been used in numerous previously cleared products.

Testing

Product and animal testing was conducted to evaluate conformance to product specification.

The results showed the system met specification.

Summary of Substantial Equivalence

The DTS G2 is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Truthful and Accuracy statement

As required by 21 CFR §807.87(k)

I certify that, in my capacity as Chief Technology Officer of Miramar Labs, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Steven Kim
(Printed Name)

9/23/08
(Dated)

(Premarket Notification Number)

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Class III Summary and Certification

The device in this notification is a Class II device; therefore this section is not applicable.

Financial Certification or Disclosure Statement

There is no clinical data supplied with this notification therefore this section is not applicable.

Performance Standards, Declarations of Conformity and Summary Reports

No performance standards applicable to this product have been promulgated by FDA.

Miramar Labs certifies that their DTS G2 device will conform to the requirements of the following electrical safety standards prior to distribution:

- IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1988 + A1:1991 + A2:1995)
- IEC 60601-1-2: Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2001+A1:2004).

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Device Description

Background

Electrical energy, in the form of Radiofrequency (RF) and Microwave, has been used in medical applications for many years. The application of these energy types to tissue can result in controlled heating of the tissue over the normal range. The absorption of the energy by the tissue cells can raise the temperature of the tissue to levels that cause tissue coagulation. The level of coagulation is controlled by the operator based on the energy delivered (combination of power and time).

Generally, both RF and Microwave coagulation devices have an external energy generator which is connected to an antenna or energy probe. The probe directs the energy to the target tissue and is specifically designed for the type and amount of energy delivered. Both methods require tissue contact to operate.

Device

The Dermatologic Treatment System (DTS) G2 with the DTS LT Applicator is designed to coagulate dermatologic and other general soft tissue using a surface contact device. The Applicator has a vacuum chamber to acquire and isolate the target tissue (see Figure 1). The applicator also has a surface cooling feature, which can keep the surface of the target tissue protected at certain energy delivery conditions while coagulating the tissue below it. The microwave energy is delivered through 4 microwave antennas embedded in the Applicator housing. The user has the ability to select the number of antennas that they would like to activate, depending on the size of lesion that they would like to create. If more than one antennas are selected on the front panel of the Generator, the energy is delivered to the antennas in a serial fashion through a switching feature built into the Applicator and controlled by the circuitry within the Generator. Only one antenna can be activated at a given time (i.e. physically not possible to deliver energy to more than one antenna at the same time).

The antennas are specifically designed to operate at 5800MHz to deliver the energy provided by the generator. Additionally, there are 4 temperature sensors placed on the inside surface of the vacuum chamber to monitor the tissue surface temperature under each of the antennas. The temperature under the active antenna is displayed on the front panel of the Generator. There is also a thermocouple in the coolant line within the Applicator to monitor the coolant temperature, which is displayed on the front panel of the Generator.

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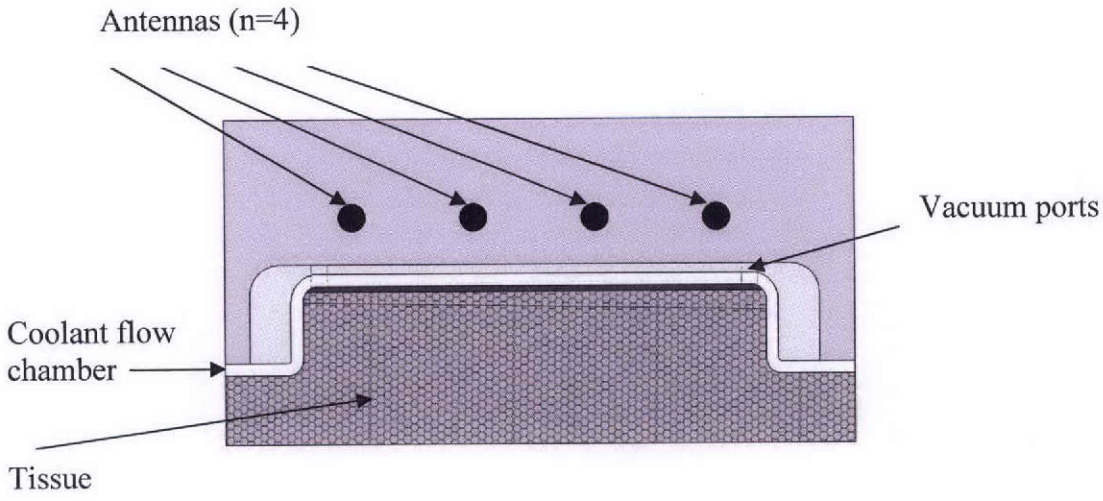

Figure 1. Cross-sectional view of Applicator with tissue acquired within the vacuum chamber.

System Overview

The DTS G2 System consists of the following major components (see Figure 2):

1. DTS G2 Microwave Generator
2. DTS LT Applicator with Disposable Head
3. Nanotherm Chiller and Recirculator
4. Isolation Transformer

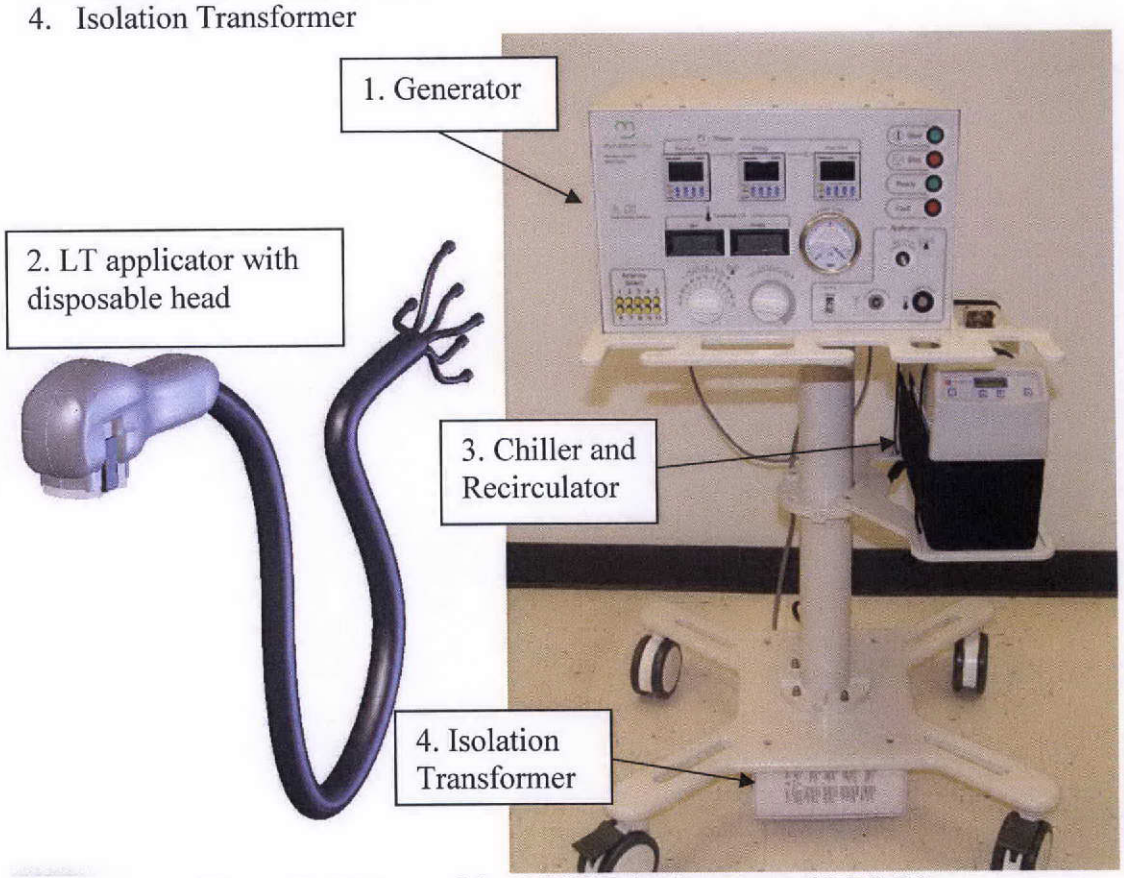

Figure 2. Picture of the DTS LT Applicator and DTS G2.

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As shown in the Figure 3 below, the system uses AC mains power and interfaces with both the user and the patient. On the front panel of the generator, the user interface allows for manual setting of the power and duration of treatment. Microwave energy is delivered at 5800MHz for the user-set duration. The output power is pre-set by the user via the power control dial. The power can be set between 40-100 Watts in 5 Watt increments. The generator also has an integrated vacuum pump that is activated during the pre-cool, energy delivery, and post-cool cycles. The generator has a vacuum level adjustment knob that is set by the user.

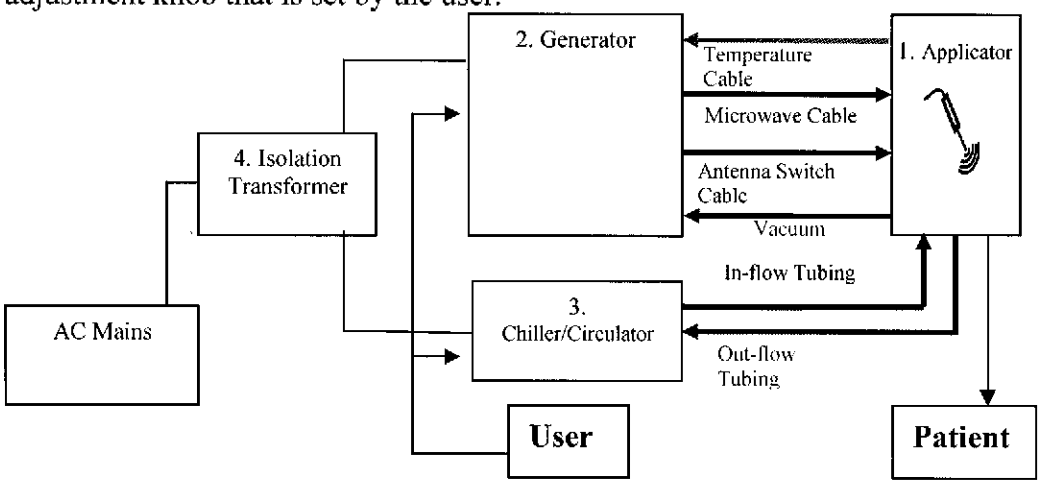

Figure 3. Block diagram of DTS G2 System.

Generator

The generator unit contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module, vacuum pump and the front panel/control board assembly. A block diagram of the components of the generator is included in Attachment A.

The generator provides the following functions:

- Generation of microwave energy at 5.8 GHz, from 40 to 100 Watts set by the user in 5 Watt increments.
- Generation of vacuum set by the user (approx range 0-25 mmHg).
- User setting of pre-cool, energy delivery, and post-cool time durations in 0.01 second increments.
- Display of skin and coolant temperatures

The control panel has an overlay that meets IEC-60601 requirements and has the following features (see manual in Attachment B for more details):

- Start & Stop buttons
- Energy delivery indicator light (Ready LED)
- Fault indicator light
- Microwave power output connector (microwave power output)
- Power setting up/down via rotary knob (Watts)

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- Pre-cool, energy delivery, and post-cool time duration settings – up/down (seconds) with elapsed time indicator
- Antenna selection buttons – on/off toggle
- Vacuum tubing connector (from applicator)
- Antenna switch connector (from applicator)
- Temperature input connector (from applicator)
- Skin Temperature and Coolant Temperature displays (from applicator)
- Vacuum gage
- Vacuum level adjustment knob

The Generator is powered by 120 VAC line power. The system does not contain any software.

LT Applicator

The Applicator consists of two components: the Disposable Head (provided sterile) and the Applicator Body. The Applicator includes a vacuum acquisition chamber, a surface cooling feature, and four microwave antennas. The vacuum acquisition chamber is a void within the Applicator where the target tissue can be localized for focused treatment. The surface cooling feature allows the user to minimize or prevent coagulation at the surface of the target soft tissue, if desired. The Applicator is permanently attached to a flexible microwave cable that carries the energy from the generator to the antennas. The applicator also has 3 permanently attached polymer tubes: one for vacuum transmission and two for the chiller fluid flow in and out. Two additional cables (temperature measurement and antenna switching) are also part of the applicator. See Figure 4.

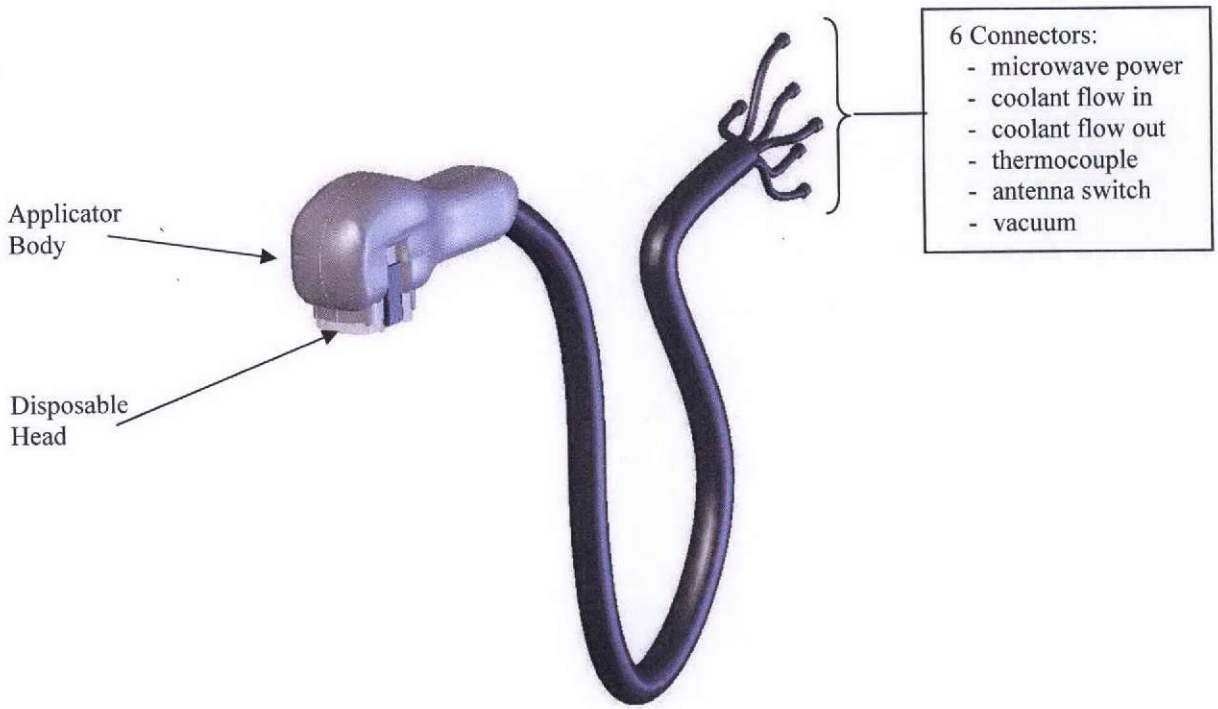

Figure 4: LT Applicator with connectors

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NanoTherm Chiller/Circulator

The NanoTherm Chiller/Circulator is a solid-state chiller designed to chill the fluid in its reservoir and pump the chilled fluid at a fixed pressure through inlet and outlet ports on the back of the unit. The Nanotherm is used to create fluid flow through the Applicator cooling chamber to cool the surface of the target tissue. The Applicator has integrated inlet and outlet tubing to be used with the Nanotherm Chiller/Circulator. This is a closed loop system where the chilled fluid is circulated through the applicator and back to the NanoTherm Chiller/Circulator fluid reservoir. The User Manual of the NanoTherm Chiller/Circulator is included in Attachment B.

System tests have been conducted that demonstrate that the user-contacting surfaces of the DTS Applicator do not reach harmful temperatures when operated within the range of typical energies as shown in the IFU. Appropriate warnings have been included in the Applicator IFU to advise the user to keep his/her hand away from the tissue acquisition chamber.

Method of Operation

The operation of the product follows these steps:

1. The (sterile) Disposable Head is connected to the Applicator Body.
2. The Applicator is connected to the Generator and NanoTherm Chiller/Circulator.
    a. Microwave cable of Applicator is connected to the Microwave Power Output connector on the Generator.
    b. The Vacuum Tube of the Applicator is connected to the Vacuum Connector of the Generator.
    c. The Inlet and Outlet Cooling Tubes of the Applicator are connected to the inlet and outlet connectors on the NanoTherm Chiller/Circulator.
    d. The Antenna Switch cable of the Applicator is connected to the Antenna Switch Connector on the Generator.
    e. The Thermocouple Cable is connected to the Temperature Connector on the Generator.
3. The Generator is powered on and user sets the following parameters: power (watts), pre-cool time (sec), energy delivery time (sec), post-cool time (sec), vacuum level (inches Hg), desired active antennas selected
4. The NanoTherm Chiller/Circulator is powered on, the coolant temperature is set and the cooling flow is turned on.
5. The user places the Applicator onto the target tissue surface.
6. The user activates the Generator either by pressing the Footswitch or pushing the Start button on the front panel of the Generator.
7. When energy delivery and post-cool cycle is complete, the vacuum is powered off and the Applicator is removed from the tissue surface.
8. If additional applications of energy are desired, steps 5-7 can be repeated. If the user desires to change the settings, steps 3-7 can be repeated.
9. Once the procedure is completed, the Generator and NanoTherm Chiller/Circulator are turned off, and the Applicator can be disconnected from the equipment.

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Substantial Equivalence

The DTS G2 device, the subject of this submission, uses microwave energy to cause tissue coagulation and hemostasis. The predicate devices (the MTCS and the Thermage ThermaCool TC System) use electrical energy, in the form of Microwave and Radiofrequency (RF), respectively, to cause tissue coagulation and hemostasis. All systems utilize surface cooling to reduce the heating of surface tissue and the amount of energy delivered is controlled manually by the user.

Generally, all the systems have an external energy generator which is connected to an antenna or energy probe. The probe directs the energy to the target tissue and is specifically designed for the type and amount of energy delivered. All systems require tissue contact to operate, and the patient-contacting components are single use and provided sterile.

A detailed comparison of the subject device and the two predicates is listed in the table below. A discussion of any differences follows the table. Finally, the provided information is used in conjunction with the 510(k) Substantial Equivalence Decision-Making Process Flowchart to demonstrate that the DTS G2 system is substantially equivalent to the predicate devices. Information about the predicate devices can be found in Attachment C.

Predicate Device Comparison

Feature	MTCS (cleared)	DTS (subject of this submission)	ThermaCool TC System	SE
510(k) Number	K072870	pending	K013639	NA
Product Code	NEY	NEY	GEI	Yes
CFR Reference	21CFR§878.4400	21CFR§878.4400	21CFR§878.4400	Yes
Manufacturer	Foundry Newco X, Inc.	Miramar Labs, Inc.	Thermage, Inc.	NA
Indications for Use	Coagulation of soft tissue	Dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Yes – same as ThermaCool
Manual or automatic	Manual setting	Manual setting	Manual setting	Yes – same as both predicates
Software	None	None	Software controls overall function	Yes – same as MTCS
Energy	Microwave	Microwave	Radiofrequency	Yes – same as MTCS

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Feature	MTCS (cleared)	DTS (subject of this submission)	ThermaCool TC System	SE
Power - maximum	60 Watts in 5 Watt increments	100 Watts in 5 Watt increments	250 Watts	Yes – similar to MTCS
Frequency	2.4 GHz	5.8 GHz	6.0 MHz	Yes – similar to MTCS
Patient Contacting Part Supplied Sterile	Disposable hand piece is ETO sterilized	Disposable hand piece cover is ETO sterilized	Disposable tip is ETO sterilized	Yes – same as both predicates
Cooling	Peristaltic pump	Chiller/recirculator pump	Cooling module software controlled	Yes – similar to MTCS
Coolant	Water	Water	Cryogen	Yes – same as MTCS
Applicator Design	Dual antenna with vacuum and surface cooling feature	Quad antenna with vacuum and surface cooling feature	Tip function is software controlled with surface cooling	Yes – similar to MTCS
Vacuum Source	Medela Basic 30 Vacuum Pump	Built into the Generator	No vacuum	Yes – same as MTCS
Electrical Safety and EMC	Compliance to IEC 60601-1 and 60601-2	Compliance to IEC 60601-1 and 60601-2	Compliance to IEC 60601-1 and 60601-2	Yes – same as both predicates
Expiration Dating for handpiece	6 months	6 months	Expiration dating for disposable tip 1 year	Yes – same as MTCS
Product Testing	Clinical simulation treating results met specifications	Clinical simulation treating results met specifications	Clinical simulation treating results met specifications	Yes

For all of the listed characteristics (indications, technology and performance specifications), the DTS G2 device is substantially equivalent to one or both of the predicate devices. There are four areas where the DTS G2 device is similar in specification but not exactly the same. These areas are explained below.

Maximum Power

The highest power setting available is 100W in the DTS G2 system, which falls between the maximum power specifications for the two predicate devices. The appropriate power to use with this device for the clinical application is chosen by the user, based on the lesion size guidelines provided in the Applicator IFU (see Attachment B).

Frequency of energy delivery

The frequency of the microwave energy delivered by the DTS G2 system is 5.8 MHz, which is 2 times higher than the MTCS predicate device. In general, the frequency of the device determines the target depth of the energy (higher frequency penetrates less). The higher frequency of the DTS G2 device is a better match for the additional dermatological indication, while still allowing the user flexibility to reach the tissue depths of

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the predicate device. The user is provided with example data (see the Applicator IFU in Attachment B) to indicate the approximate target depths. The data provided from ex vivo animal testing demonstrates that there are no affects on safety or effectiveness of the device with the different frequency.

Cooling System

The subject device and the predicate devices have slightly different cooling mechanisms. The DTS G2 system is closest to the MTCS system, where cool water is circulated in a channel next to the skin. The difference comes from the type of pump that is used to circulate the water. The chiller/recirculator pump in the DTS G2 system is a medical grade subsystem that provides a more regulated coolant temperature. The user manual for the pump can be found in Attachment B. The use of a different pump has no effect on the safety or effectiveness of the DTS G2 system.

Antenna Design

The antenna design is slightly different between the two microwave devices (the DTS G2 and the MTCS). The DTS G2 device has four antennas mounted in the applicator head (see Figure 1 in the Device Description section), whereas the MTCS had just two. The use of four antennas allows for a larger lesion to be created with a single placement of the applicator. (Each of the antennas is powered in turn, but there is not a separate pre-cool and post-cool cycle). This design change was a result of feedback from clinicians to allow for an overall faster procedure which is more comfortable for the patient. It does not have an affect on the safety or effectiveness of the device.

Summary

Miramar Labs believes that the DTS G2 device that is the subject of this submission can be determined as substantially equivalent to the predicate devices. Following the Substantial Equivalence flowchart (see Figure 5):

Item (3): Does the New Device Have the Same Indications Statement?

Yes, the DTS G2 system has the same indications statement as the Thermage ThermaCool TC System.

Item (5): Does the New Device Have the Same Technological Characteristics, e.g., Design, Materials, etc?

Yes, the DTS G2 system is a microwave energy device, with surface cooling and is made of materials that are used by the predicate devices and/or commonly used in medical devices.

Item (7): Are the Descriptive Characteristics Precise Enough to Ensure Equivalence

Yes. The product description, technical specifications and tissue study results show that the DTS G2 system successfully creates the desired soft tissue and skin lesions.

In conclusion, the DTS G2 System is substantially equivalent to the predicate devices.

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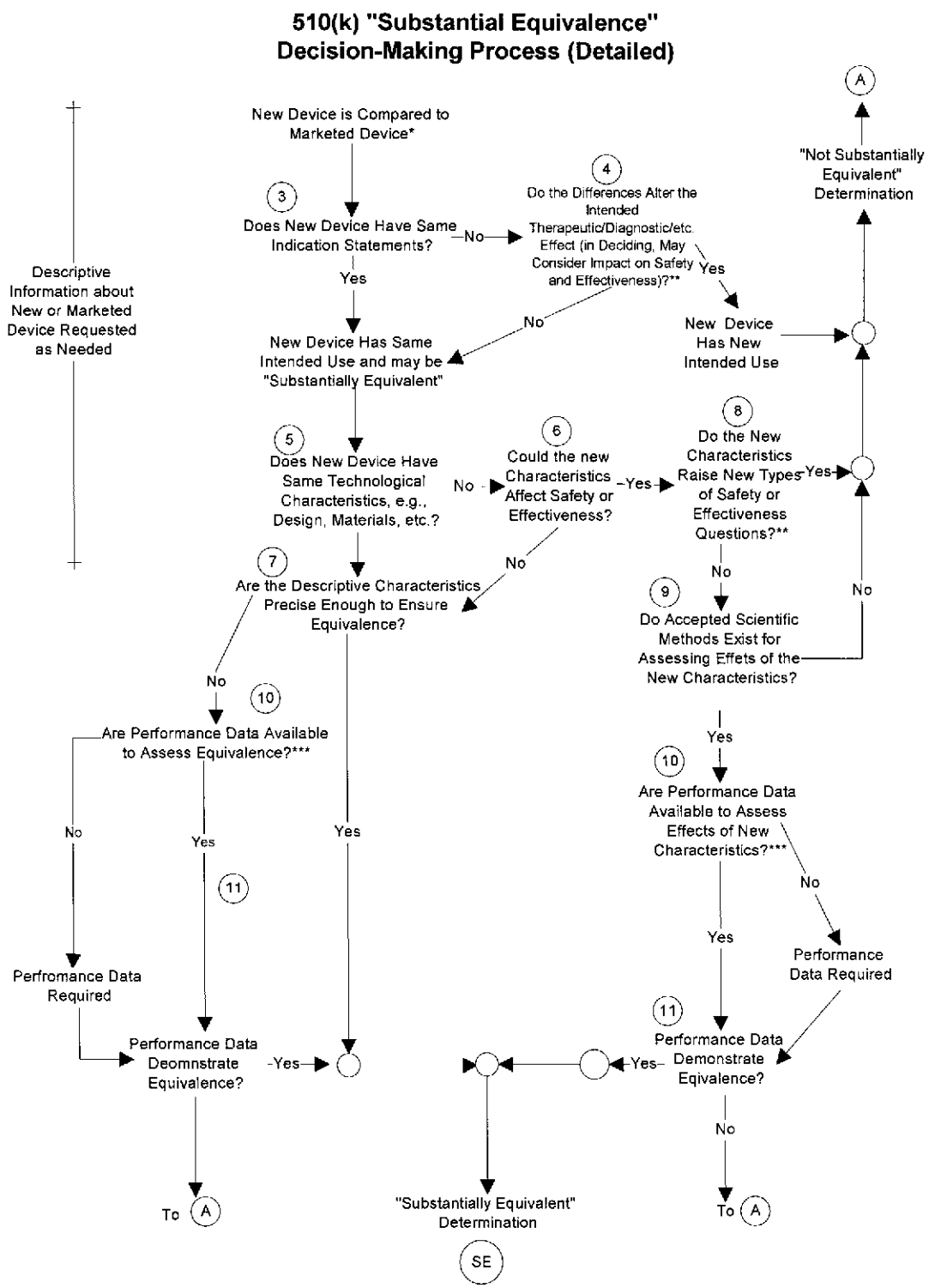

* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (Pre-Amendments or reclassified post-Amendments) of devices is unclear

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Figure 5. Substantial Equivalence Decision-Making Process

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Proposed Labeling

Instructions for Use and User Manuals are contained in Attachment B.
Product labels are contained in Attachment D.

Sterilization, Packaging and Expiration Dating

Packaging and Expiration Dating

The Disposable Head of the Applicator will be packaged in an industry standard heat sealed Tyvek and polyester sterile barrier pouch. Packaging testing and validations will be performed prior to market release. The pouch will be provided inside a paper carton.

As all materials used to construct the DTS-LT Applicator Head are well characterized and have been used in numerous previously cleared devices, initial expiration dating will be six (6) months. Accelerated and real-time aging tests will be performed in accordance with accepted methods in order to extend expiration dating.

Sterilization

The Disposable Head of the DTS LT Applicator will be supplied sterile. The device will be sterilized with Ethylene Oxide and is for single use only. The device is not intended to be re-used or re-sterilized by the user.

The sterilization process of the Disposable Head will be validated to a sterility assurance level (SAL) of 10^{-6} in accordance with ANSI/AAMI/ISO 11135-1 (Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices).

Acceptable EtO residual levels will be in conformance with the requirements of consensus standard ISO 10993-7: Biological Evaluation of Medical Devices Part 7 Ethylene Oxide Sterilization Residuals. The Disposable Head of the DTS LT Applicator is a "limited exposure" device in accordance with ISO 10993-1:2003, subclause 4.3. Allowable limits for limited exposure devices are: 20 mg EtO and 12 mg ECH (average daily dose). Verification that the EtO and ECH residuals are below allowable limits shall be confirmed as part of the EtO cycle and product aeration validation. Manufactured product shall also be routinely monitored for EtO and ECH residuals (minimum annually).

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Biocompatibility

All patient-contacting materials used to construct the DTS LT Applicator Head are well-characterized materials previously used in other medical applications (see Figure 6 and Table 2).

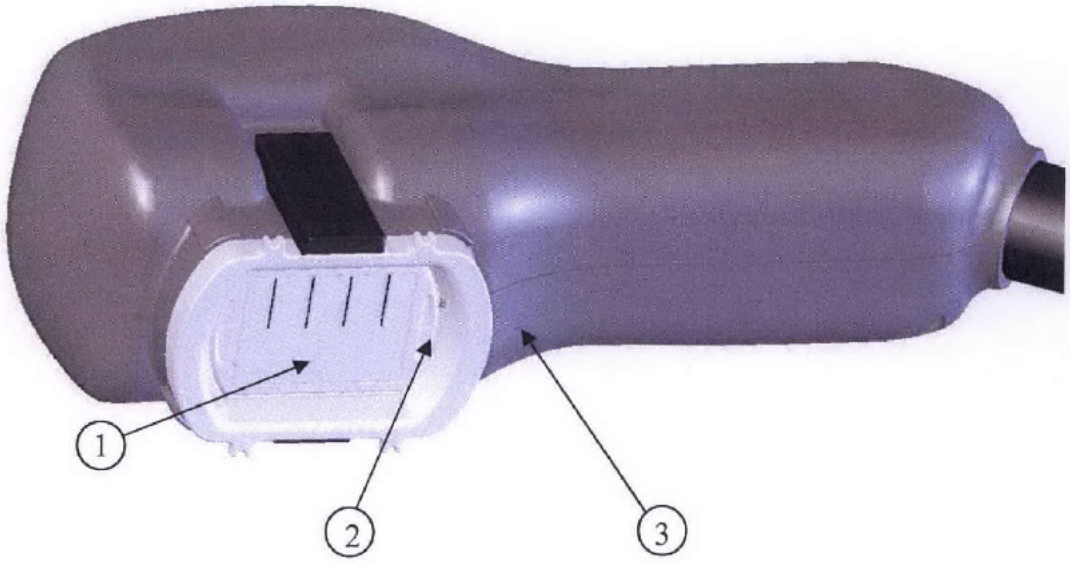

Figure 6: LT Applicator showing location of patient contacting materials: (b)(4) [redacted]

Material	Company	Device	K number	Component	Tissue contacted
(b)(4) [redacted]	Novare Surgical Systems	Realhand HD Instruments	K071488	Surgical Instruments Handle	Blood and tissue - surgical
(b)(4) [redacted]	Electromedics	FAS-CLEAN Electrosurgical Coated Active Blade	K073616	Electrosurgical Blade	Blood and tissue - surgical
(b)(4) [redacted]	VeinRx	InfusionCath	K052738	Bonding adhesive	Blood and tissue - surgical

Table 2. Patient-contacting materials and their use in cleared devices.

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As all of the materials used in the manufacture of the DTS LT Applicator Head are commonly-used medical device materials and **Miramar Labs, Inc. has not modified or recompounded any of the materials,** no additional biocompatibility testing is required. 510(k) summaries for the listed cleared devices and additional biocompatibility information for the materials used is contained in Attachment E.

Software

The Dermatologic Treatment System G2 does not contain any software.

Electromagnetic Compatibility and Electrical Safety

The System is designed to comply with the electrical safety (IEC60601-1) and electromagnetic compatibility (IEC60601-1-2) standards. Testing to both standards will be completed prior to market release.

Performance Testing – Bench

Samples of the device were subjected to clinical simulation testing with animal tissue. Results showed the product met specification in the following areas:

- (b)(4) [redacted]
- [redacted]
- [redacted]
- [redacted]

Measurements of the temperatures reached along the applicator head and cables were made to demonstrate that the user-contacting surfaces of the applicator remained within specification under simulated use conditions. The measurements were taken during the Ex-Vivo lesion creation testing, with power/time settings as shown below in Tables 4 thru 6. None of the temperatures showed any significant changes from the baseline ambient temperature demonstrating that the user contacting areas do not heat up at all during energy delivery. There is a statement in the Applicator IFU (see Attachment B) that cautions the user not to place his/her hand in the tissue acquisition chamber.

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Performance Testing - Animal

Lesion creation testing on various Ex-Vivo soft tissues (muscle, liver, and kidney) as well as In-Vivo skin tissue in a porcine model were performed. The results of the testing are summarized in the tables below. This serves as guidance for the user to understand the effects of varying energy delivery parameters. **Lesion size may vary in the clinical setting.**

The testing showed that the system performed as expected and generated lesions that were comparable to the predicate device (the MTCS microwave system).

DERMATOLOGIC TISSUE (In-Vivo porcine skin model)
The following tables show the approximate lesion size created by the DTS LT Applicator at various power/time settings with a single antenna activated. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 8.

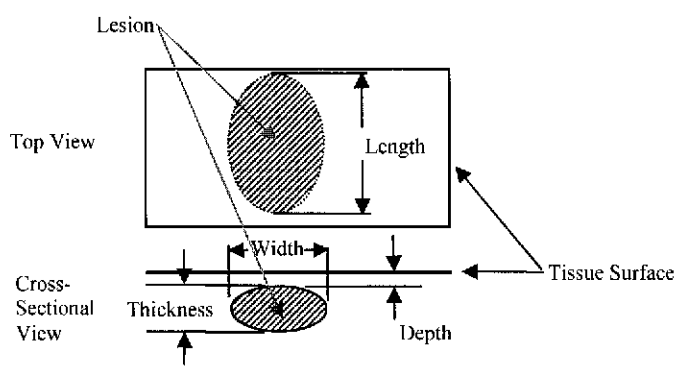

Figure 7. Lesion size and depth nomenclature.

Power (W) @ 10 °C	Lesion Dimension (mm)	2 sec.	3 sec.	4 sec.	5 sec.	7 sec.	10 sec.
40	**Length** Width **Thickness** Depth	—	—	—	**5.5** 2.0 **0.8** 1.3	**7.6** 2.9 **2.2** 0.9	**8.3** 4.2 **3.7** 0.3
60	**Length** Width **Thickness** Depth	—	—	**8.3** 3.3 **1.9** 1.1	**8.8** 4.2 **3.0** 0.6	**10.0** 5.8 **4.4** 0.3	—
80	**Length** Width **Thickness** Depth	—	**8.4** 3.7 **2.1** 0.9	**9.3** 4.8 **4.1** 0.3	**9.8** 6.0 **4.1** 0.0	—	—
100	**Length** Width **Thickness** Depth	**7.0** 3.2 **1.8** 0.8	**9.0** 4.7 **3.5** 0.1	**10.2** 5.8 **4.3** 0.0	—	—	—

*Table 3. Approximate lesion sizes created in In-Vivo porcine skin. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.*

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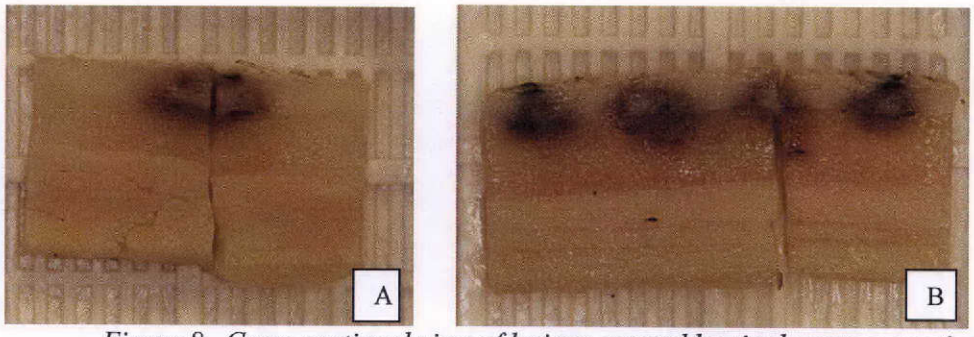

Figure 8. Cross-sectional view of lesions created by single antenna activation (A) versus lesions created with 4 antennas activated (B) in an In-Vivo porcine skin model.

GENERAL SOFT TISSUE (Ex-vivo porcine tissue models)

The following tables show the approximate lesion size created by the DTS G2 System at various power/time settings with a single antenna activated for different tissues. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 8 with the skin model. A representative cross-sectional photo of a lesion created with the DTS G2 System is shown for each tissue type.

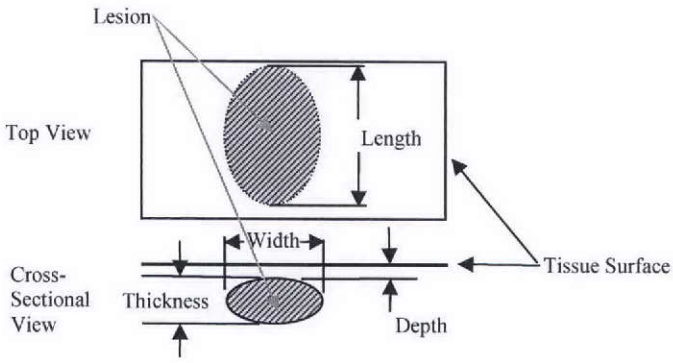

Figure 9. Lesion size and depth nomenclature.

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Muscle tissue								
Power (W) @ 10 °C	**Lesion Dimension (mm)**	**4 sec.**	**5 sec.**	**6 sec.**	**7 sec.**	**9 sec.**	**12 sec.**	**14 sec.**
40	**Length** Width **Thickness** Depth	—	—	—	—	**6.1** 2.8 **1.8** 0.6	**8.0** 5.1 **2.5** 0.3	**9.3** 4.6 **2.1** 0.4
60	**Length** Width **Thickness** Depth	—	—	**7.6** 3.8 **1.9** 0.3	**7.6** 4.8 **3.0** 0.6	**8.8** 5.3 **3.1** 0.4	—	—
80	**Length** Width **Thickness** Depth	—	**7.8** 4.1 **2.5** 0.5	**8.4** 5.9 **2.9** 0.3	**9.5** 6.6 **3.1** 0.3	—	—	—
100	**Length** Width **Thickness** Depth	**8.1** 5.4 **2.5** 0.3	**9.3** 6.6 **2.9** 0.3	**10.0** 7.4 **3.4** 0.0	—	—	—	—

Table 4. Approximate lesion sizes created in Ex-Vivo muscle tissue. Coolant set at 10°C. All lesion size dimensions are in ***millimeters****.*

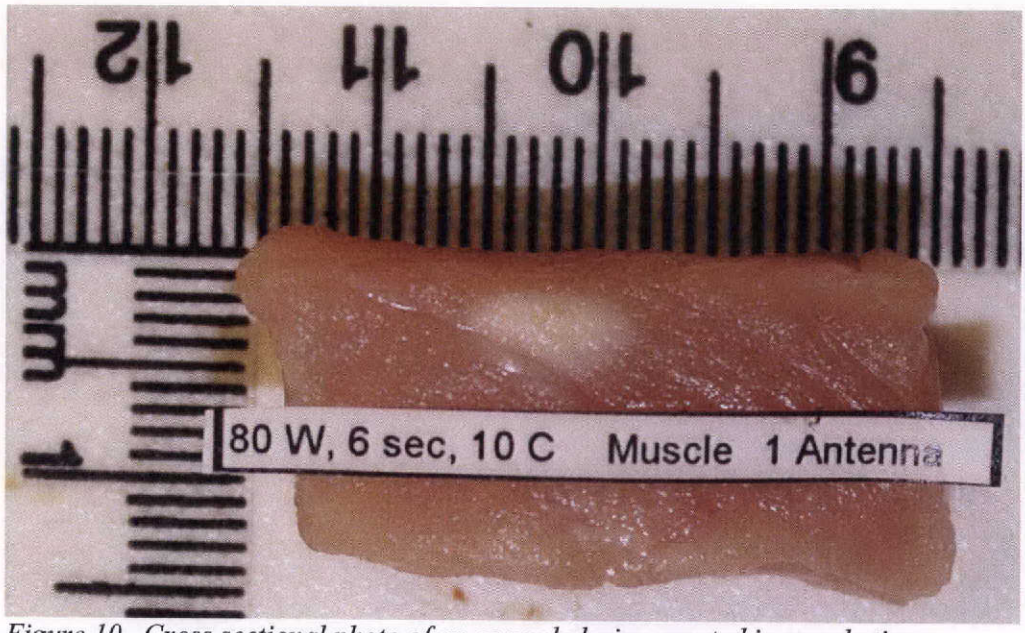

Figure 10. Cross sectional photo of an example lesion created in muscle tissue.

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Liver tissue								
Power (W) @ 10 °C	**Lesion Dimension (mm)**	**4 sec.**	**5 sec.**	**6 sec.**	**7 sec.**	**9 sec.**	**12 sec.**	**14 sec.**
40	**Length** Width **Thickness** Depth	–	–	–	–	**7.4** 2.6 **1.8** 0.9	**7.5** 2.9 **2.3** 0.8	**7.6** 4.3 **3.0** 0.7
60	**Length** Width **Thickness** Depth	–	–	**7.5** 2.5 **1.6** 0.8	**7.8** 3.3 **2.6** 0.6	**9.4** 3.8 **2.9** 0.6	–	–
80	**Length** Width **Thickness** Depth	–	**7.1** 3.3 **2.0** 0.5	**8.5** 3.9 **2.5** 0.5	**8.8** 5.4 **2.9** 0.3	–	–	–
100	**Length** Width **Thickness** Depth	**7.6** 3.8 **1.5** 0.6	**8.9** 5.0 **2.9** 0.3	**9.3** 5.5 **2.6** 0.3	–	–	–	–

Table 5. Approximate lesion sizes created in Ex-Vivo liver tissue. Coolant set at 10°C. All lesion size dimensions are in ***millimeters****.*

Figure 11. Cross sectional photo of an example lesion created in liver tissue.

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Kidney tissue								
Power (W) @ 10 °C	**Lesion Dimension (mm)**	**4 sec.**	**5 sec.**	**6 sec.**	**7 sec.**	**9 sec.**	**12 sec.**	**14 sec.**
40	**Length** Width **Thickness** Depth	—	—	—	—	**7.1** 2.3 **2.1** 1.0	**8.1** 4.0 **2.8** 0.9	**8.5** 3.8 **2.6** 0.8
60	**Length** Width **Thickness** Depth	—	—	**8.1** 2.3 **2.3** 0.8	**8.4** 3.0 **2.6** 0.8	**9.0** 4.1 **3.6** 0.3	—	—
80	**Length** Width **Thickness** Depth	—	**8.9** 4.2 **2.5** 0.5	**9.0** 4.3 **3.0** 0.6	**9.5** 5.4 **4.0** 0.3	—	—	—
100	**Length** Width **Thickness** Depth	**8.9** 3.7 **3.1** 0.5	**9.5** 5.6 **3.9** 0.3	**10.1** 6.1 **3.9** 0.4	—	—	—	—

*Table 6. Approximate lesion sizes created in Ex-Vivo kidney tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.*

Figure 12. Cross sectional photo of an example lesion created in kidney tissue.

Performance Testing - Clinical

No clinical testing was performed in support of this notification. Certification Form FDA-3674 can be found in Attachment F.

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ATTACHMENT A

Product Drawings

List of Contents in Attachment A:

1. **Block Diagram of the DTS G2 Microwave Generator Controller**

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(b)(4) Diagram

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ATTACHMENT B

INSTRUCTIONS FOR USE and USER MANUALS

List of Contents in Attachment B:

1. **DTS G2 Generator User Manual – DRAFT**
2. **DTS LT Applicator Instructions for Use – DRAFT**
3. **NanoTherm Chiller/Circulator User Manual**

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miramarlabs

Dermatologic Treatment System (DTS)
G2 Generator

User Manual

CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.

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1. CONTACT INFORMATION

Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park
CA 94025
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

1.1. EXPLANATION OF SYMBOLS

	Attention: See user manual for additional information Service By Qualified Personnel Only
	Fuse
	Type BF (Body Floating) Applied Part
LOT	Serial Number
	On (Main Power)
	Off (Main Power)
	Start
	Stop
	Non-Ionizing Radiation
	Timer
	Temperature
	Equipotential ground connection
	Manufacturer
	Date of Manufacture
	Waste electrical and electronic equipment

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2. SYSTEM DESCRIPTION

The Miramar Labs Dermatologic Treatment System (DTS) G2 Generator is designed to deliver precise amounts of microwave energy to dermal and sub-dermal tissue while providing the ability to protect the tissue surface (skin) with an active contact cooling system. Microwave energy up to 100 Watts at 5.8 GHz can be generated and a portion of that delivered to the target tissue via specially designed Applicators. The Applicator may have one or more microwave antennas, a tissue acquisition vacuum chamber, and a surface cooling plate with a flow channel.

The Dermatologic Treatment System (DTS) G2 consists of the following major components:

1. DTS Applicator
2. Generator
3. ThermoTek NanoTherm Chiller/Circulator
4. Isolation Transformer
5. Mobile Cart (not shown in Figure 1)
6. Foot Switch (not shown in Figure 1)

See Figure 1 for basic block diagram of how the components of the system are connected.

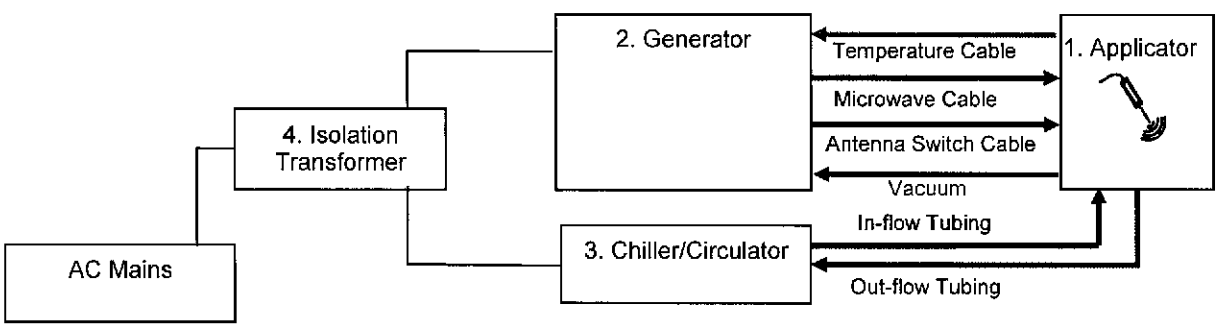

Figure 1. Block diagram of DTS G2 system components.

The Applicator is connected to the two components of the Dermatologic Treatment System (DTS) G2 that provide the required functions, the Generator and the Chiller/Circulator. The Chiller/Circulator provides the circulating cooling fluid that is flowing through the Applicator to prevent or minimize the thermal damage to the surface of the target tissue, if desired by the user.

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2.1. FRONT PANEL DISPLAY AND CONTROL FEATURES

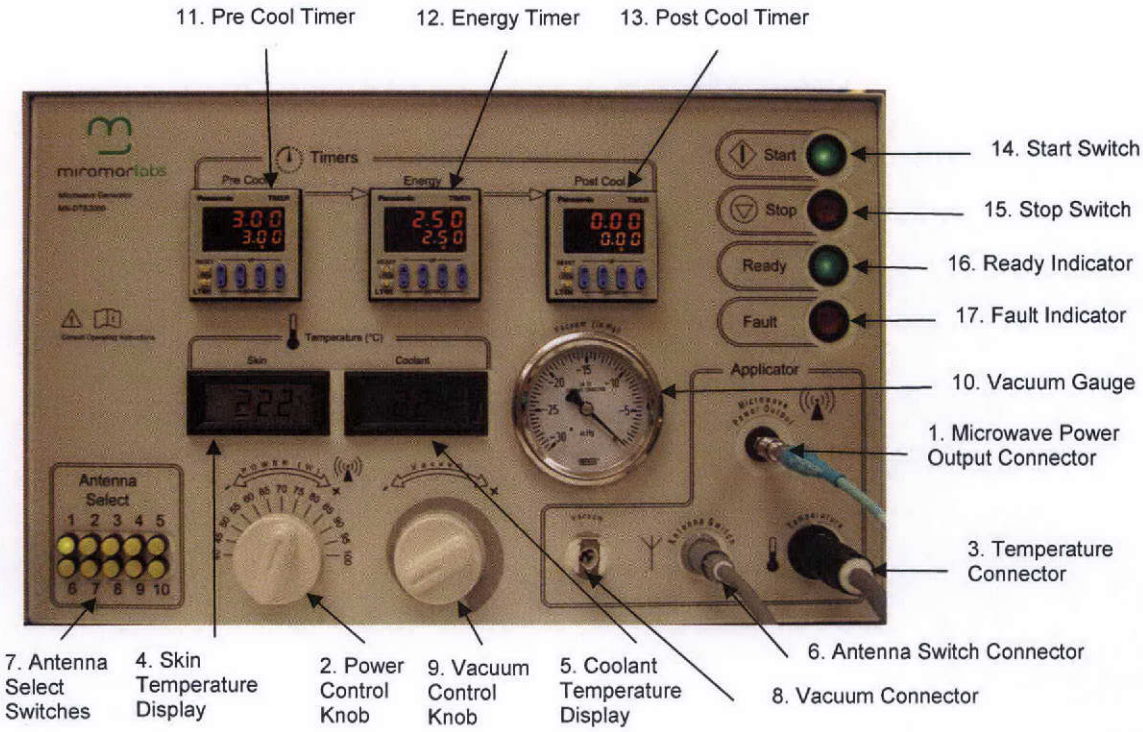

Figure 2. Generator Front Panel

1. Microwave Power Output Connector
   The Generator provides microwave power to the antennas via a coaxial QMA-type connector. The coaxial microwave cable of the Applicator is connected to this connector.

2. Power Control Knob
   A control knob on the front panel of the Generator provides the user with the ability to adjust the amount of power delivered to the Applicator.

3. Temperature Connector
   A temperature monitoring system inside the Generator provides continuous temperature monitoring of the cooling fluid line at a location inside the applicator. A second temperature monitoring system inside the Generator provides temperature monitoring of the thermocouples on the cooling plate of the Applicator between each antenna and the surface of the target tissue. This temperature monitoring is automatically switched between each of the thermocouples on the cooling plate of the applicator in coordination with automated antenna switching to provide the skin/cooling plate interface temperature associated with the active antenna.

4. Skin Temperature Display
   The skin/cooling plate interface temperature associated with the active antenna is displayed on the front panel of the Generator (°C).

5. Coolant Temperature Display
   The coolant temperature measured within the Applicator is displayed on the front panel of the Generator (°C).

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6. Antenna Switch Connector
   The antenna switch connector of the Applicator is connected on the front panel of the Generator to allow switching between antennas in Applicators that have more than one antenna.

7. Antenna Select Switches
   The user can activate one or more of the antennas (if more than one is available on a given Applicator) by pressing the appropriate antenna select switches on the front panel of the Generator. If more than one antenna is selected, the Generator will automatically deliver the energy for the set energy duration time to each of the antennas in a sequential fashion. The activation of multiple antennas enables the creation of a larger zone of heating.

8. Vacuum Connector
   A vacuum pump inside the Generator provides vacuum for tissue acquisition into the Applicator.

9. Vacuum Control Knob
   The vacuum level can be controlled by a knob on the front panel of the Generator.

10. Vacuum Gauge
    The vacuum gauge on the front panel of the Generator displays the vacuum level to the user.

11. Pre Cool Timer
    The Generator pre cool timer allows the user to set the pre-cool duration.

12. Energy Timer
    The Generator energy timer allows the user to set the energy delivery duration.

13. Post Cool Timer
    The Generator post cool timer allows the user to set the post-cool duration.

14. Start Switch
    The pre-cool, energy delivery, and post-cool sequence shall commence upon pressing the start button. The start button is enabled when the generator Ready Indicator is illuminated.

15. Stop Switch
    The stop button can be used to abort the sequence at any time.

16. Ready Indicator
    The Ready Indicator will be illuminated when the AC mains power is turned on and no fault conditions exist.

17. Fault Indicator
    The Fault Indicator will be illuminated when a fault condition exists. Refer to Section 10 Troubleshooting Guide for details on potential fault modes and potential resolutions.

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2.2. REAR PANEL FEATURES

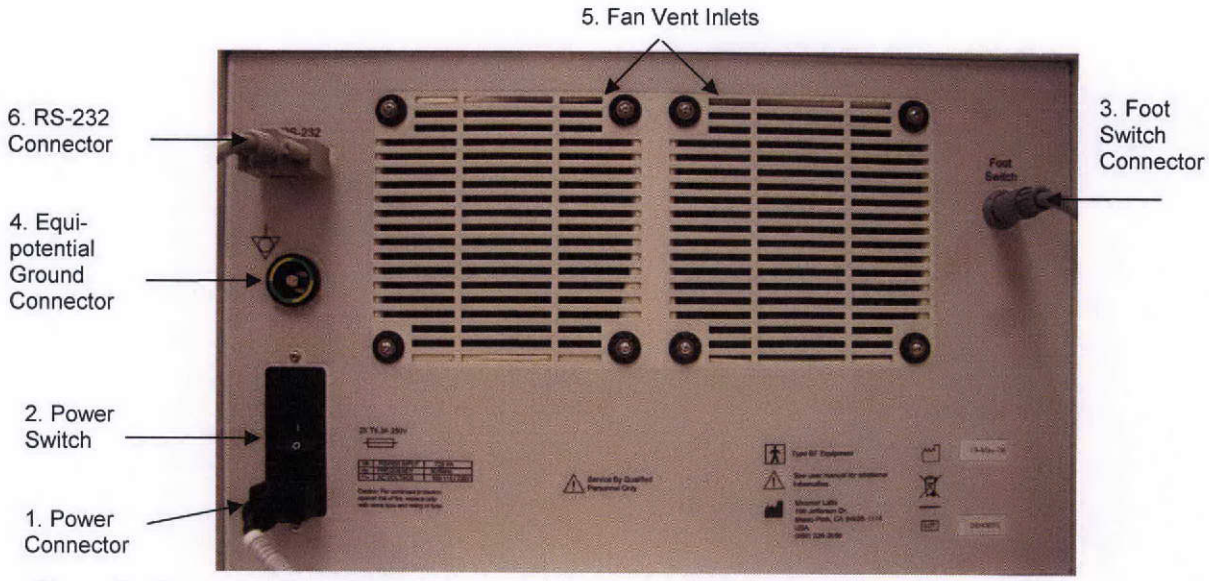

Figure 3. Generator Rear Panel

1. Power Connector
   AC mains power cord connection. This receptacle contains the Generator fuses just above the Power Switch (See instructions on How to Change the Fuses, section 2.3).

2. Power Switch
   AC mains power switch

3. Foot Switch Connector
   The Start/Stop function (as described on the Generator front-panel control) can be controlled by a foot switch (provided) that is connected to the rear panel.

4. Equipotential Ground Connector
   Use the equipotential ground connector for grounding to ensure that the generator is at the same ground potential as other equipment in the vicinity.

5. Fan Vent Inlets
   Vents allow the fans to draw ambient cooling air into the Generator. Do not block these vents to ensure proper cooling of the Generator.

6. RS-232 Connector
   The Generator provides the following data output through an RS-232 connection: antenna(s) selected, set power, actual forward power, reverse power, skin/cooling plate interface temperature (associated with the active antenna) and coolant temperature during energy delivery. This data can be collected through data acquisition devices (i.e. data-logger).

2.3. HOW TO CHANGE THE FUSES

CAUTION: Do not use repaired fuses or short-circuited fuse holders.

There are fuses in the power entry modules of the Generator, Chiller/Circulator and Isolation Transformer.

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Only use standard fuses, 2 each, current rated T6.3A/250 V @ 100-115 V ~ in the Generator.

Only use standard fuses, current rated T7A/250 V @ 100-115 V ~ in the Chiller/Circulator.

Only use standard fuses, current rated T10A/250 V @ 100-115 V ~ in the Isolation Transformer.

1. Ensure the generator, chiller and isolation transformer power switches are in the OFF (0) position.
2. Unplug the system power cord at the isolation transformer from the AC mains at the power outlet.
3. Snap the A/C RECEPTACLE-ON/OFF switch cap open by placing a flat screwdriver in the pre-marked slot located on top of the switch.
4. Remove fuses from either side of the holder and replace with standard time delay fuses, current rated T6.3A/250 V @ 100-120 V ~ for the generator, T7A/250 V @ 100-120 V ~ for the chiller/circulator, T10A/250 V @ 100-120 V ~ for the isolation transformer.
5. Replace holder and snap the cap closed.

3. CAUTIONS

Federal US law restricts this device to sale by or on the order of a licensed physician.

CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.

4. INDICATIONS FOR USE

The Dermatologic Treatment System (DTS) G2 is indicated for use in the reduction of sweat production associated with axillary hyperhidrosis and the reduction of axillary hair. This device is under investigation, and clinical data to support this indication has not been collected.

5. CONTRAINDICATIONS

The Dermatologic Treatment System (DTS) G2 is contraindicated for patients with heart pacemakers and other electronic device implants.

6. POTENTIAL ADVERSE EVENTS

Potential adverse events could include, but are not limited to: abcess formation, skin ulcer formation, motion limitation, hyper/hypo- pigmentation, skin burns/scars, skin dryness, and numbness/tingling.

7. WARNINGS AND PRECAUTIONS

- ❑ Carefully read the User Manuals for the Miramar Labs Dermatologic Treatment System (DTS) G2 Generator and the Nanotherm Chiller/Circulator, and the

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Applicator IFU prior to use. Observe all warnings and precautions. Failure to do so may result in complications.

- The DTS G2 is for use by qualified clinical personnel who have been instructed and trained in the correct use of the equipment by designated Company representatives.
- Safety of the DTS G2 has not been evaluated on patients with cardiac pacemakers or other electronic implants. The DTS G2 system should not be used on such patients.
- Operate the DTS G2 in environmental temperatures between 16°C and 26°C (60°F and 80°F); and between 30% and 60% relative humidity (non-condensing).
- Use only the components and parts supplied by Miramar Labs.
- DO NOT attempt to repair or alter any of the System components.
- DO NOT allow fluid to contact generator, cables or connectors unless the generator is being cleaned. Do not hang fluids above the generator. The generator may not function correctly if the electronic circuitry or the connectors are wet. Do not soak cables.
- DO NOT operate if wet. Electrical shock may occur.
- DO NOT operate if there is no Applicator connected or if the Applicator is not positioned at the intended target site. See Applicator IFU for proper positioning of the applicator.
- Clean, disinfect, and maintain the electrical units in accordance with the operating instructions.
- Turn the electrical units Off using the main power On/Off switch and disconnect the power cord from the AC supply before cleaning.
- DO NOT remove the cover of any of the system components. There are no user-serviceable parts inside the components of the DTS G2. Opening the cover of any of the DTS G2 components may result in electrical shock or thermal burns.
- For warnings and precautions associated with the chiller portion of the DTS G2, see the NanoTherm Industrial User Manual. Also read the Applicator IFU.
- This equipment/system is intended for use by healthcare professionals only. The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Provide as much distance as possible between the DTS G2 and other electronic equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interteference. It may be necessary to take mitigation measures, such as reorientating or relocating the Generator or shielding the location.
- The DTS G2 should not be used or pause/terminate therapy cycle when the temperature shows abnormal fluctuations.

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- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- Electrosurgical components, such as the Applicator, may remain hot after activation. Keep all electrosurgical equipment away from flammable materials to avoid combustion.
- Prolonged or unneccessary activation of the DTS G2 may lead to unintentional damage to surrounding tissue.
- The output power selected should be as low as possible for the intended purpose.
- Do not obstruct the activation light or tone. The activation tone and light are important safety features.
- Use only Miramar Labs Applicators designed to be used with the DTS G2 Generator.
- Do not bend cables at acute angles or coil them tightly; the cable might break.
- The main power cord of the Isolation Transformer must be connected to a properly grounded receptacle. Extension cords and/or adaptor plugs must not be used. Plug equipment into 100-115V AC 60 Hz power receptacles.

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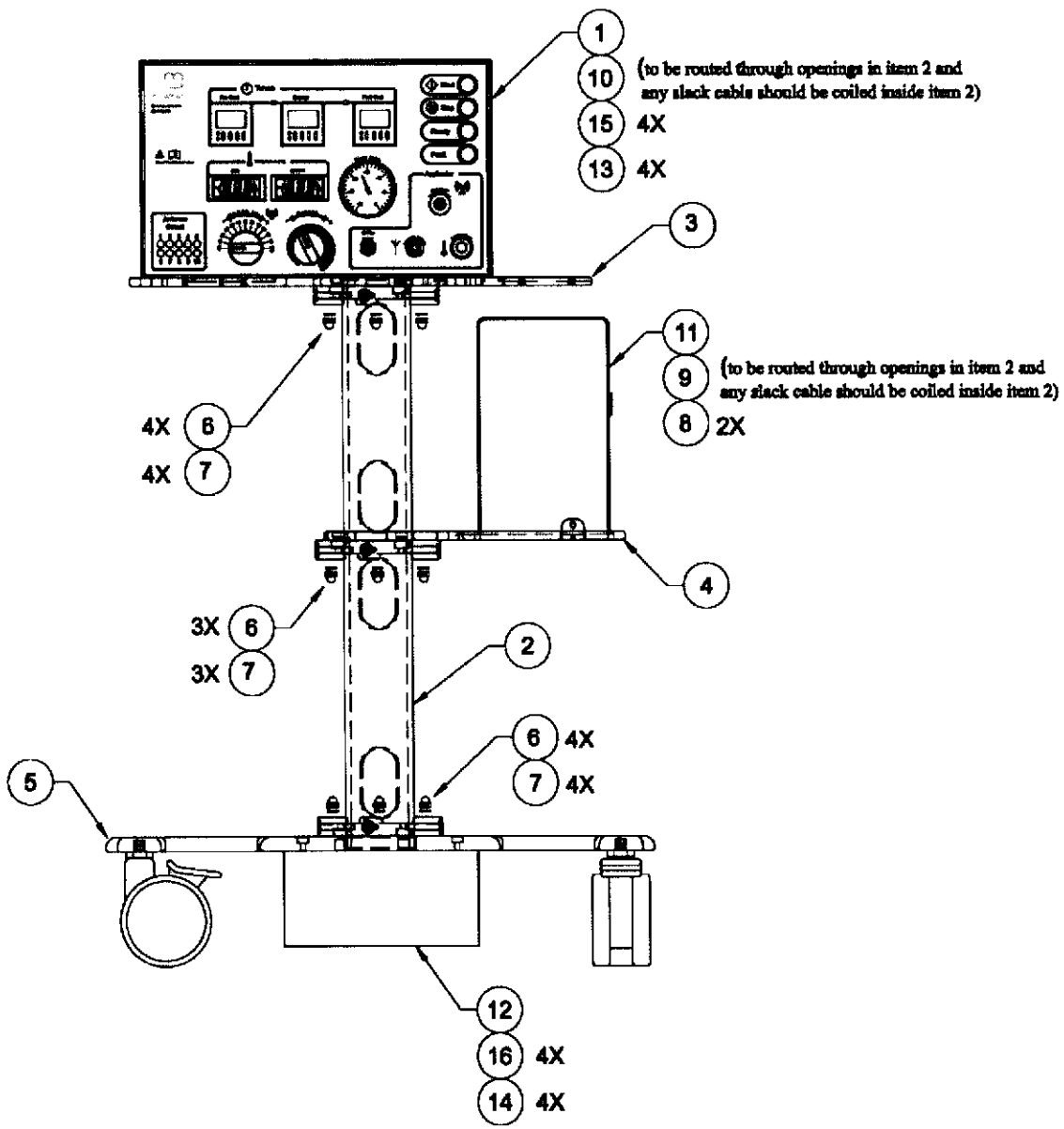
8. OPERATING INSTRUCTIONS

8.1. UNPACKING AND EQUIPMENT SET-UP

- ❑ Open each of the four cases containing the cart, generator, chiller, isolation transformer and miscellaneous cables, hardware, tools and manuals and remove the contents. Inspect all components for shipping damage. If damage has occurred, contact Miramar Labs. Verify all components are present (see section 10).

1. Refer to figure 3 below for remainder of set-up.

Figure 3. Equipment Set-up



2. Attach the isolation transformer (12) to the bottom of the cart base (5) using the four 10-32 x 5/8" long screws (14) with four #10 internal tooth lock washers (16)

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being sure to orient the connectors to the rear of the cart (the front of the cart has locking casters).

3. Attach the vertical support pole (2) to the cart base (5) using four acorn nuts (6) with four flat washers (7).
4. Attach the chiller shelf (4) to the support pole (2) using three acorn nuts (6) with three flat washers (7).
5. Attach the generator shelf (3) to the support pole (2) using four acorn nuts (6) with four flat washers (7).
6. Attach the generator (1) to the generator shelf (3) using the four 8-32 x 5/8" long screws (13) with four #8 internal tooth lock washers (15) being sure to orient the rear of the generator to the rear of the cart (the front of the cart has locking casters).
7. Attach the chiller (11) to the chiller shelf (4) using the thumb screw on the rear of the chiller (part of 11) and the two black nylon cinching straps (8).
8. Ensure the AC receptacle on/off switch, located on rear panel of the generator is off (O). Connect the longer of the two power jumper cords (10, 2 meter length) to the generator (1) and route the cable inside of the support pole (2) through the oval opening closest to the top and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
9. Connect the shorter of the two power jumper cords (9, 1.5 meter length) to the chiller (11) and route the cable inside of the support pole (2) through the oval opening just under the chiller shelf (4) and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
10. Connect the AC mains power cable (part of 12) to the isolation transformer (12).
11. Retain all packing materials, tools and manuals.

8.2. SYSTEM SETUP AND WARM-UP

1. Connect the AC mains power cable from the isolation transformer to a properly grounded AC outlet and switch the isolation transformer AC receptacle on/off switch, located on the rear panel, to the on (I) position.
2. Connect the foot switch to the connector labeled "Foot Switch" on the rear panel, if desired.
3. Set the desired power output power by rotating the rotary power knob on the front panel. Power is adjustable over the range from 40 Watts to 100 Watts in 5 Watt increments.
4. Place the Applicator in the holster provided on the front right side of the cart. Connect the microwave cable of the Applicator to the "Microwave Power Output" quick-connect QMA style connector on the front panel of the Generator.
5. Connect the vacuum tubing of the Applicator to the "Vacuum" connector on the front panel of the Generator.
6. Connect the temperature cable of the Applicator to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator.
7. Connect the antenna control cable of the Applicator to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator.
8. Select the desired Applicator antennas by pushing the "Antenna Select" push button switches located at the bottom left corner of the front panel of the Generator.

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9. Connect the cooling flow tubing of the Applicator into the Chiller/Circulator
   a. Connect the "into chiller" tubing into the "flow-in" receptacle of the Chiller/Circulator.
   b. Connect the "out from chiller" tubing into the "flow-out" receptacle of the Chiller/Circulator.
   c. Ensure the applicator fluid tubing is not placed over or on the equipment in order to prevent fluid ingress into the generator, chiller/circulator or isolation transformer, especially when disconnecting the applicator fluid tubing connectors from the chiller/circulator.
   d. Turn on the power to Chiller/Circulator, set the cooling temperature, and run until temperature is stabilized on the applicator cooling fluid temperature readout (depending on the set temperature, this can take up to 30 minutes).
   e. Only use de-ionized water in the Chiller/Circulator. Check the fluid level in the Chiller/Circulator before starting each therapy session. Coolant should be added until the fluid level is visible at the base of the reservoir neck. If the coolant level can be seen lower than halfway down the illuminated fluid level window, more coolant should be added.
10. Turn on the power to the Generator using the switch located on the AC inlet module located on the rear panel of the Generator by switching the on/off switch to the on (I) position.
11. Ensure that the "Start" and "Ready" lights are illuminated, that the two temperature displays show temperatures, that the three timers illuminate, that any selected Applicator "Antenna Switches" are illuminated and that the "Vacuum" gauge shows a vacuum level.
12. Set the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration by pressing the rocker buttons immediately below each digit display on the appropriate timer module and then pressing the reset button on that timer module. Each timer can be set to a time range of 0.00 to 99.99 seconds.
13. **WARNING:** The FAULT LED is illuminated if the system detects a malfunction (see Troubleshooting, section 0).
14. Position the system close to the patient.
15. Ensure all air vents on the equipment are not obstructed.

8.3. OPERATION

1. Confirm that the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration settings on the Timer Controller are correct. If adjustments need to be made for any of the three durations, press the rocker buttons to the desired time on the appropriate timer panel and press the Reset button. ⚠ Important note regarding the Pre-Cool cycle: In order to assess proper tissue acquisition into the Applicator vacuum chamber prior to energy delivery, do not set the Pre-Cool timer to less than 3 seconds.

2. Adjust vacuum control knob to the desired setting. Use the lowest setting necessary to get adequate tissue acquisition into the Applicator vacuum chamber. Note that vacuum will not be applied to the Applicator until the "Start" button is pressed. A vacuum level tissue acquisition test can be performed by setting the "Energy" timer to 0 seconds to confirm that the vacuum level is adequate to engage the tissue in the Applicator.

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3. Place the DTS applicator on the target tissue. **CAUTION**: DO NOT operate if the applicator is not connected or if the applicator is not correctly positioned on the patient. See Applicator Instructions for Use for correct positioning of the applicator on the patient.

4. Push the "START" button on the Generator (or depress the foot switch). An audible buzzer will indicate when microwave energy is being delivered. Another sound (1 second duration) will indicate when the entire therapy cycle has been completed, at which time the vacuum will also be turned off to the Applicator. During the pre cool, energy and post cool cycles, each of the associated timers will count down from the user selected values to zero. If more than one antenna has been selected, the energy timer will count down the number of times that corresponds to the number of antennas selected before transitioning into the post cool cycle.

5. Press the "Stop" switch (or depress the foot switch) to abort the procedure.

6. Repeat steps 1-4 for additional treatments.

8.4. SYSTEM SHUTDOWN PROCEDURE

1. Turn off the power to all of the components of the system.
2. Disconnect the cable plugged into the isolation transformer from the AC mains source and coil cable on back of the Generator shelf.
3. Place foot switch in location provided on back of Generator shelf and coil excess cable on back of Generator shelf.
4. Disconnect DTS Applicator from the Generator and Chiller/Circulator and remove/dry up any fluids that may have dripped out of the tubing or chiller.

9. CLEANING AND MAINTENANCE

9.1. CLEANING

- Components of the DTS G2 cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter connectors on Generator.
- Make sure power to the DTS G2 components are turned OFF and the power cord unplugged before cleaning.
- Do not spray or pour cleaning agents or any other liquids on the DTS G2 components.
- Dampen a clean dry cloth with a multi-purpose hospital grade detergent.
- Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into the housing or electrical components.
- Gently dry the entire Generator, including cords.
- Do not soak any of the cords or cables, especially the connectors, since this can affect electrical performance.

9.2. STORAGE

The DTS G2 system components should be stored in a cool, dry place out of direct sunlight.

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9.3. SERVICE INFORMATION

The DTS G2 has been Manufacturer tested. There are no serviceable parts inside the DTS G2 components. Contact Miramar Labs for service.

10. HOW SUPPLIED

The Miramar Labs DTS G2 is supplied with the following components:

10.1. DESCRIPTION OF DTS G2 COMPONENTS

Item	Description	Qty
1	DTS G2 Generator User Manual (this document)	1
2	DTS G2 Generator	1
3	Nanotherm Chiller/Circulator and User Manual	1
4	Isolation Transformer	1
5	Cart (assembly required, see section 8.1)	1
6	Various cables and adapters, foot switch	As Required

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11. TROUBLESHOOTING GUIDE

Problem	Troubleshooting Tips
No, or irregular system operation or no power.	1. Ensure that power switches of the isolation transformer, Generator and Chiller are all turned on (I). 2. Ensure that power cords from Generator and Chiller are plugged into the isolation transformer. 3. Ensure that the isolation transformer is plugged into a proper electrical outlet matching its electrical specification. 4. Ensure that fuses in isolation transformer, Generator and Chiller are intact and have Miramar Labs personnel replace fuses if needed (see How to Change Fuses, section 2.3). 5. If problem persists, contact Miramar Labs representative.
Red "Fault" light on right side of Generator front panel is illuminated; preventing initiation of therapy cycle with the "Start" button.	1. Ensure that the antenna control cable of the applicator is properly connected to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Ensure that the temperature cable of the applicator is properly connected to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 7. Replace Applicator if the coolant temperature display exceeds 45°C . After replacement of the applicator, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 9. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates immediately after initiation of therapy cycle with the "Start" button.	1. Ensure that the chiller temperature is set properly. 2. Ensure that the chiller is not in standby mode. 3. Ensure that the coolant level in the chiller is adequate. 4. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 5. Replace Applicator if the skin temperature display exceeds 45°C . After replacement of the applicator, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 6. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 7. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates during the energy delivery cycle and the energy delivery cycle terminates prematurely	1. Ensure that the microwave cable of the Applicator is properly connected to the QMA quick-connect "Microwave Power Output" connector on the front panel of the Generator. Turn the generator power off and back on. After the connector has been properly connected and after the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Check the Applicator for any visible indication of a damaged or kinked microwave cable and replace Applicator if damage is suspected. Turn the generator power off and back on. After the applicator microwave cable has been checked or the applicator has been replaced (if needed) and the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 7. Replace Applicator if the skin temperature display exceeds 45°C . After replacement of the applicator, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. Check the power settings to ensure that the power level is not set too high and reduce the power level as needed. 9. Check the energy delivery timer settings to ensure that the energy delivery duration is not set too long and reduce the energy delivery time as needed. 10. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 11. If problem persists, contact a Miramar Labs representative.

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12. SPECIFICATIONS

AC input voltage	100-115V AC, 60 Hz
Protection	Protectively earthed, Class I
Microwave Output Frequency	5800MHz ± 50 MHz
Microwave Output Power	Adjustable from 40 to 100 Watts in 5 Watt increments
Patient Isolation	Class BF (body floating) for applied parts
Duty Cycle	Continuous
Environmental Operating Temperature/Humidity	Ambient Temperature: +60˚F to +80˚F (+16˚C to+26˚C) Relative Humidity (Non-condensing): 30% - 60%
Environmental Storage/Shipping Temperature/Humidity	Ambient Temperature: 0˚C to +50˚C Relative Humidity (Non-condensing): 20% to 85%
CONFORMS TO	<u>Safety:</u> UL 60601-1 Issued:2003/04/25 Ed:1 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety CSA C22.2#601.1 Issue:1990/01/11 (R2005) Medical Electrical Equipment - Part 1: General Requirements for Safety-General Instruction No 1; Update No 2 CENELEC EN60601-1 Issue:2006/10/01 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance <u>EMC:</u> IEC 60601-1-2 Issued:2004/11/01 Ed:2.1 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests-Edition 2.1; Consolidated Reprint –

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Manufactured by:

Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park
CA 94025
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

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

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INSTRUCTIONS FOR USE

DTS-LT APPLICATOR

DRAFT 09/23/08

Miramar Labs, Inc.

199 Jefferson Dr.
Menlo Park, CA 94025
Phone: 650-326-2656
Fax: 650-326-3108

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

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DTS-LT Applicator Instructions for Use

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

BEFORE USING THE SYSTEM:

Please refer to Dermatologic Treatment System (DTS) G2 Generator User Manual for detailed instructions on connecting and operating the entire system. Components of the DTS System are designed to be used together as a single unit.

Failure to understand and follow provided instructions, may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

- The Dermatologic Treatment System (DTS) G2 is indicated for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis.

IMPORTANT:

- The procedures should only be performed by physicians and operating room staff familiar with the equipment and techniques involved.

WARNINGS AND CAUTIONS:

- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
- DO NOT apply power with Applicator not in contact with the target tissue
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

- Refer to DTS Generator User Manual for detailed instructions on how to activate system generator and properly connect associated components.
- Refer to the NanoTherm Chiller/Circulator User Manual for detailed instructions on how to set chiller temperature and activate the flow.
- Activate the cooling flow for surface cooling.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level
- Set power and durations of pre-cool, energy delivery, and post cool to desired levels.
- Place the Applicator on the target tissue (see figure below for proper technique of holding the handle).
- Confirm the generator settings before proceeding with the procedure.

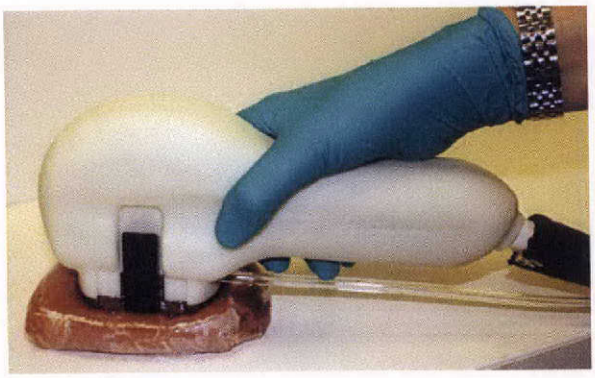

Figure 1. Proper technique for holding the handle of the Applicator

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DERMATOLOGIC TISSUE

NOTE:
The following tables show the approximate lesion size created by the DTS LT Applicator at various power/time settings with a single antenna activated. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 3. The results are from In-Vivo porcine skin model. Lesion sizes may vary in clinical setting.

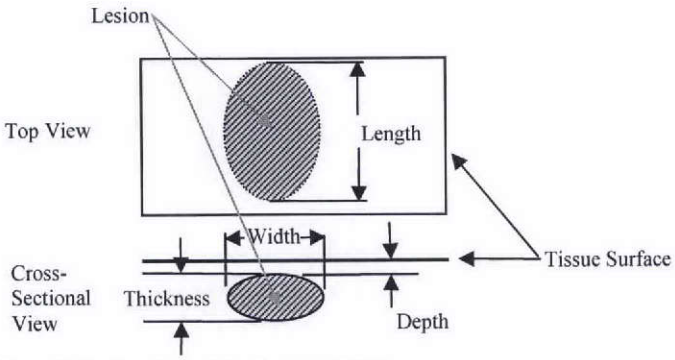

Figure 2. Lesion size and depth nomenclature.

Power (W) @ 10 °C	Lesion Dimension (mm)	2 sec.	3 sec.	4 sec.	5 sec.	7 sec.	10 sec.
40	**Length** Width **Thickness** Depth	–	–	–	**5.5** 2.0 **0.8** 1.3	**7.6** 2.9 **2.2** 0.9	**8.3** 4.2 **3.7** 0.3
60	**Length** Width **Thickness** Depth	–	–	**8.3** 3.3 **1.9** 1.1	**8.8** 4.2 **3.0** 0.6	**10.0** 5.8 **4.4** 0.3	–
80	**Length** Width **Thickness** Depth	–	**8.4** 3.7 **2.1** 0.9	**9.3** 4.8 **4.1** 0.3	**9.8** 6.0 **4.1** 0.0	–	–
100	**Length** Width **Thickness** Depth	**7.0** 3.2 **1.8** 0.8	**9.0** 4.7 **3.5** 0.1	**10.2** 5.8 **4.3** 0.0	–	–	–

Table 1. Approximate lesion sizes created in In-Vivo porcine skin. Coolant set at 10°C. All lesion size dimensions are in **millimeters**. The numbers are in the following sequence A / B / C / D (see Figure 2 for definition).

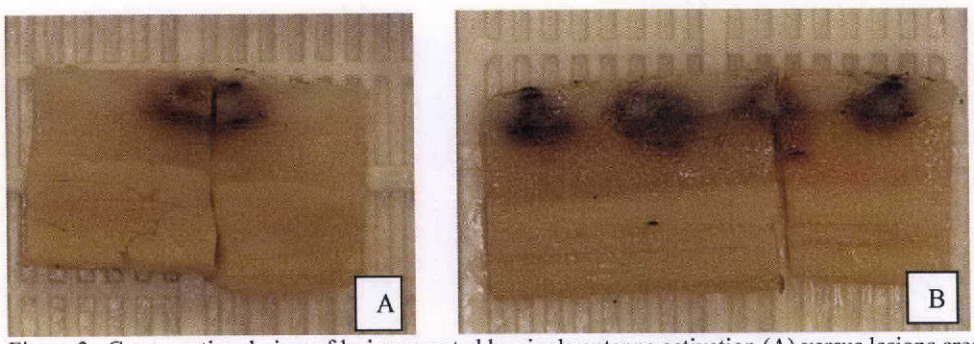

Figure 3. Cross-sectional view of lesions created by single antenna activation (A) versus lesions created with 4 antennas activated (B) in an In-Vivo porcine skin model.

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GENERAL SOFT TISSUE

NOTE:
The following tables show the approximate lesion size created by the DTS LT Applicator at various power/time settings with a single antenna activated for different tissues. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 3 with the skin model. The results are from Ex-Vivo porcine tissue models. Lesion sizes may vary in clinical setting.

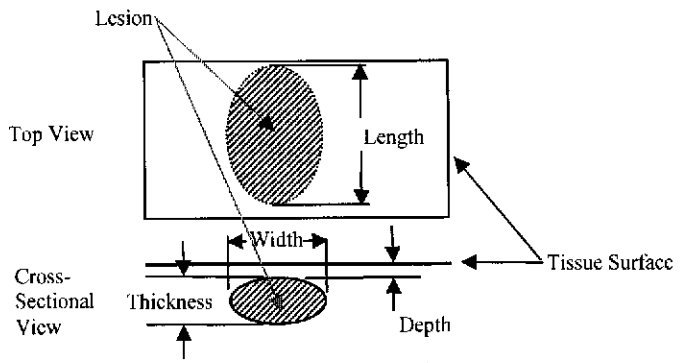

Figure 4. Lesion size and depth nomenclature.

Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.	12 sec.	14 sec.
40	**Length**					**6.1**	**8.0**	**9.3**
	Width	—	—	—	—	2.8	5.1	4.6
	Thickness					**1.8**	**2.5**	**2.1**
	Depth					0.6	0.3	0.4
60	**Length**			**7.6**	**7.6**	**8.8**		
	Width	—	—	3.8	4.8	5.3	—	—
	Thickness			**1.9**	**3.0**	**3.1**		
	Depth			0.3	0.6	0.4		
80	**Length**		**7.8**	**8.4**	**9.5**			
	Width	—	4.1	5.9	6.6	—	—	—
	Thickness		**2.5**	**2.9**	**3.1**			
	Depth		0.5	0.3	0.3			
100	**Length**	**8.1**	**9.3**	**10.0**				
	Width	5.4	6.6	7.4	—	—	—	—
	Thickness	**2.5**	**2.9**	**3.4**				
	Depth	0.3	0.3	0.0				

Table 2. Approximate lesion sizes created in Ex-Vivo muscle tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.	12 sec.	14 sec.
40	**Length**	—	—	—	—	**7.4**	**7.5**	**7.6**
	Width					2.6	2.9	4.3
	Thickness					**1.8**	**2.3**	**3.0**
	Depth					0.9	0.8	0.7
60	**Length**	—	—	**7.5**	**7.8**	**9.4**	—	—
	Width			2.5	3.3	3.8		
	Thickness			**1.6**	**2.6**	**2.9**		
	Depth			0.8	0.6	0.6		
80	**Length**	—	**7.1**	**8.5**	**8.8**	—	—	—
	Width		3.3	3.9	5.4			
	Thickness		**2.0**	**2.5**	**2.9**			
	Depth		0.5	0.5	0.3			
100	**Length**	**7.6**	**8.9**	**9.3**	—	—	—	—
	Width	3.8	5.0	5.5				
	Thickness	**1.5**	**2.9**	**2.6**				
	Depth	0.6	0.3	0.3				

Table 3. Approximate lesion sizes created in Ex-Vivo liver tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.	12 sec.	14 sec.
40	**Length**	—	—	—	—	**7.1**	**8.1**	**8.5**
	Width					2.3	4.0	3.8
	Thickness					**2.1**	**2.8**	**2.6**
	Depth					1.0	0.9	0.8
60	**Length**	—	—	**8.1**	**8.4**	**9.0**	—	—
	Width			2.3	3.0	4.1		
	Thickness			**2.3**	**2.6**	**3.6**		
	Depth			0.8	0.8	0.3		
80	**Length**	—	**8.9**	**9.0**	**9.5**	—	—	—
	Width		4.2	4.3	5.4			
	Thickness		**2.5**	**3.0**	**4.0**			
	Depth		0.5	0.6	0.3			
100	**Length**	**8.9**	**9.5**	**10.1**	—	—	—	—
	Width	3.7	5.6	6.1				
	Thickness	**3.1**	**3.9**	**3.9**				
	Depth	0.5	0.3	0.4				

Table 4. Approximate lesion sizes created in Ex-Vivo kidney tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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PROCEDURE NOTES

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to DTS Generator User Manual for troubleshooting.

AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from Generator and Chiller/Circulator and discard.
- Turn off Generator after procedure.

STORAGE:

- Store Applicator away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:

⚠.....**Read Instructions**

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NanoTherm™ Industrial User Manual

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1. Introduction

Please read the entire manual carefully before trying to operate the NanoTherm™ system. It is unsafe to start using the NanoTherm system before reading the entire user manual.

At ThermoTek, we pledge to provide the highest quality product with excellent support and service. If we can do anything to make your NanoTherm experience better, please do not hesitate to contact us.

User Assistance Information:

The NanoTherm System is manufactured by:

ThermoTek, Inc.
1454 Halsey Way
Carrollton, TX 75007
(972) 242-3232
(877) 242-3232 (toll free service number)

Visit us on the web at www.thermotekusa.com

Icons Used for Warnings and Cautions:

- Electrical Shock Risk
- Burn Risk
- Frostbite or Cryogenic Burn Risk
- General Caution

Do not drink or ingest the coolant mixture.

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   2. 95% distilled water and 5% alcohol mixture prevents bacterial growth. Replace every 90 days. 8-7
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2. General Warnings and Cautions

2.1 Precautions:

When using the NanoTherm system, basic safety precautions should always be followed to reduce the risk of fire, electric shock and personal injury. Please read the entire manual carefully before trying to operate the unit. Precautions include:

2.2 Warnings:

- Never push objects of any kind into the unit through the air filter or frame.
- Never spill liquid of any kind on the unit.
- Do not overfill the reservoir of the unit.
- If the unit gets wet, unplug the unit from the wall and allow the unit to dry before use.
- The unit must be operated with the supplied power cord and plugged into a 3-prong grounded outlet.
- Do not operate the unit if it has any noticeable or physical damage or is leaking fluid.
- Do not operate the unit with a damaged or frayed power cord.
- The unit is not intended to be used in a wet environment or when relative humidity is greater than 60%.
- Do not spray the unit with any water solvents or cleaners.
- Do not drop the unit or cause impact to the unit.
- Do not use this device without the supplied air filter.
- Do not use near equipment that generates electromagnetic or other interferences as this may be harmful to the unit.
- Do not touch the heat sink fins on the sides of the unit during or immediately after operation.
- Do not stick a finger or any other foreign objects into the reservoir.
- Do not attempt to sterilize this device by any means.
- Use only the approved coolant in the NanoTherm unit.

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⚠ Slots and openings in the cabinet are provided for ventilation to protect the unit from overheating. These openings must not be blocked or covered at any time except by the supplied air filter.

⚠ Observe all warning labels. Never remove the warning labels.

⚠ **Do not drink or ingest the coolant.**

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3. NanoTherm Device Description

The NanoTherm system is an electronic heating and cooling system. The NanoTherm system provides precisely controlled fluid temperature for cooling and heating applications. This lightweight, portable system utilizes solid-state thermoelectric heat pumps that heat and cool with electricity in a safe and environmentally friendly manner.

3.1 Features:

- Fluid Temperature Range between 10°C – 40°C
- Lightweight and Portable Package
- User-Friendly Interface
- 110 VAC Power Input
- Illuminated Fluid Level Indication
- Easy to read Liquid Crystal Display
- Quiet Operation
- Flow Switch
- RS232 Communication

3.2 General Specifications:

- Weight: 15 lbs.
- Hose Length: 7 ft.
- Hospital Grade Power Cord
- Dimensions: 5.25"W x 8.75"H x 14.25"D
- Operating Fluid: 90% Distilled Water/10% Isopropyl Alcohol
- Safety: UL Medical Listing 60601, CE

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

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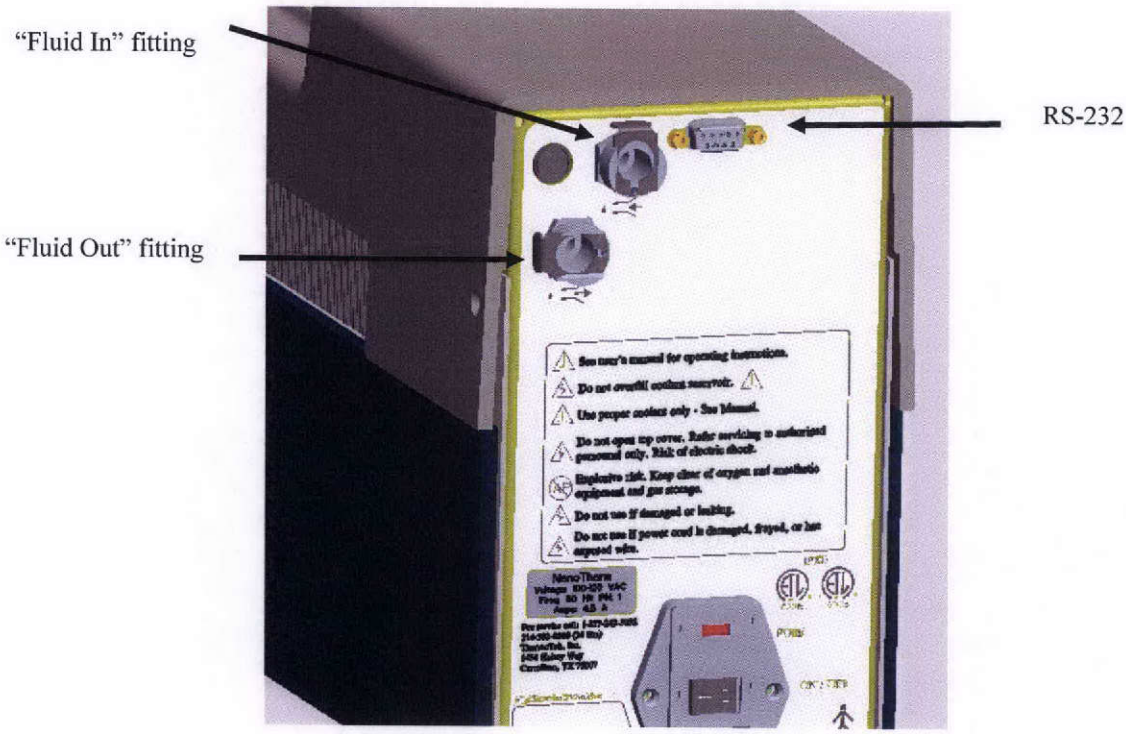
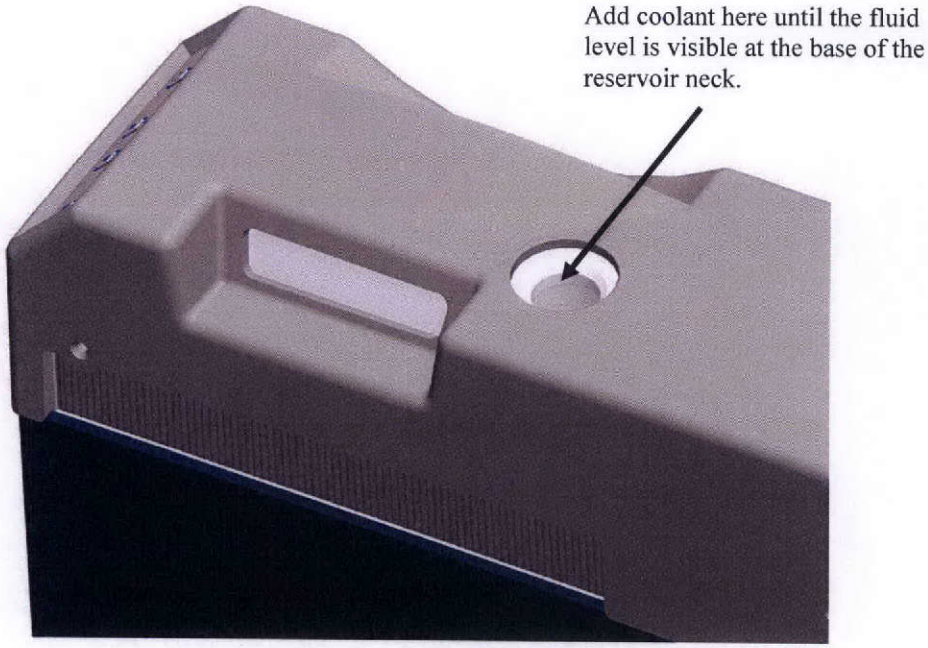
3.3 Device Description:

Rear Panel Connections



Coolant Reservoir Fill Location



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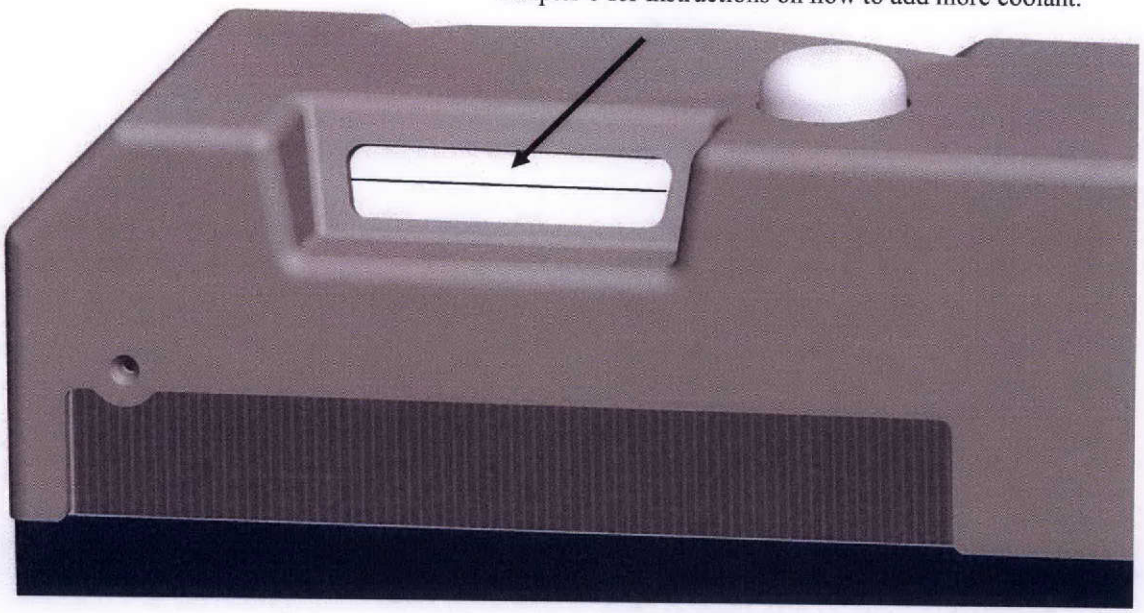
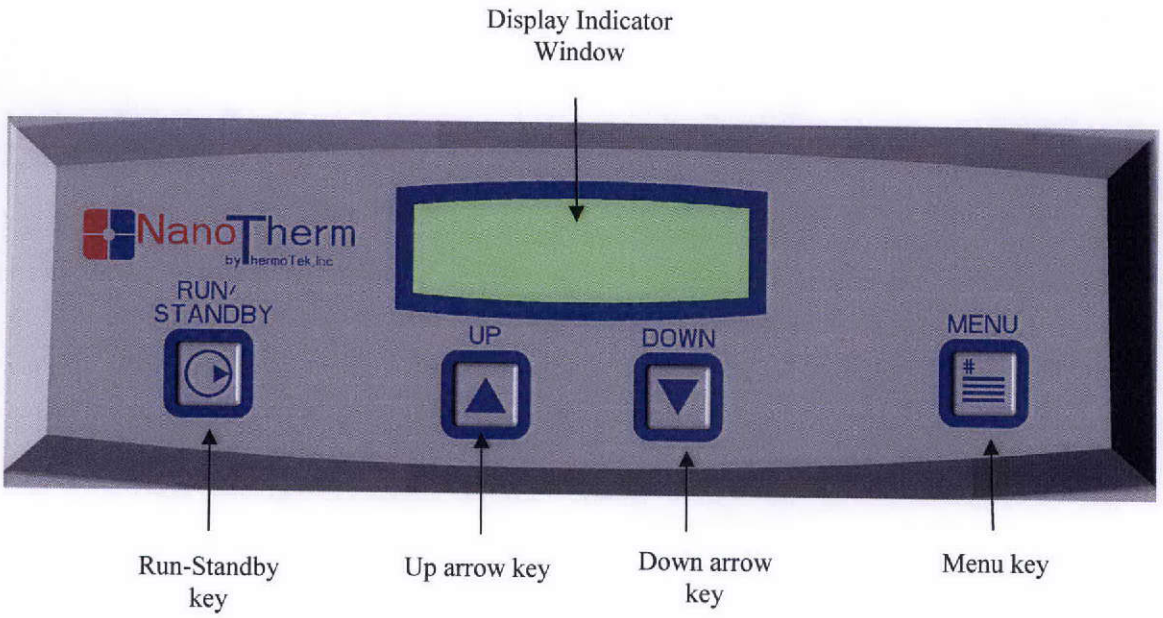
Reservoir Coolant Level Window

If the coolant level can be seen lower than halfway down the window, more coolant should be added. See Chapter 6 for instructions on how to add more coolant.



Keypad Interface and Illuminated Display



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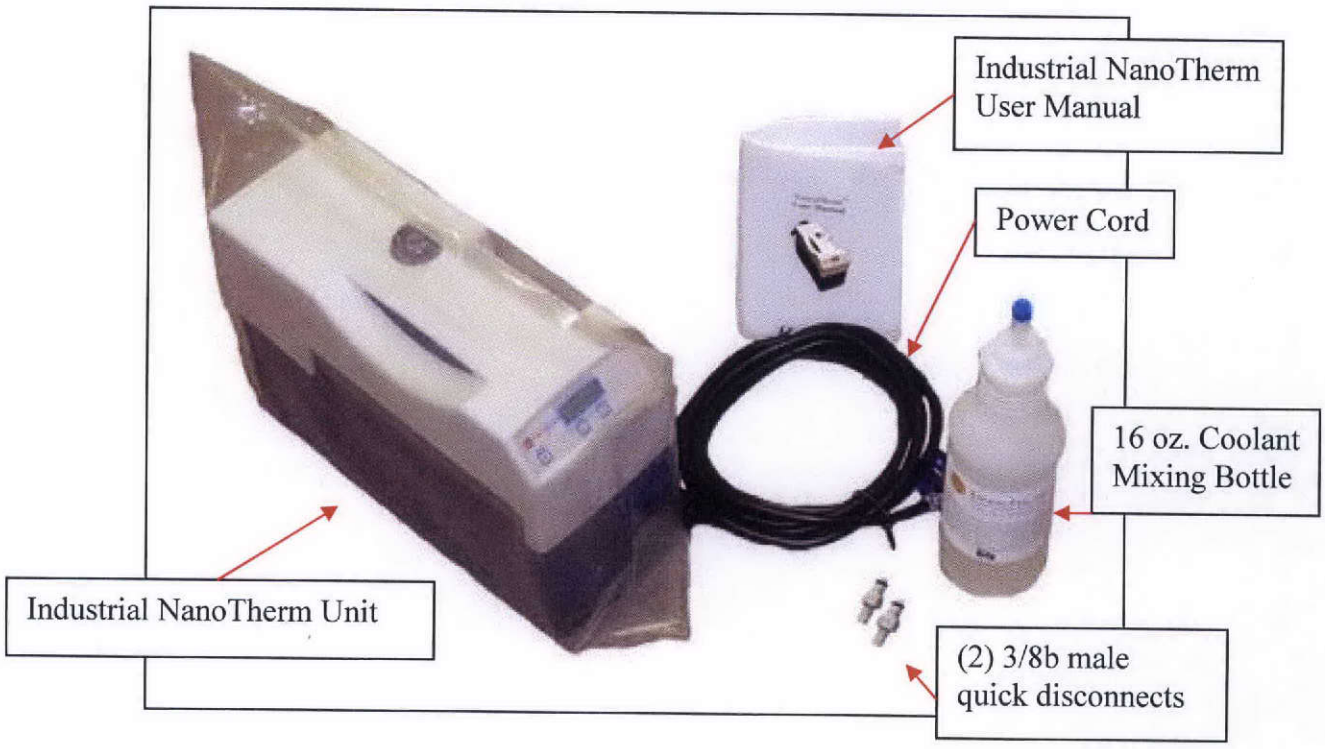
4. Unpacking Your NanoTherm System

When you first unpack the carrying case you should have the following items:



All of these items are needed for safe system operation. If any of these items are missing from the carrying case or shipping container, please contact ThermoTek Customer Service at 877-242-3232.

Immediately upon unpacking your NanoTherm System, inspect your unit. If the unit shows shipping damage, contact the transportation company and file a freight damage claim. **Be sure to retain all packing material and the original box or case.**

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5. Environmental Conditions You Should be Aware of Before Operating Your NanoTherm Device

The NanoTherm system is intended for indoor use only.

Do not operate the NanoTherm system in or near a wet environment.

The NanoTherm system is not to be used in a confined space. Adequate air flow distance from the unit sides must be maintained during operation. Inadequate air flow can result in overheating of internal electrical components and undesirable or excessive noise.

Only use the NanoTherm system in an ambient environment between 60-80 °F (degrees Fahrenheit) and a relative humidity below 60%.

Failure to meet these operating environment conditions may result in:

Condensate buildup inside the unit.

Overheating or freezing of the unit.

Internal electronics malfunction

- A reduction in the heating or cooling capabilities of the unit
- A potential to blow the unit's electrical fuse due to an internal electrical overload.
- The inability of the unit to properly regulate and administer fluid temperature during system operation.

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6. How to Set Up Your NanoTherm System

1. Connect the unit to the application using a fluid transport from ThermoTek, or hoses using Colder PLC or PLCD insert fittings.

2. Keep unit upright and on a level surface.

3. Make sure there is a 6-inch clearance and free path for flow of air entry and exit around the unit prior to operation.

4. Verify the power switch is in the OFF position.

5. Remove the reservoir cap and add coolant to the reservoir until the fluid level reaches the bottom of the neck. **See Recommended Coolants (Section 8.3).**

6. DO NOT overfill the reservoir.

7. Install the appropriate end of the power cord into the unit. Plug the male end into the appropriate AC voltage within the specified voltage.

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7. Operating Instructions for Your NanoTherm System

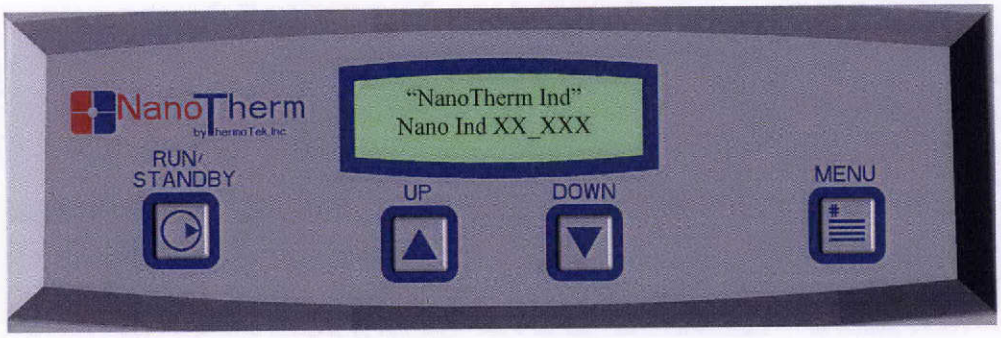
Refer to Chapter 6 "How to Set Up Your NanoTherm System" before beginning any application.

7.1. Start Up and Operating Position:

1. Verify the unit is plugged into the appropriate AC voltage outlet.

2. Turn the unit to the ON position. The ON/OFF switch is located on the rear panel of the unit.

3. When the unit is first powered up, a green back light will illuminate the display screen located on the front panel of the unit and the fans will turn on. The message **NanoTherm Ind, Nano Ind_XX_XXX** will appear on the display screen.



4. Once the unit is powered up, it may be necessary to add more fluid to the reservoir. The system will display a low coolant flow alarm if coolant is low. Press the RUN/STANDBY key to clear the alarm.

Note: Optional External Flow switch detection is disabled for 5 seconds during initial system prime.

5. During the power up sequence, there will be a moment when the keypad is disabled and you will hear the pump being powered up and brought up to speed. The fans will be initiated at this time. This sequence will be repeated each time the unit is powered up or taken from standby to operation.

6. The unit will automatically control to the last set temperature.

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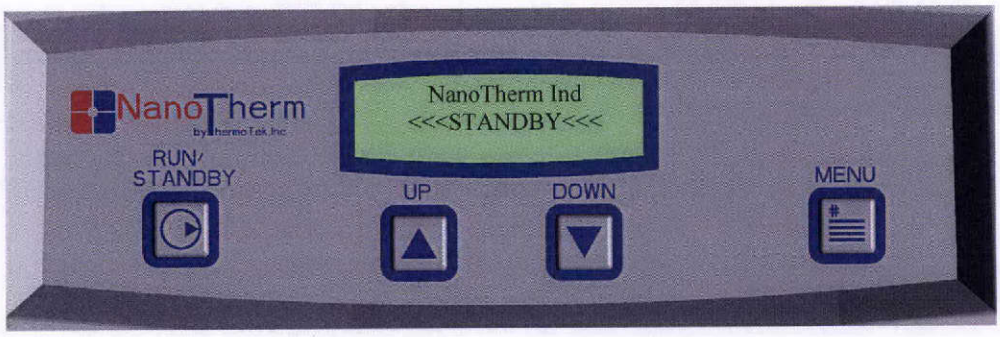
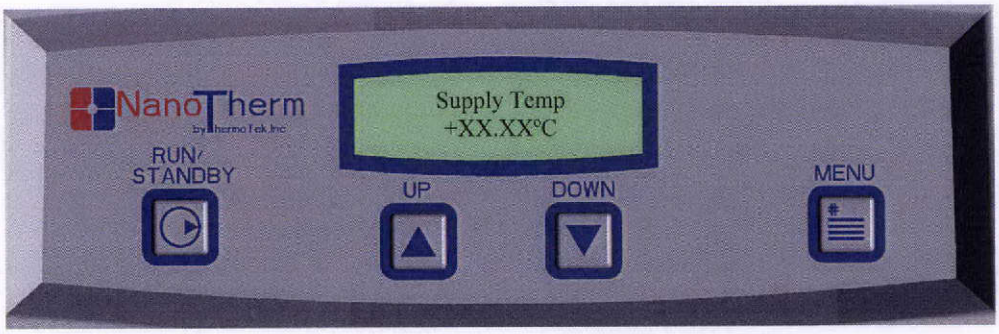
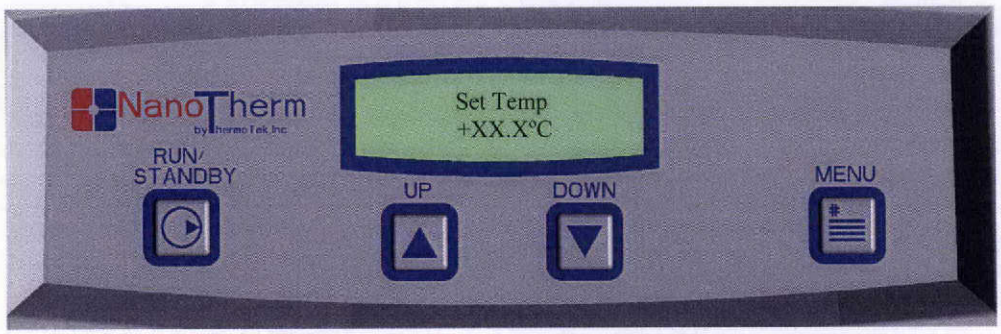
7. To stop the coolant flow to your application, press the RUN/STANDBY key on the keypad. A display message will read "STANDBY". The unit will stop running. The pump will stop and after a few seconds the fans will turn off.



8. To restart the unit, press the RUN/STANDBY key. The unit display will read "Supply Temp + XX.XX°C". Set the unit to the desired temperature.



9. To change the set temperature, press the MENU key on the keypad until the display reads "SET TEMPERATURE". To lower the fluid temperature, press the DOWN key on the keypad. To raise the fluid temperature, press the UP key on the keypad.



Note: If you hold the appropriate key down, the set point will scroll in tenths of degrees and then change to full °C increments.

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10. To determine the current fluid temperature in your application, press the MENU key until the display reads "SUPPLY TEMP".

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8. Display Messages and Alarm Indicators

8.1. Normal Operation

The following list contains display messages that you may encounter during normal operation:

- **RUN/STANDBY:** Standby mode indicates that the pump is OFF and the unit is ready for use. Press the pump RUN/STANDBY key to begin the heating/cooling application.
- **SUPPLY TEMP:** Indicates the unit is controlling to set temperature.
- **SET TEMPERATURE:** Shows the current set temperature. This can be adjusted by pressing the UP and DOWN keys to the desired temperature setting.
- **LIFE TIMER:** Displays total system hours.
- **FLOW SWITCH:** Enabled or Disabled.
- **HEAT SINK TEMP:** Internal heat sink temperature reading.
- **PLATE TEMP:** Internal reservoir plate temperature reading.

8.2. Warnings, Alarms, and System Errors

The NanoTherm System has many internal software safeguards to help protect the unit from unsafe operation. In this section you will find a list of possible system warnings and alarms that may occur if a potentially unsafe situation arises while using the NanoTherm unit.

Warnings indicate that an unsafe condition could or is about to occur. Warning notifications combine the use of a flashing description on the upper line of the display and a fast beeping noise.

Alarms indicate that an unsafe condition is currently present and halts all current applications to protect the user. The alarm state must be corrected before any application can be restarted. Alarm notification combines the use of "ALARM ACTIVE" text on the upper line and an alarm description on the lower line of the display. An audible notification is also initiated by a slow beeping noise. Press the RUN/STANDBY key to clear the active alarm. If the alarm state is still present, the alarm message will reappear and prevent the start of any application.

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System Errors indicate that an internal software or hardware error has occurred and that an unsafe condition is currently present and all current applications are halted to protect the user. An example of this is when there is a problem reading from one of the internal sensors. System errors typically require service to the unit to identify and correct the problem. If you encounter a system error, please write down the 3-digit number indicated on the display and contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time.

Below is a list of common user-related warnings and alarms that may occur during application operation of the unit.

!!ALARM ACTIVE!! HIGH H-SINK TEMP: Anytime the unit is turned ON, the software constantly monitors the temperature of the heat sink fins visible on either side of the unit. If the software determines that the heat sink fin temperature is hotter than a safe level this alarm activates.

!!ALARM ACTIVE!! HIGH TEMP ALARM: Anytime the unit is turned ON, the software constantly monitors the temperature of the internal coolant manifold. If the software determines that the temperature of the manifold is hotter than a safe level this alarm activates.

!!ALARM ACTIVE!! LOW H-SINK TEMP: Anytime the unit is turned ON, the software constantly monitors the temperature of the heat sink fins visible on either side of the unit. If the software determines that the heat sink fin temperature is colder than a safe level this alarm activates.

!!ALARM ACTIVE!! LOW TEMP ALARM: Anytime the unit is turned ON, the software constantly monitors the temperature of the internal coolant manifold. If the software determines that the temperature of the manifold is colder than a safe level this alarm activates.

SYSTEM ERROR XXX: This alarm indicates that an internal software or hardware error has occurred. The unit potentially requires service by an authorized technician. If you encounter a system alarm, please write down the 3-digit number indicated on the display and contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time.

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8.3. Recommended Coolants:

1. Distilled water: For operation from 10°C to 40°C only. Replace monthly to prevent biological growth.

2. 95% distilled water and 5% alcohol mixture prevents bacterial growth. Replace every 90 days.

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9. Things You Can Do To Keep Your NanoTherm System Performing

⚠ Do not use abrasive or solvent-based cleaners on the unit.

⚠ There are no user serviceable internal parts. The system warranty is voided if the tamper seals are breached or removed.

⚠ Keep water away from vents, power ON/OFF switch and the power cord connection of the unit.

⚠ To avoid possible electric shock, do not remove the cover of the unit.

⚠ Do not immerse the unit in water or any liquid.

- **Check the fluid level weekly.**
- **Wipe the exterior of the unit with a damp cloth.**

  Do not use abrasive or solvent-based cleaners on the unit.

- **Cleaning the filter:**

  1. The filter is attached to the unit with Velcro strips. Carefully remove (separate) the filter from the Velcro strips installed to the unit.
  2. Use warm, soapy water to clean the filter.
  3. Allow the filter to air dry completely before re-installing to the unit.

- **Re-installing the filter:**

  ⚠ The air filter must be completely dry before installing on the unit. Using a wet air filter has a strong risk of causing an internal electrical short and is hazardous to both the user and the unit.

  1. Turn the unit OFF and disconnect the power cord.
  2. Starting at the rear of either side of the unit, begin attaching one end of the air filter towards and around the front of the unit using the Velcro strips.
  3. Continue attaching the air filter around to the opposite side of the unit.
  4. The filter should be taught without bulge across the top and bottom of the filter to prevent bypassing of air.

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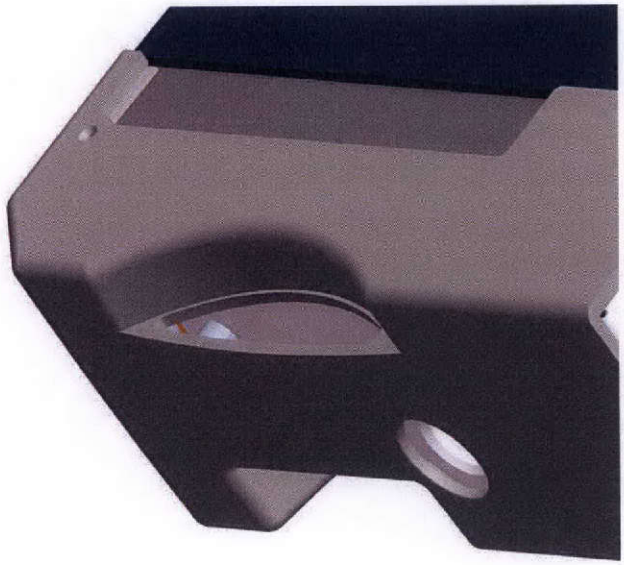
10. Draining the Fluid from the Unit

If the unit is going to be stored for a long period of time or periodically between uses, the unit should be drained of fluid.

1. Turn the unit OFF and unplug from electrical source.
2. Remove the reservoir cap from the unit by twisting the cap counter-clockwise.
3. Lift the unit on both ends and tip backward to empty the fluid from the reservoir into a bucket or sink.



4. Continue to tip the unit until the reservoir is completely empty of all fluid.

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11. Storage and Re-Packing the Unit

When user application is complete and it is time to return or store the NanoTherm system, you can use the transport box.

1. Turn the unit OFF and unplug from the electrical source
2. Disconnect all fittings from the rear panel of the unit.
3. Follow the "Draining the Fluid from the Unit" instructions in Chapter 10.
4. Do not screw the unit's reservoir cap on, but rather leave it off to allow the unit to dry completely. This helps avoid the risk of microbial growth in the unit during storage or long transport.
5. Collect the following items together:
    - NanoTherm Unit
    - Reservoir Cap
    - Power Cord
    - User Manual
    - Coolant Mixing Bottle
    - Hand-carry Box with Package Inserts
6. Store the above items in the original packaging box or in the travel case you received.
7. Store indoors in an ambient environment between 40 °F and 105 °F.

Failure to properly store the unit may result in the following:

⚠ Damage to the unit.

⚠ Catastrophic system damage if the unit is not properly drained.

⚠ Microbial growth inside the unit if not properly drained.

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12. Troubleshooting Guide

Refer to Chapter 5 "Environmental Conditions You Should Be Aware of Before Operating Your NanoTherm Device" for a list of acceptable environmental conditions for safe operation.

This unit is NOT intended for field repair. Do not attempt to service the unit in any way other than using the instructions listed in this guide.

If the unit is displaying an alarm, warning, or system error not listed in the above Troubleshooting Guide, contact Customer Support. See the Customer Support contact information below.

If your issue cannot be resolved with the following scenarios, first contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time.

Problem	Cause	Suggested Actions
Nothing happens when I turn the unit to the ON position.	No AC Power to the unit.	Make sure the unit is plugged into the appropriate electrical outlet. Make sure the power cord is also plugged into the therapy unit.
	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

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Problem	Cause	Suggested Actions
My unit gives me a HIGH H- SINK alarm.	Dirty air filter.	Check the filter. If it is dirty, clean or replace with new filter. Refer to Chapter 9 for details.
	Unit operated in a place with restricted airflow.	Make sure the unit is operated in a location with adequate airflow from all sides. Make sure there is at least 6" of clearance around the unit.
	Unit is operated in a hot ambient environment	Make sure the unit is operated indoors in an ambient < 80° F
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a LOW H- SINK alarm.	Unit is operated in a cold ambient environment.	Make sure the unit is operated indoors in an ambient > 60° F.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a HIGH TEMP alarm.	The unit was filled with hot coolant.	Make sure the unit is filled with room temperature fluid.
	Unit is operated in a hot ambient environment.	Make sure the unit is operated indoors in an ambient < 80° F.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

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Problem	Cause	Suggested Actions
My unit gives me a LOW TEMP alarm.	The unit was filled with cold coolant.	Make sure the unit is filled with room temperature fluid.
	Unit is operated in a cold ambient environment.	Make sure the unit is operated indoors in an ambient > 60° F.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a SYSTEM ERROR XXX alarm.	Reservoir cap is not screwed tightly.	Make sure the unit is unplugged from the AC outlet. Check the reservoir cap and secure it tightly. Connect to AC power and restart unit.

Problem	Cause	Suggested Actions
The unit is leaking. **(cont'd on next page)**	The coolant ports are not connected / seated properly.	Make sure the unit is unplugged from the AC outlet. Check the coolant connections; disconnect and reconnect the ports to make sure they are seated properly.
	Physical damage to the unit.	Inspect the unit for physical damage. . If the unit shows any cracks or dents and is leaking, the unit should not be used. Contact ThermoTek Customer Support.

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Problem	Cause	Suggested Actions
The unit is heating when it should be cooling (or cooling when it should be heating)	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	The unit is in Alarms Active state.	Check display for alarm events. If alarms are displayed use the trouble-shooting guide to resolve the issue.

Problem	Cause	Suggested Actions
Unit turns on, but it is not heating or cooling.	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists
	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.

Problem	Cause	Suggested Actions
The unit is noisy.	Foreign objects lodged inside the air filter.	Turn the unit off and unplug it from the power source. Remove the air filter and inspect the chassis vents for any foreign objects that may be lodged inside or present in the unit. If the foreign object cannot be removed, Contact ThermoTek Customer Support.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	Unit not connected to AC power.	Make sure the unit is connected to the AC outlet. Make sure the power switch on unit is switched to the ON position.

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Problem	Cause	Suggested Actions
The display is not functioning.	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	Unit not connected to AC power	Make sure the unit is connected to the AC outlet. Make sure the power switch on unit is switched to the ON position.

Problem	Cause	Suggested Actions
The keypad is not responding	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

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

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13. Service and Customer Support

ThermoTek, Inc. is committed to servicing our NanoTherm™ unit both during and after sale to the customer. If you have any questions concerning the operation of your NanoTherm™ unit, please refer to the following to contact us at our Carrollton, Texas facility:

- **Sales Organization:** (972) 242-3232
- **Toll Free Number:** (877) 242-3232
  (between 8:00am and 5:00pm CST, Monday through Friday)
- **ThermoTek Website:** www.thermotekusa.com

Do not drink or ingest the coolant mixture.

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

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14. Accessories and Replacement Parts

Boxes/Foam:

Part Number	Description
0P2HNTFSET	Packing Foam
0P2HNTSBX0	Shipping Box
0P7ANANTRC	Traveling Case, Single

Replacement Parts:

Part Number	Description
0P2CDMARFT	Washable Air Filter
0P2DDMRSPG	Reservoir Cap
0P3C12MGCP	Cord, Power 13A/110 VAC, Medical Grade
0P2HNAN0FL	Mixing Bottle, Thermoflow
0P2HNAN0SP	Mixing Bottle, Spout
0P2EBBMQKD	Fittings

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

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15. Specifications

NanoTherm Part Number	0P9TNAN001
Dimensions	5.25"W x 8.75"H x 14.25"D
Ambient Operating Range	60 – 80 °F
Relative Humidity	< 60% RH
Set Temperature Range	10°C – 40°C
Centrifugal Pump	12-volt Brushless DC
Weight without Fluid	15-pounds
System Fluid Capacity	32-ounces
Power Consumption (Max)	450 Watts
Input Voltage (Nominal)	100-120 VAC, 60 Hz, Single Phase
Input Current (Max)	4.5 Amps
Accuracy	± 2 °F
Refrigerant	None
Heating/Cooling Function	Yes, Standard
RS232 Interface	Yes, Standard
Recommended Coolants	90% distilled water, 10% alcohol

18.1 Calibration

The NanoTherm unit is comprised of components that are of high accuracy and low drift. Under normal operation, the unit does not require calibration. The end user has the option to send the unit to ThermoTek for calibration or request documentation from the factory, which details the calibration steps.

18.2 Product Listing

The NanoTherm unit has been tested and listed by ETL to meet or exceed the requirements for UL Medical Listing 60601 Standards. This product is classified as a Type B Medical Equipment, Class II

ThermoTek is a registered medical equipment manufacturer with The United States Food and Drug Administration (FDA).

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

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17. Warranty and Disclaimer Information

ThermoTek Inc. warrants for twelve months from the date of shipment to the end user, any ThermoTek NanoTherm™ unit according to the following terms:

All parts of the unit manufactured or supplied by ThermoTek Inc. shall be free from defects in material and workmanship for a period of one year from the date of shipment. ThermoTek Inc. shall repair or exchange the product within the warranty period when the unit has been found in the reasonable judgment of ThermoTek to have defective material or workmanship. The unit must be returned to an authorized ThermoTek Service Center. The buyer shall pay for the expense of returning the unit to the authorized ThermoTek Service Center for warranty service. ThermoTek Inc. will pay for the expense of returning the unit back to the buyer. Return units must be in the ThermoTek approved box and packing material to ensure safe transport. Removal of the warranty seals or other attempts of servicing the inside of the unit shall void this warranty.

The buyer shall be responsible and assessed a fee for test and calibration if no defects are found with the ThermoTek product.

In the event that the product or any portion thereof is not installed or used in accordance with the manufacturer's Operating Instructions, any and all warranties either expressed or implied shall be and are hereby voided. Only upon the proper installation and use of the items shall this warranty apply. This warranty does not cover any unit that has been altered or modified so as to change its intended use. In addition, this warranty does not extend to the use of parts, accessories, or fluids which are either incompatible with the unit or adversely affect its operation, performance, or durability.

Because ThermoTek Inc. constantly provides our customers with the latest technology, we reserve the right to change or improve the design of any unit without assuming any obligation to modify any unit previously manufactured.

All units returned for warranty claims must have a Returned Materials Authorization (herein referred to as RMA) number on the outside of the container. Please call ThermoTek Customer Service at 972-242-3232 for an RMA number. Before returning a system to the factory, it must be drained of all fluids and packed in the original packaging.

In order to quickly process your warranty repair request, your customer service representative will require the following information about your system:

- Model Number
- Serial Number
- Description of Problem
- Contact Name and Phone Number

This information is on the serial plate located on the back side of the unit.

DISCLAIMER
THE INFORMATION CONTAINED IN THIS DOCUMENT IS PROVIDED "AS IS". THERMOTEK EXPRESSLY DISCLAIMS ALL INFORMATION INCLUDING, BUT NOT LIMITED TO, EXPRESS AND IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE, OR NON-INFRINGEMENT. IN NO EVENT WILL THERMOTEK BE LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, LOST BUSINESS OR LOST DATA, RESULTING FROM THE USE OF OR RELIANCE UPON THE INFORMATION, WHETHER OR NOT THERMOTEK HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ThermoTek Inc. assumes no responsibility for the accuracy or completeness of the information presented which is subject to change without notice. Mention of non-ThermoTek products or services is for information purposes only and constitutes neither an endorsement nor a recommendation.

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

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1454 Halsey Way
Carrollton, Texas 75007
Ph: 972-242-3232 Fax: 972-446-1195
Website: www.thermotekusa.com

For customer service information please see Section 13 of this manual.

0P1DNANDSL
Revision: X3
9/07

402

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

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ATTACHMENT C

PREDICATE INFORMATION

List of Contents in Attachment C:

1. **510(k) Summary for K072870 – MTCS device**
2. **510(k) Summary for K013639 – Thermage ThermaCool TC System**
3. **Technical User Manual for K013639**

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K072870

510(k) Summary

JAN 14 2008

General Information

Classification	Class II
Trade Name	Microwave Tissue Coagulation System (MTCS)
Submitter	Foundry Newco X, Inc. 199 Jefferson Drive Menlo Park, CA 94045 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Steven Kim Chief Technology Officer

Intended Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

Predicate Devices

K011676	VivaWave Microwave Ablation System
K052919	Microsulis MTA System
K984552	Radionics Cool-Tip RF System
K021368	Medela Vacuum Pump Model 30
K003978	AFX Microwave Generator

Device Description

The Microwave Tissue Coagulation System (MTCS) is designed to coagulate soft tissue using a surface contact applicator. The system consists of an applicator, external microwave generator, vacuum pump, and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

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The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator.

Materials

All materials used in the manufacture of the MTCS are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification.

The results showed the system met specification.

Summary of Substantial Equivalence

The MTCS is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2008

Foundry Newco X, Inc.
% Mr. Steven Kim
Chief Technology Officer
199 Jefferson Drive
Menlo Park, California 94025

Re: K072870
Trade/Device Name: Microwave Tissue Coagulation System (MTCS)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: December 19, 2007
Received: December 20, 2007

Dear Mr. Kim:

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. 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.

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

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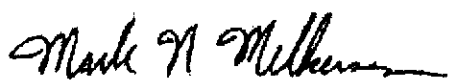
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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K072870

Indications for Use

Device Name: Microwave Tissue Coagulation System (MTCS)

510(k) Number (if known):

Indications for Use: The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

X
Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

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 General, Restorative, and Neurological Devices

510(k) Number K072870

408

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

JAN 2 9 2002

K013639

14.0 510(k) Safety Summary

A. Name of Device

Trade Name: Thermage ThermaCool TC System (Model TC)

Common Name: Electrosurgical Unit and Accessories

Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

Contact Person: Pamela M. Buckman, RN, MS
Sr. Director of Regulatory/Clinical Affairs

B. Predicate Devices

ThermaCool TC System (including coolant canister and footswitch:

Device	Premarket Notification
Thermage ThermaCool IIA System	K013034, Cleared 10/4/01
Thermage ThermaCool II System	K003183, Cleared 12/8/00
Thermage ThermaCool System	K000944, Cleared 7/19/00

Other ThermaCool TC System Accessories (return pad, coupling fluid and skin marking paper):

Accessory	Predicate	Premarket Notification
Return Pad	Nikomed Electrosurgical Grounding Pad	K000079, Cleared 2/4/00
Coupling Fluid	Cadwell Lectron II	K933804, Cleared 3/22/94
Skin Marking Paper	Skin Marker	Class I, Exempt (878.4660)

C. Device Description

The Thermage ThermaCool TC System consists of the following components:

- RF Generator
- Coolant Control Center
- Coolant Canister
- Handpiece Assembly (consisting of Handpiece and Treatment Tip)
- Accessory cables and tubing
- Optional footswitch component
- Accessories: coupling fluid, return pad and skin marking paper

The Handpiece Assembly and Coolant Control Center connect to the RF Generator.

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

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D. Indicated Use

The Thermage ThermaCool TC System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

E. Technical characteristics

The technological characteristics of the Thermage ThermaCool TC System are substantially equivalent to those of the Thermage ThermaCool IIA System, ThermaCool II System, and ThermaCool System.

F. Summary

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool TC System is substantially equivalent to devices currently cleared for marketing in the United States.

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
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Ms. Pamela M. Buckman, RN, MS
Sr. Director of Regulatory/Clinical Affairs
Thermage
4058 Point Eden Way
Hayward, California 94545-3721

Re: K013639
Trade Name: Thermage Thermacool TC System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 2, 2002
Received: November 5, 2001

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket 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 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. 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.

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

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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) 594-4659. 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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510(k) NUMBER (IF KNOWN): K013639

DEVICE NAME: Thermage ThermaCool TC System (Model TC)

INDICATIONS FOR USE:

The Thermage ThermaCool TC System (Model TC) is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

413

Questions? Contact FDA/CDRH/OCE/DID at CDRH-510kRTNumbers.gov or 301-796-5118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Thermage

ThermaCool TC System

TECHNICAL USER'S MANUAL

Thermage, Inc.
4058 Point Eden Way
Hayward, CA 94545-3721
USA
Telephone: 510-782-2286
Facsimile: 510-782-2887

CAUTION: Federal (U.S.A.) law restricts this device for sale by or on the order of a physician.

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

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1. Introduction

The Thermage ThermaCool TC System presented in this User's Manual consists of the following:

Thermage ThermaCool TC System (U.S. Domestic version)

- Thermage ThermaCool TC Generator (Model TG-1A-115)
- Thermage ThermaCool TC Coolant Control Center (Model TM-1A)
- Thermage ThermaCool TC Handpiece (Model TH-1)
- Thermage ThermaCool TC Treatment Tip
- Thermage ThermaCool TC Return Pad (Model TR-1)
- Thermage ThermaCool TC Cryogen Coolant Canister (Model TC-1)
- Thermage ThermaCool TC Coupling Fluid (Model TF-1).
- Electric Footswitch, optional (Model TW-1)
- Accessory cables

Thermage ThermaCool TC System (International version)

- Thermage ThermaCool TC Generator (Model TG-1A-230)
- Thermage ThermaCool TC Coolant Control Center (Model TM-1A)
- Thermage ThermaCool TC Handpiece (Model TH-1)
- Thermage ThermaCool TC Treatment Tip
- Thermage ThermaCool TC Return Pad (Model TR-1)
- Thermage ThermaCool TC Cryogen Coolant Canister (Model TC-1)
- Thermage ThermaCool TC Coupling Fluid (Model TF-1).
- Electric Footswitch, optional (Model TW-1)
- Accessory cables

For the user's convenience:

- The Thermage ThermaCool TC System (Thermage ThermaCool: RF Generator, optional electric Footswitch, Coolant Control Center, Handpiece, Treatment Tip, and accessory cables) will also be referred to in this User's Manual as the "System".
- The Thermage ThermaCool TC Generator will also be referred to in this User's Manual as the "Generator" or "RFG".
- The Thermage ThermaCool TC Coolant Control Center will also be referred to in this User's Manual as the "Coolant Control Center" or "CCC".
- The Thermage ThermaCool TC Handpiece Assembly (Handpiece and "RF Electrode" Treatment Tip) will also be referred to in this User's Manual as the "Handpiece Assembly" or "HA".

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

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This User's Manual provides a description of the System, its controls and displays, and a sequence for its operation. This User's Manual also supplies other information of importance to the user. This manual is intended as a User's Manual only. Do not operate the System before thoroughly reading this manual.

2. Indicated Use

The System is indicated for use in Dermatological and General Surgical procedures for electrocoagulation and hemostasis. The Generator supplies up to 330 watts of Radio Frequency power, while continuously monitoring output power, output energy, treatment duration, and measured impedance. The Generator also controls the Coolant Control Center, which circulates coolant through the Handpiece Assembly. The Handpiece Assembly delivers RF energy while cooling tissue by conduction.

The Handpiece Assembly consists of the reusable Handpiece and the sterile, single-patient use Treatment Tip.

3. Contraindications

The Thermage ThermaCool TC System is contraindicated for use in patients with either an Implantable Pacemaker or an Automatic Implantable Cardioverter/Defribillator (AICD), as they may be adversely affected by radio frequency (RF) fields or current.

4. Warnings And Precautions

⚠ The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained operating room staff. It is important that all warnings, precautions, and the operating instructions supplied be read, understood and followed before use.

4.1. WARNINGS

- *Do not operate the Generator before thoroughly reading this manual.*
- *The voltage selector and the power entry module have been set to the same voltage setting to prevent Generator malfunction and potential instrument damage. The voltage selector is factory set and should not be changed by the user.*
- *Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.*
- *Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents.*
- *Risk of fire. Replace fuses as marked.*
- *While using this device during a procedure, the patient must not be allowed to come into direct contact with grounded metal objects such as a surgical table frame, the instrument table, etc.*

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

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- *When the Generator is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment.*
- *Avoid breathing high concentrations of coolant vapor. Deliberate inhalation of the vapor is extremely dangerous due to asphyxiation. Death can occur without warning.*
- *Direct contact with liquid coolant may cause frostbite. Avoid contact with eyes and skin when handling coolant.*
- *Never touch the Treatment Tip's electrode surface when RF power is being applied.*
- *The use and proper placement of the return pad (dispersive electrode) is a key element in the safe and effective use of this device, particularly in the prevention of burns.*
- *Do not re-use the Handpiece Assembly Treatment Tip. It is a single-patient use item and is not intended for multiple patients. Reuse of the Treatment Tip can lead to failure and patient injury.*
- *The User should avoid direct contact with the patient during RF treatment. Use of insulating gloves (i.e. latex) is recommended to prevent inadvertent electrical shock.*
- *Remove all coolant from the Coolant Control Center prior to transportation. A "flushing" sound may be heard during coolant release. Parts of the unit may be very cold – use caution and avoid these surfaces.*

4.2. PRECAUTIONS

- Allow system to equilibrate to room temperature for a minimum of 4 hours if the system has been stored at temperatures below 10° C.
- The activation tone and light are important safety features. Do not obstruct the activation visual indicator. Do not disable the audible tone.
- Do not remove the cover of the Generator, Handpiece or Coolant Control Center, as there is a potential for electrical shock. Refer to authorized personnel for service.
- Use only the Thermage Footswitch with the Generator.
- The mains power cord of the Generator **MUST** be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must **NOT** be used.
- Do not wrap instrument cables around metal objects. Wrapping cables around metal objects may induce hazardous currents.
- Keep the Treatment Level as low as possible to achieve the desired end effect.
- Do not use a return pad with a Mode B Treatment Tip.
- Use only Thermage provided return pad (dispersive electrode).
- Use only Thermage provided cables and tubing with the Coolant Control Center and Generator.
- Use only Thermage provided Coolant with the Coolant Control Center.

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

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- Do not puncture or incinerate coolant container.
- Do not apply open flame or other sources of heat to coolant container.
- Do not expose coolant container to direct sunlight or store at temperatures above 120°F (49°C).
- Wear protective goggles and gloves when handling open coolant containers.
- Use only the Thermage Coolant Control Center. Do not use irrigant solutions (e.g. saline, Ringer's Lactate, sterile water, etc.).
- Ensure the Treatment Tip is fully seated in the Handpiece before using.
- The Treatment Tip must be in full tissue contact (flush to tissue and not partially lifted) to operate properly.
- Federal (U.S.A.) law restricts this device for sale by or on the order of a physician.
- Attention should be given to the return pad (dispersive electrode) while treating for signs of heating. Each return pad should be reliably attached with its entire area to the patient's body.
- Prior to delivery of RF energy, a thin, even layer of Thermage ThermaCool TC Coupling Fluid shall be applied to the treatment site.

Refer servicing to Thermage, Inc.

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

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5. Description – Thermage ThermaCool TC Generator

Inspect the Generator for any signs of physical damage to the front panel, chassis or cover. **If any physical damage is found, DO NOT USE THE SYSTEM. Contact Thermage, Inc. for a replacement**. Thermage, Inc. must approve all returns.

5.1. Preparing The Generator For Use

The Generator may be placed on a mounting cart or on any sturdy table or platform. It is preferred to use the Thermage ThermaCool TC Cart. Refer to hospital procedures or local codes for detailed information.

Provide space around the back, sides and top of the Generator for convective cooling. Under continuous use for extended periods of time, it is normal for the top and rear panel to be warm.

5.2. Generator Mains Power Cord

The Generator is shipped with an approved Hospital Grade mains power cord.

Do not use extension cords or three-prong to two-prong adapters. The mains power cord assembly should be periodically checked for damaged insulation or connectors.

5.3. Generator Cleaning

A 70% Isopropyl alcohol solution on damp cloth may be used to clean the Generator cover, front panel, and mains power cable. The Generator is not sterilizable. Do not allow fluids to enter the chassis. **Do not spray or pour liquids directly on the unit.**

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

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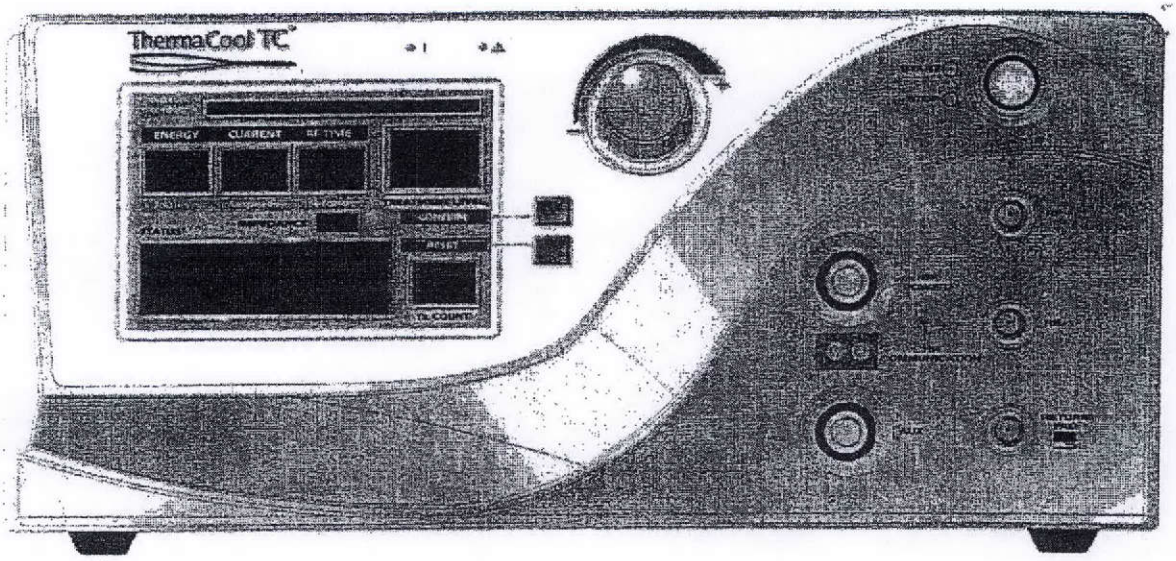
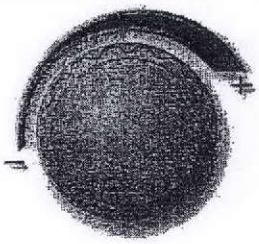
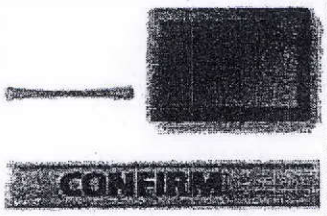
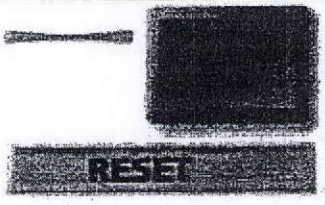
Figure 5-1: Thermage ThermaCool TC Generator Front View



5.4. Generator Controls

A description of the control buttons and their functions are given below. Please refer to Figure 5-1 for location of each item on the front panel.

5.4.1. Generator Buttons

Graphic	Description
	**Treatment Level Knob:** Increases or Decreases the value displayed in the Treatment Level window on the screen by rotating the knob clockwise or counter clockwise, respectively. The Treatment Level increases or decreases in 0.5 increments.
	**Button 1:** The function of this button is dependent upon the system state. Labeling on the screen next to the button will indicate function. Commonly, the word "CONFIRM" will be next to this button, indicating that the button must be pushed to select the Treatment Level after the Knob has been rotated to the proper position.
	**Button 2:** The function of this button is dependent upon the system state. Labeling on the screen next to the button will indicate function. Commonly, the word "RESET" will be next to this button, indicating that the button must be pushed to clear the Treatment Count.

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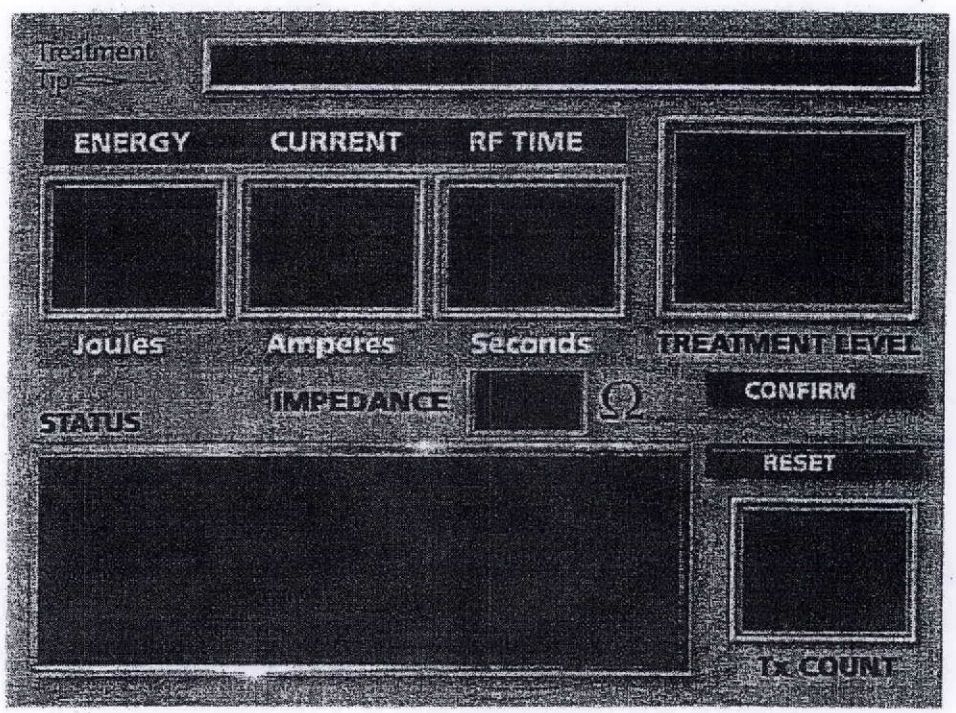
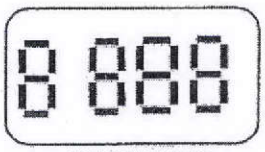
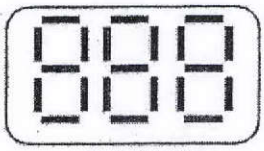
Graphic	Description
START STOP	**START/STOP:** Starts and stops the treatment cycle. The switch blinks when in the READY or the ARMED modes, and remains lit when RF energy is being delivered.

5.4.2. Generator Displays



Graphic	Description
CURRENT  AMPERES	**Current Display:** In STAND-BY, READY and ARMED modes, displays the current, in Amperes, that will be applied. During ACTIVE mode, displays the measured current.
ENERGY  JOULES	**Energy Display:** In STAND-BY, READY and ARMED modes, displays the maximum energy, in Joules, that will be applied. During ACTIVE mode, displays the measured energy.

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IMPEDANCE (Ω)	**Impedance Display:** Displays the measured impedance of the patient/system, in Ohms, during RF delivery. This display shows as blank during STAND-BY and READY modes. This display also shows the Error Codes.
STATUS	**Status Box:** Indicates the current status of the system and provides step-by-step instruction of how to proceed with the treatment. Additionally, provides instruction for fault investigation.
RF TIME SECONDS	**Time Display:** In STAND-BY (parameter setting) and READY (system initialization) modes, displays the estimated time duration, in seconds, for which RF energy will be applied, as determined by the selected Treatment Level. In ACTIVE mode, displays the RF delivery time.
Tx COUNT	**Treatment Count:** Displays the number of treatment deliveries, up to 999 deliveries, since the Generator was turned on or the clear button was pressed
TREATMENT LEVEL	**Treatment Level:** Displays the selected Treatment Level for each electrode type. For each electrode type, there are pre-selected combinations of Power, Energy, Current, Time and Cooling parameters that correspond to each Level, and are represented by the Range number. Higher numbers in the second and third digit position (1-9) correspond to increasing Power and Energy levels for the type of electrode being used. The "0" Treatment Level is set as the Tuning Levels for each electrode type. Refer to Treatment Level Settings Section.
Treatment Tip	**Treatment Tip:** Displays Treatment Tip information.

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5.4.3. Generator Indicators

Generator Indicators	
Graphic and Text	**Description**
	POWER LED: This green indicator illuminates when the system is powered ON.
	FAULT LED: This red indicator illuminates when the system is in the Fault (error condition) mode.

5.4.4. Generator Front Panel Receptacles

Generator Front Panel Receptacles	
Graphic and Text	**Description**
HP COMMUNICATION	**HANDPIECE COMMUNICATION Receptacle:** This Fiber Optic Connection allows transmission of operation, control and measurement signals between the Handpiece Assembly and Generator
HP POWER	**HANDPIECE POWER Receptacle:** This 4-pin Receptacle connects to the Handpiece. It provides power to the Handpiece and valve activation signals. This connection is patient isolated.
RETURN PAD	**RETURN PAD Receptacle:** This 50 Ω coaxial cable receptacle connects to the Return Pad Cable. RF power is returned through this port. This connection is patient isolated, and is not active during Mode B Treatment Tip use.
RF + RF −	**RF POWER Receptacle:** These 50 Ω coaxial cable receptacles connect to the Generator RF Power Cable from the Handpiece. RF power is delivered through these ports. These connections are patient isolated.

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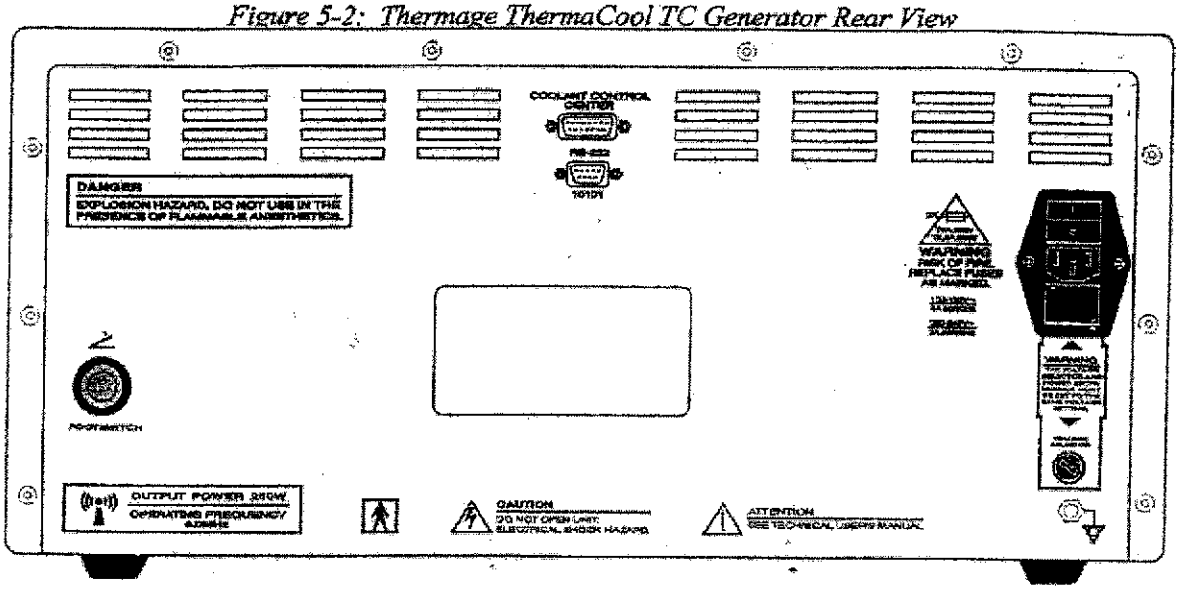
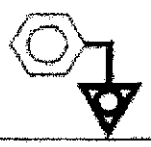
Figure 5-2: Thermage ThermaCool TC Generator Rear View



5.4.5. Generator Rear Panel Functions (Refer to Figure 5-2)

Generator Rear Panel Functions	
Graphic Symbol	**Description**
	**Equipotential Ground Stud:** Provides a means of securely linking the earth ground of the Generator to other grounded equipment.
RS-232 10101	**RS-232 Port:** For manufacturing, factory service and test purposes.
VOLTAGE SELECTOR	**Voltage Selector**: This switch configures the generator to either 115V~ (110 setting) or 230V~ (220 setting), in conjunction with the Power Entry Module. Only Qualified service personnel with the appropriate tool may change the configuration. Unauthorized tampering with this switch setting could damage instrument and void warranty. **For example, the voltage selector shown here is set to 110VAC**
COOLANT CONTROL CENTER	**Coolant Control Center Receptacle:** This DB15 receptacle connects the Generator to Coolant Control Center Cable, which allows communication between the Generator and the Coolant Control Center.

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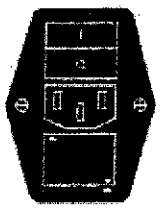
Generator Rear Panel Functions	
Graphic Symbol	**Description**
	**POWER switch:** Provides ON/OFF power control.
	FOOTSWITCH Receptacle: This receptacle accepts the tube leading from the Footswitch and makes an airtight connection. The Footswitch acts as a toggle, so that a single depression of the Footswitch will start or terminate the ARMED mode of the system.

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6. Description – Thermage ThermaCool TC Coolant Control Center (CCC)

6.1. Introduction

The Coolant Control Center will store, monitor and deliver coolant to the Handpiece Assembly. The CCC function is controlled by the Generator, which also supplies power to the CCC.

The coolant used in this unit is HFC-134a (1,1,1,2-Tetrafluoroethane).

6.2. Preparing The CCC For Use

The Coolant Control Center may be placed on a mounting cart or on any sturdy table or platform. Proper operation of the Coolant Control Center requires installation on a level surface, or vertically mounted on a pole using the supplied pole mount. If the Coolant Control Center is not installed level or vertical, the Tilt sensor will activate and the system may not operate properly.

Provide space around all sides of the CCC for convective cooling. Under continuous use for extended periods of time, it is normal for the top and rear panel to be warm.

6.3. CCC Cleaning

A 70% Isopropyl alcohol solution and damp cloth may be used to clean the unit cover, front panel, and power cable. **The unit is not sterilizable.** Do not allow fluids to enter the chassis. Do not spray or pour liquids directly on the unit.

6.4. CCC Connections, Indicators and Receptacles

A description of the indicators and receptacles are given below. Please refer to Figure 6-1, 6-2, and 6-3 for location of each item on the front/side/rear panel and top of enclosure.

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6.4.1. CCC Indicators - Front Panel

Left side of Front Panel		Right side of Front Panel	
Legend	**Description**	**Legend**	**Description**
Power	**Power Indicator:** This green indicator illuminates when the system is powered on.		
Error-See Manual	**Error- See Manual Indicator:** This red indicator illuminates when there is a CCC fault. See Manual for Instructions.	**Please Wait**	**Please Wait Indicator:** This blue indicator illuminates when coolant is being delivered.
Coolant OK	**Coolant OK Indicator:** This green indicator illuminates when there is a satisfactory quantity of coolant in the system.		
Coolant Low	**Coolant Low Indicator:** This yellow indicator illuminates when the quantity of coolant is getting low.	**Pressure Low**	**Pressure Low Indicator** – This yellow indicator illuminates when the coolant pressure is low. If there is sufficient coolant, this condition is self-correcting.
Replace Can	**Replace Can Indicator:** This red indicator illuminates when there is not a sufficient quantity of coolant for safe operation. Additional coolant MUST be added to the system.	**Tilt Error**	**Tilt Error Indicator** – This yellow indicator illuminates when the unit is not level or vertical.

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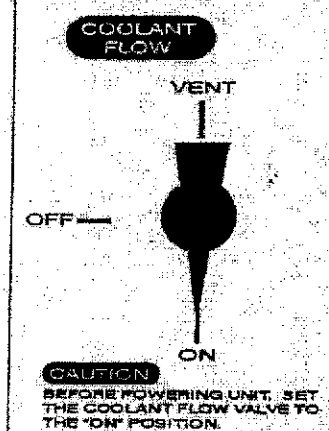
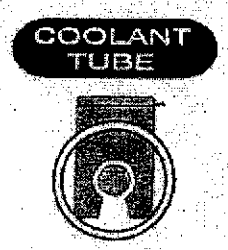
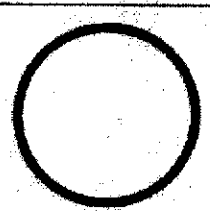
6.4.2. CCC Connections and Controls - Side Panel

CCC Side Panel	
Graphic	**Description**
	**Coolant Flow Control:** Provides the ability to control the coolant supply. "ON" allows coolant to flow from the canister to the CCC. Can also be used to empty the unit when there is no canister attached. "OFF" prevents the coolant from entering the CCC. "VENT" empties the canister.
	**Coolant Connection:** For the Handpiece tubing, which provides coolant to the Handpiece Assembly.

6.4.3. CCC Connection - Top of Enclosure

CCC Top of Enclosure	
Graphic	**Description**
	**Coolant Canister Port:** This is a covered access port on top of the CCC. Provides access to install or remove the coolant canister. During normal operation, the surface around the port will be warm.

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6.4.4. CCC Receptacles - Rear Panel

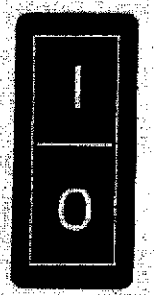
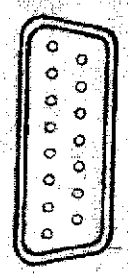
CCC Rear Panel	
Graphic	**Description**
	**POWER switch:** Provides ON/OFF power control.
	**RFG Connection:** Provides the connection from the Generator.

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Figure 6-1: Thermage ThermaCool TC Coolant Control Center Front View

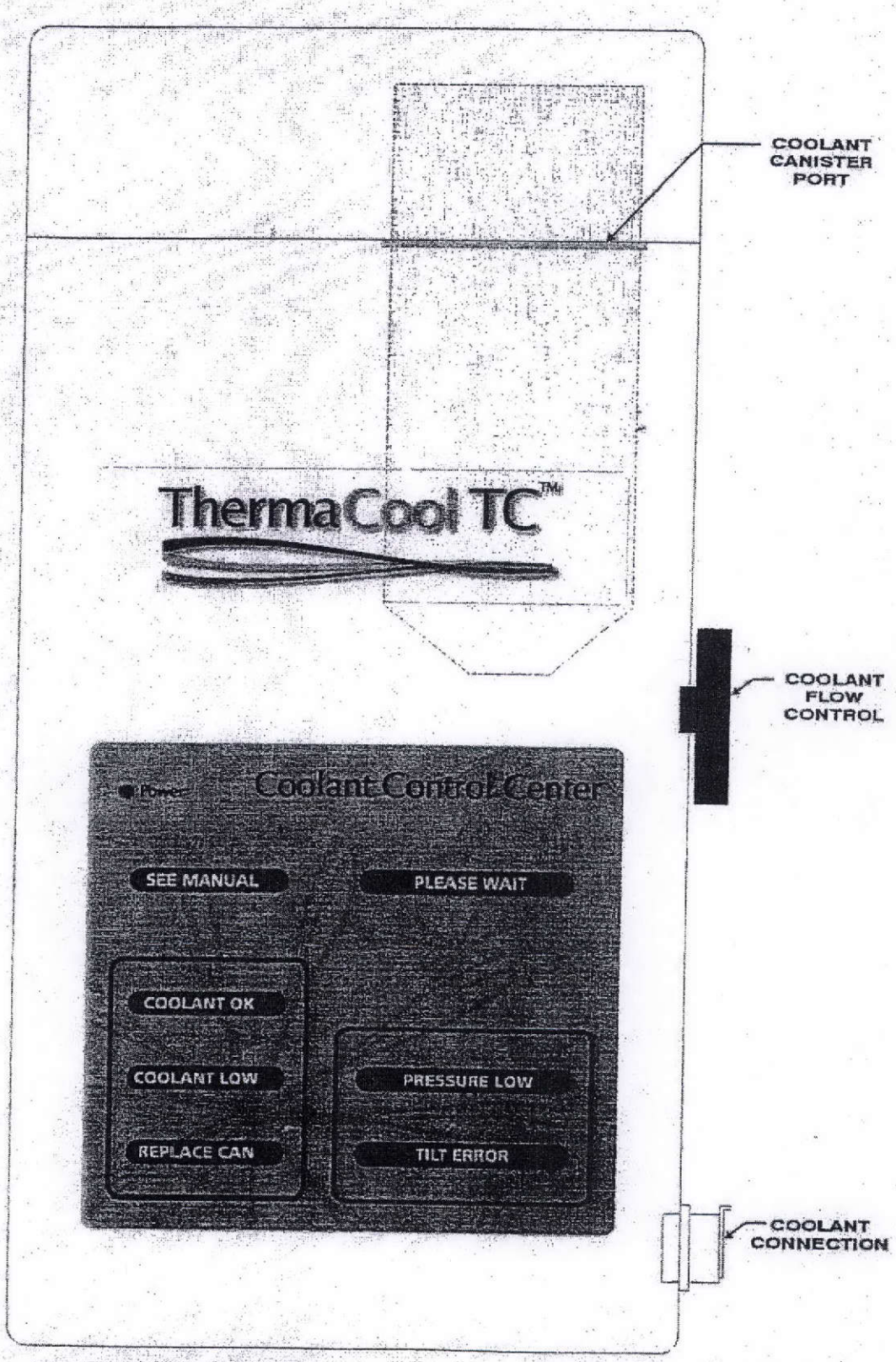

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Figure 6-2: Thermage ThermaCool TC Coolant Control Center Side View

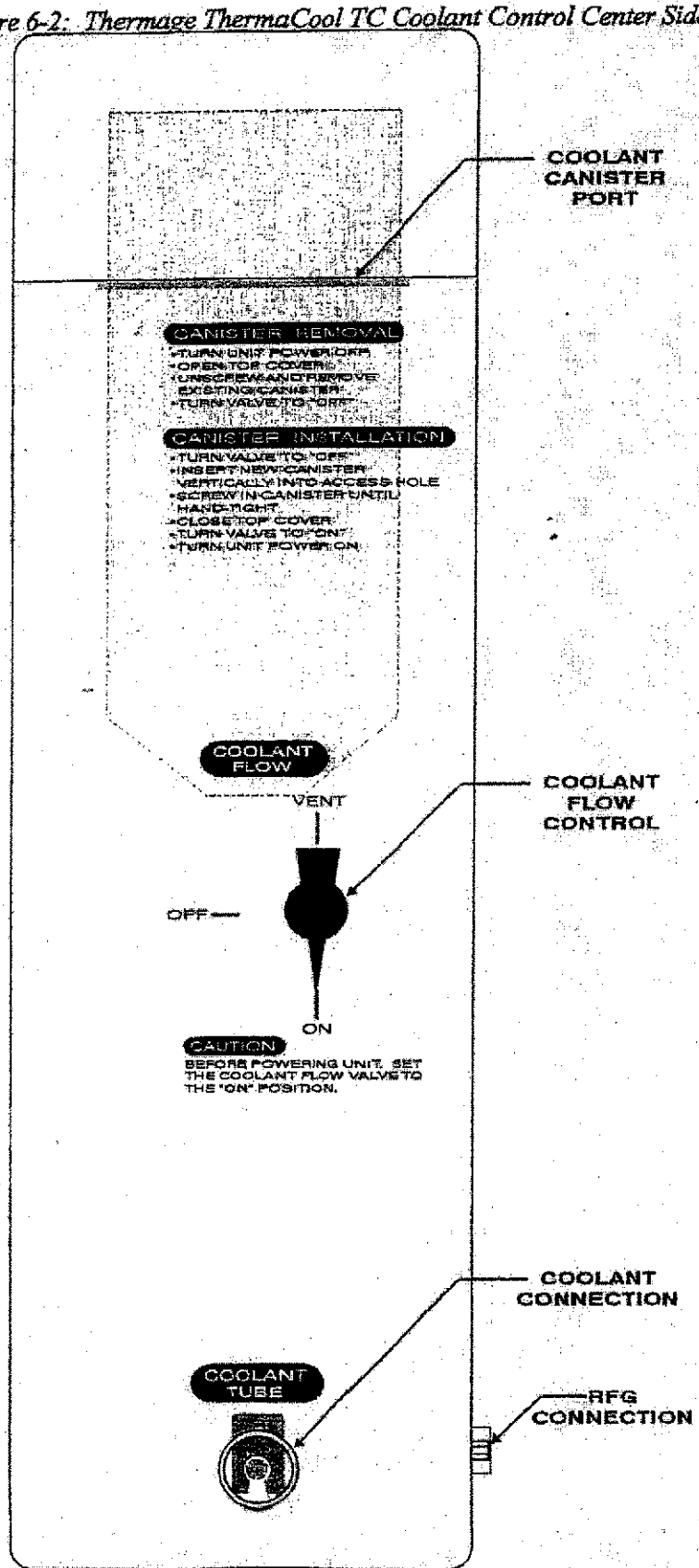

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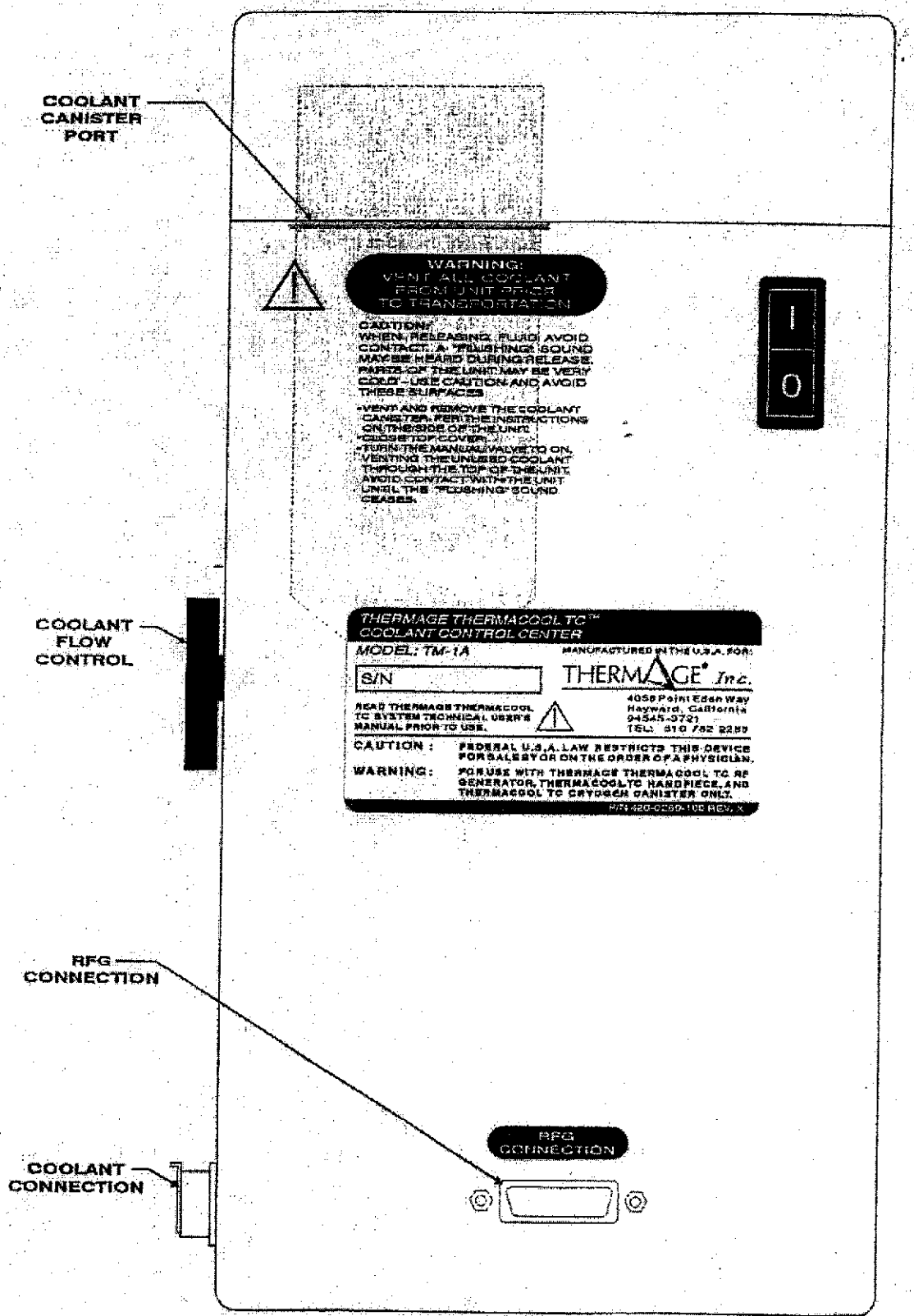
Figure 6-3: Thermage ThermaCool TC Coolant Control Center Rear View



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7. Description – Thermage ThermaCool TC Handpiece Assembly (HA)

7.1. Preparing The Handpiece For Use

The Handpiece Assembly consists of two components: the Handpiece and the Treatment Tip. The Treatment Tip must be attached to the Handpiece before activation of the system.

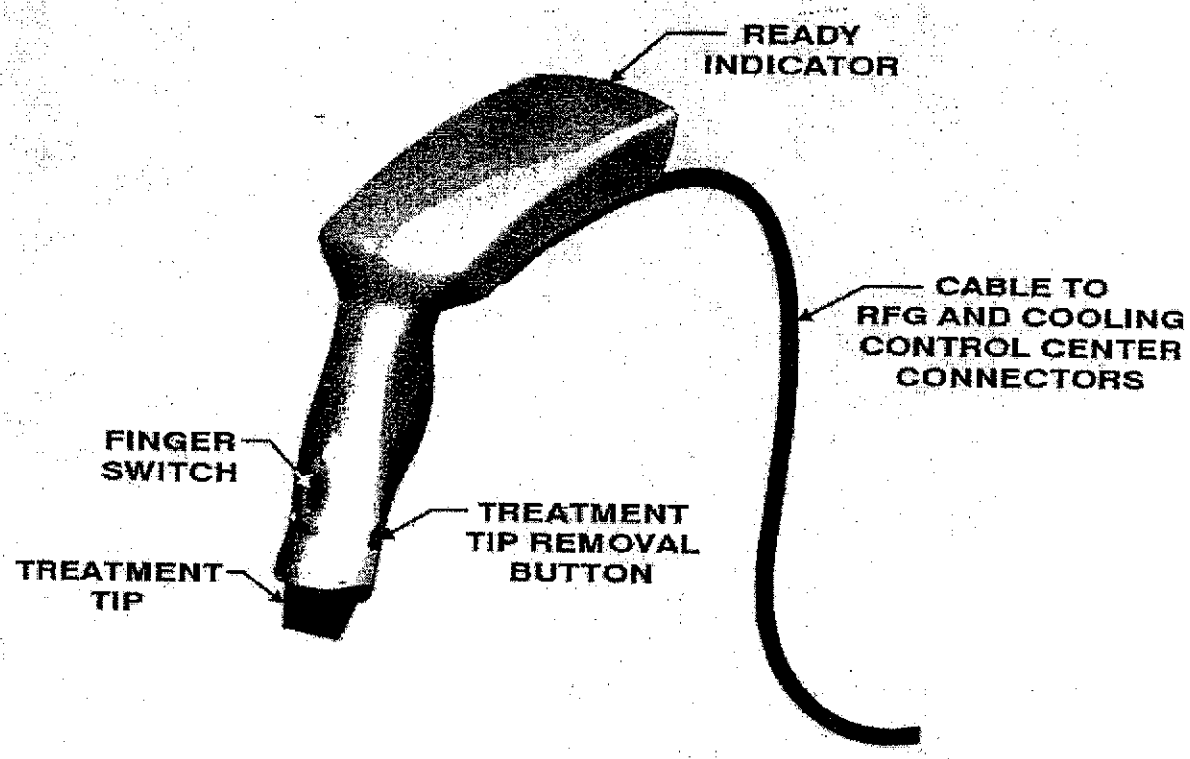
7.1.1. Handpiece

The Handpiece is a reusable, nonsterile, individually packaged and labeled device.

7.1.2. "RF Electrode" Treatment Tip

The Treatment Tip is a single patient use, sterile, individually packaged and labeled disposable.

Figure 7-1: Thermage ThermaCool TC Handpiece



7.2. HA Cleaning Instructions

7.2.1. Handpiece Cleaning

A 70% Isopropyl alcohol solution on damp cloth may be used to clean the Handpiece. The Handpiece is not sterilizable.

Do not allow fluids to enter the Handpiece.

Do not spray or pour liquids directly on the Handpiece.

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7.2.2. Treatment Tip Cleaning

The Treatment Tip is supplied sterile and therefore it does not need cleaning prior to use. The Treatment Tip is designed for single patient use only and **must not be reused.**

7.3. HA Controls

A description of the control Finger Switch and indicator and their functions are given below under the HA Control and HA Ready Indicator sub-sections. Please refer to Figure 7-1 for the location of the Finger Switch and the Indicator.

7.3.1. HA Control

	Finger Switch: Depressing and holding the Finger Switch allows the operator to start the ARMED mode, while still holding the Handpiece Assembly. Releasing the Finger Switch terminates the ARMED mode and can interrupt RF delivery.

7.3.2. HA Ready Indicator

	Ready Indicator ON: This green indicator illuminates when the system is ready to be ARMED.

8. Description – Thermage ThermaCool Accessories

8.1. Footswitch (optional)

Use of a ThermaCool TC Footswitch (TW-1) allows the operator to start the ARMED mode, or end it, without using his or her hands. A depression results in a change from the READY mode to the ARMED mode. A release of the Footswitch will cause the Generator to exit the ARMED mode and return to the READY mode. Release of the Footswitch can also interrupt RF delivery.

Activation or deactivation of the ARMED mode can also be performed with the HA Finger Switch. In subsequent sections of the manual, actions described as being performed by the HA Finger Switch can also be done by the Footswitch.

A mild detergent and damp cloth may be used to clean the Footswitch and guard. The Footswitch is not sterilizable.

8.2. Return Pad (Standard Treatment Tips only)

Use a ThermaCool TC Return Pad (Reorder # TR-1) with a Standard configuration Treatment Tip.

Do not use a return pad with a Mode B Treatment Tip.

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The Return Pad is a non-monitoring, 20 sq. inch dispersive electrode. The pad is intended for one time use only and does not need to be cleaned prior to use. This is a non-sterile device.

Place the Return Pad on a well-vascularized area, after shaving any hair, and thoroughly drying the skin. Ensure the entire area is in contact with the tissue. See the Directions For Use accompanying the Return Pad

8.3. Coolant Canister

Use a Thermage supplied ThermaCool TC Cryogen Canister (Reorder # TC-1). This canister is disposable, does not require cleaning and is non-sterile.

8.3.1. Installing Coolant Canister

Note: Coolant should only be introduced to the CCC when power to the CCC has been turned off.

- Turn the manual CCC Coolant Flow valve to "OFF"
- Unlatch the CCC Top and tilt it out of the way. Remove the existing used canister for disposal by rotating it counter-clockwise until it is free of the CCC. There may be a small release of coolant while removing the canister. The empty canister may be disposed of as trash.
- Invert, and then insert the new canister into the CCC Canister Port.
- Install the new canister by rotating it clockwise until hand-tight (CAUTION: Do not over tighten canister). There may be a small release of coolant while installing the canister.
- Close the CCC Top Lid Port over the Canister Port.
- Turn the Coolant Flow valve to "ON". There might be a "flowing liquid sound" indicating that coolant is being delivered to the CCC.
  - If no "flowing liquid sound" is heard, correct installation can be verified by briefly turning the Coolant Flow valve to "Vent". If a "flowing liquid sound" is heard, the canister has been connected and contains coolant. Rotate the Coolant Flow valve to the "ON" position. Otherwise, repeat the installation with a new Canister.
- In the event that it is necessary to change the canister during a treatment session, set the Generator to STAND-BY (or turn power off), turn the CCC power off, and follow the directions above. Once the canister has been replaced and power restored to the CCC, treatment may continue.

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8.4. Other Accessories: Cables, etc.

Description	Model	Figure 9-1 ID
Coupling Fluid	TF-1	N/A
Generator to Coolant Control Center Cable	A 52	Not Shown
Return Pad Cable (Standard Treatment Tips only)	A-54	4
System Cart	TS-1A	5

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9. Thermage ThermaCool TC System Instructions For Use

9.1. Introduction

The Thermage ThermaCool System is intended for use in Dermatological and General Surgical procedures for electrocoagulation and hemostasis. The Generator delivers Radio Frequency energy, while conductively cooling the contact surface, using the Coolant Control Center and the Handpiece Assembly. The Generator measures and displays RF output power, load impedance, energy and elapsed time of RF delivery.

9.2. ThermaCool TC System Set-Up Procedure

9.2.1. Connection of the Coolant Control Center

Connect the *Generator to Coolant Control Center cable* to the Generator and Coolant Control Center.

Ensure that the Handpiece Assembly tubing is connected to the Coolant Control Center and the Handpiece Assembly.

9.2.2. Handpiece Assembly Connection

Ensure all cable connections between the Generator and the Handpiece are made only when the Generator is OFF.

Three(3) cables, attached to the Handpiece Assembly, are always connected to the Generator.

- The red connection marked *RF+ Cable* is connected to the red RF+ connector on the Generator.
- The fiber optic *Handpiece Communication Cable* is connected to the HP Communication connector on the Generator.
- The plastic *Handpiece Power Cable* is connected to the HP Power connector on the Generator.

If using a Mode B Treatment Tip, the fourth *Handpiece Cable* is connected to the Generator as well. It will not cause a problem if this cable is accidentally connected for Standard Treatment Tips.

- The blue marked *RF– Cable* is connected to the blue RF– connector on the Generator.

If using a Standard Treatment Tip, an additional accessory cable is connected to the Generator as well. It will not cause a problem if this cable is accidentally connected for Mode B Treatment Tips.

- The *Return Pad Cable* is connected to the green Return Pad connector on the Generator. There is a rotary dial with 7 positions – the user will be prompted to set the appropriate position during Generator operation.

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After connecting the cables, it is necessary to connect a Treatment Tip.

- Place the Treatment Tip into the end of the Handpiece. The geometry of the Tip only allows insertion in one orientation. Press into the Handpiece until the tabs click into position.

9.2.3. Connection Of Accessories

Refer to Figure 9-1 for the relationship of all system parts.

9.2.3.1. Return Pad Connection (Standard Treatment Tips only)

When using a Standard Treatment Tip, connect the Return Pad to the clip end of the Return Pad Cable.

Do not use a Return Pad with a Mode B Treatment Tip.

9.2.3.2. Footswitch Connection (optional)

Connect the Footswitch to the Footswitch connector on the Generator, if Footswitch use is desirable.

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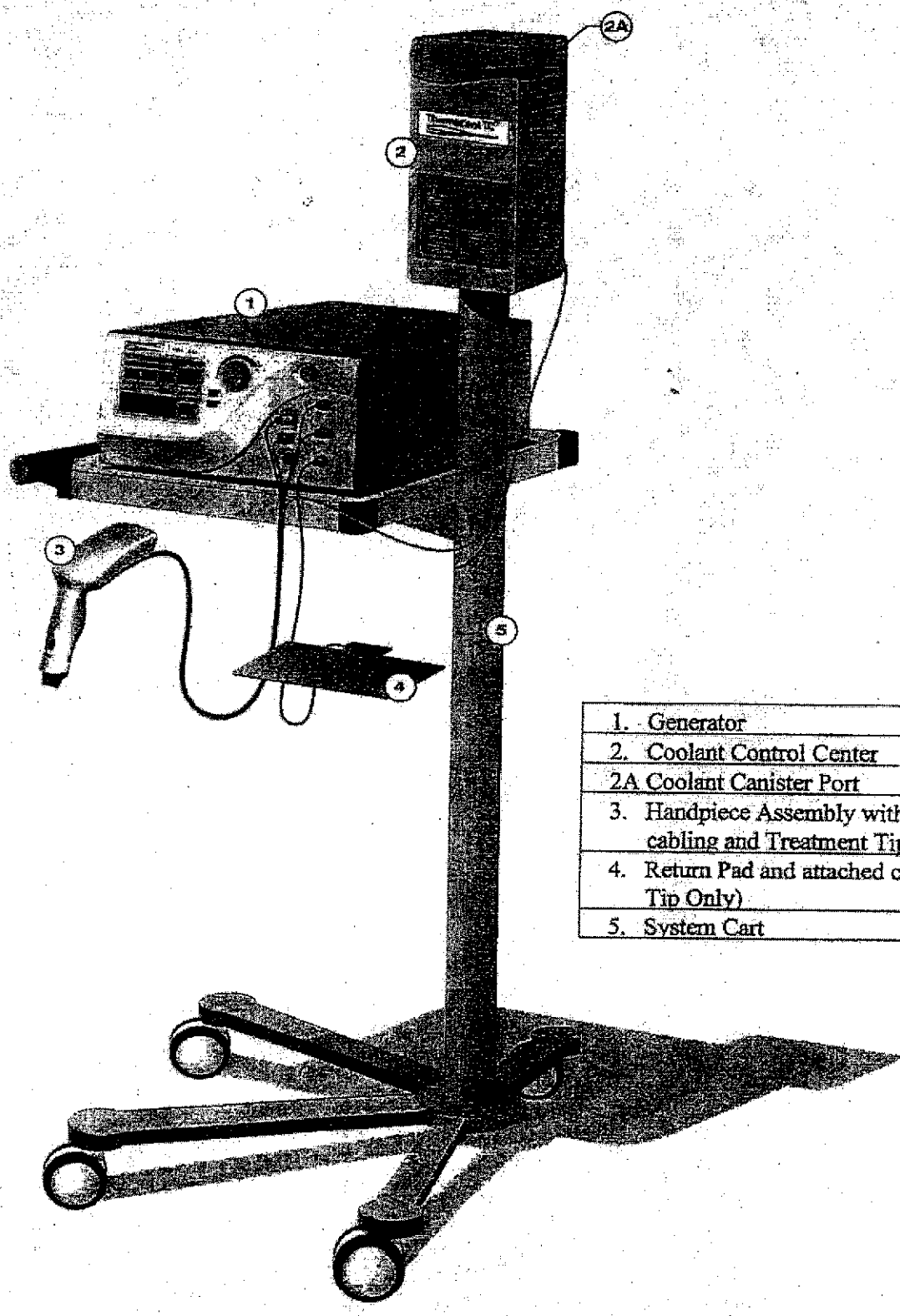
Figure 9-1: Thermage ThermaCool TC System (optional Footswitch not shown)



1.	Generator
2.	Coolant Control Center
2A	Coolant Canister Port
3.	Handpiece Assembly with attached cabling and Treatment Tip
4.	Return Pad and attached cable (Standard Tip Only)
5.	System Cart

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9.2.4. Power-Up

Plug the Generator into a grounded receptacle (extension cords and/or adapter plugs must not be used). Turn the power on using the ON/OFF switch, which is located on the power entry module on the rear panel.

The Generator will initialize, displaying the Thermage boot-up screen. After boot-up is complete, the Power On Self Tests (POST) will run. During the POST, all indicators (LEDs) will be illuminated. When the POST completes, a 5 second tone will sound indicating that the Generator is now ready for use.

If the screen or indicators fail to light, or if no tone is heard, DO NOT USE and contact Thermage, Inc. for service. If the Generator goes directly into the FAULT mode upon start-up, DO NOT USE and contact Thermage, Inc. for service.

While waiting for the Generator POST to complete, turn the power on for the Coolant Control Center using its On/Off switch. The CCC will perform its POST during which a tone will sound, and all indicators will illuminate. Check that all indicators illuminate and that a tone is audible. If any of the indicators fail to light, or no tone is heard, DO NOT USE, and contact Thermage, Inc. for service. The green "Power" indicator remains illuminated. It is common upon start-up for the Coolant Control Center to purge itself of vapor to fill its internal reservoir with coolant, and to increase the pressure of the coolant. The "Please Wait" LED will probably be illuminated until the Coolant is ready. Ensure that there is sufficient coolant ("Coolant OK" LED is illuminated) – if not, change coolant canisters.

In less than a minute, the Generator POST will be completed and the Generator will enter its preparation mode. It will check for Handpiece and Treatment Tip installation, and will wait if either or both of those are not connected. If a Standard Treatment Tip is to be used, the Generator will prompt the user to confirm that the Return Pad is connected, and will direct the user to set the rotary dial to the appropriate position (i.e., "A"). The Generator will then prompt the user to "tune" the system before treatment begins.

9.3. Generator Modes

(Note: The terms "Mode" and "State" are used interchangeably)

The Handpiece Assembly tissue contact force sensor ultimately controls application of RF power. However, the tissue contact force sensor remains inactive until other controls are activated and the system is ready. RF application can be manually terminated during a delivery by lifting the Handpiece, depressing the START/STOP button, or by "Dis-Arming" the system by releasing the Finger Switch or Footswitch.

The Generator operates in one of ten modes: POST, AUTOTUNE, STAND-BY, READY, ARMED, ACTIVE, DONE, ERROR, ALARMS, and FAULT. See Figure 9-2.

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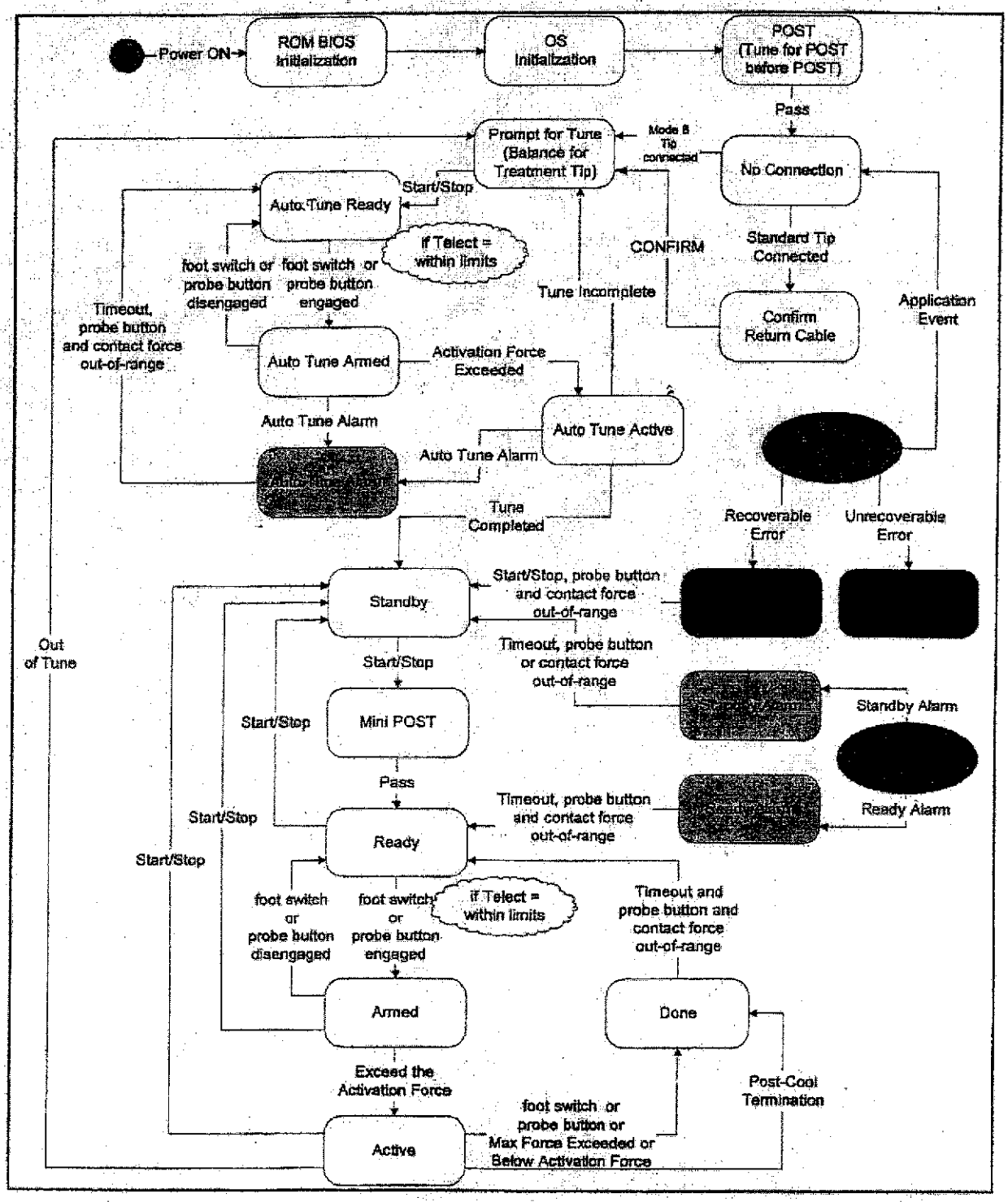
Figure 9-2: Mode diagram of Thermage ThermaCool Generator modes



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9.3.1. AUTOTUNE Mode

This state is automatically entered after the POST mode. If either the Handpiece or Treatment Tip is not connected, the system will wait before entering this mode. (For Standard Treatment Tips, the Return Cable must also be connected.)

The AUTOTUNE mode will also be entered if during treatment delivery, the Generator determines that a re-tune is necessary or if the Treatment Tip is disconnected. See Section 10.1 for more information on Tuning.

9.3.2. STAND-BY Mode

This state is automatically entered after the system performs its Autotune, or if the Front Panel START/STOP button is depressed while the System is in any mode other than POST. In this mode, the User can adjust the Treatment Level.

The Treatment Level cannot be modified after leaving the STAND-BY mode. The System enters the READY mode after depressing the Front Panel START/STOP button.

9.3.3. READY Mode

Upon entering this mode, the system performs a quick integrity test. If the test fails, then the unit will go to the FAULT State with the appropriate Error message. If the test passes, the Handpiece Assembly cooling function is initiated. This allows delivery of cooling medium if the Handpiece Assembly/Treatment Tip temperature sensors indicate that the Treatment Tip is not within the acceptable temperature range, and the Coolant Control Center is available for operation.

When the Handpiece Assembly temperature sensors are within acceptable temperature limits, the green Handpiece Assembly "Ready" light illuminates. The system can now be sent to ARMED mode. The System remains in READY mode until either the finger switch on the Handpiece Assembly or the foot switch is depressed, which then causes the system to enter the ARMED mode, or the Front Panel START/STOP button is depressed, which exits back to STAND-BY.

9.3.4. ARMED Mode

The System enters this mode after either depression of the finger switch on the Handpiece Assembly or depression of the Footswitch and while the system is in the READY mode and the Handpiece Treatment Tip is at the correct temperature. If the finger switch on the Handpiece Assembly or the Footswitch is released, the unit is "Dis-Armed" and returns to READY mode.

The System is ready to enter the ACTIVE mode and deliver RF energy, which will be initiated once tissue contact is initiated.

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Entering the ARMED mode initiates a cycle timer. RF energy delivery during ACTIVE mode will commence, if initiated at any point before the cycle timer "times out". The user will have **THREE SECONDS** to initiate the ACTIVE mode.

The System exits to:

- ACTIVE mode, once tissue contact switch is initiated, or
- READY mode, if the cycle timer "times out" or the system is "Dis-ARMED", or
- STAND-BY mode, if the Front Panel START/STOP button is depressed.

9.3.5. ACTIVE Mode

The System enters this mode when tissue contact is initiated while the system is in the ARMED mode. The Handpiece contains a force sensor which determines when the proper activation force has been achieved, which indicates tissue contact. The Counter display will increase by one (1).

A long tone indicates successful initiation of the ACTIVE Mode. Termination of the tone indicates treatment is complete. The Handpiece Assembly should be lifted off of the patient and the Finger Switch released. **Do not lift the HA off of the patient until the tone terminates.**

There are three phases to the ACTIVE mode:

- "Pre-Cool"
- "RF Energy Delivery"
- "Post-Cool"

During the "Pre-Cool" phase, coolant is applied to the Treatment Tip for a preprogrammed duration, delivery rate and frequency with temperature feedback control. Once the "Pre-Cool" cycle has terminated, the system enters the "RF Energy Delivery" phase.

The System delivers the user-selected treatment at preprogrammed values of RF and delivery time, while controlling cooling rates. The System measures and monitors relevant parameters such as RF delivery energy, power, current and impedance.

After the completion of RF energy delivery, the System initiates the "Post-Cool" phase in which it supplies coolant for a preprogrammed duration, delivery rate and frequency with temperature feedback control. Upon termination of the "Post-Cool" phase, the system enters the DONE mode. In the DONE mode, the final values of the treatment parameters are displayed

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for approximately 1 second, then the system returns to the READY mode, allowing a new treatment cycle to begin.

The release of the Finger Switch or Footswitch will terminate the "RF Energy Delivery" phase prematurely and begin the "Post-Cool" phase. Interruption of the ACTIVE Mode will be indicated by two short beep tones. The unit will otherwise continue as normal to the DONE mode. See Section 9.4.6 for other causes of Shutdown.

The System exits to:

- "Post-Cool" phase and then the DONE mode, following successful completion, or interruption of the ACTIVE mode.
- STAND-BY mode, if the Front Panel START/STOP button is depressed.

9.3.6. DONE Mode

Upon successful completion of the ACTIVE mode, the system enters the DONE mode. The POWER, ENERGY, TIME and IMPEDANCE displays will show the last measured values. After one (1) second, the termination of tissue contact and the release of the Finger Switch, the system exits this mode and enters the READY mode.

9.3.7. ALARM Mode

There are three modes that indicate abnormal system conditions: ALARM, ERROR, and FAULT. These modes can be entered from any of the other modes.

The ALARM mode indicates a minor problem that will resolve without action from the user. When the ALARM mode is entered, an error code will appear in the IMPEDANCE display and an "Alarm Tone" is sounded. The POWER and ENERGY displays will show their measured values if the mode is entered during RF delivery.

The system will not respond to any switches in ALARM mode. After two (2) seconds, the displays will clear and the system will return to STAND-BY mode or READY mode, depending on the error encountered.

A typical condition causing ALARM and return to the READY mode will be if the user attempts to enter ARMED mode prior to allowing the Handpiece to cool to acceptable temperature limits as measured by its temperature sensors. The system will generate the "Alarm tone", and then return to the READY mode.

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9.3.8. ERROR Mode

The ERROR mode indicates a recoverable problem that will require user intervention. When the ERROR mode is entered, an error code will appear in the IMPEDANCE display and an "Error Tone" is sounded. The POWER and ENERGY displays will show their measured values if the mode is entered during RF delivery.

Tables in "Section 10 Troubleshooting" can help determine the cause of the problem and the suggested course of action to take for resolution. After the condition is resolved, pressing the START/STOP button will exit ERROR mode and enter STAND-BY. The system will not operate, nor will it respond to any switches (other than START/STOP) while the unit is in ERROR mode.

9.3.9. FAULT Mode

The FAULT mode indicates an unrecoverable problem that will require System Reset. When the FAULT mode is entered, an error code will appear in the IMPEDANCE display, the "Fault" indicator is illuminated, and a "Fault Tone" is sounded. Tables in "Section 10 Troubleshooting" can help determine the cause of the problem and the suggested action to take for resolution.

The system will not operate, nor will it respond to any switches while the unit is in FAULT mode. AC mains power needs to be turned off and back on to exit the FAULT mode. A System Reset will initiate a Power On Self-Test, set the Treatment Level setting and Counter to zero, and the system will enter STAND-BY, unless a System Fault condition exists. Note that the System will have to be "re-tuned" following a FAULT mode shut down.

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9.4. Delivering RF Energy

9.4.1. Set procedure parameters

The Treatment Level is adjusted by turning the dial, and pressing the "Confirm" button, while the Generator is in the STAND-BY mode. Note that the Treatment Level can only be adjusted while in the STAND-BY mode.

Turning the dial a small amount clockwise will increment the Treatment Level by 0.5. Continuously turning the dial will rapidly increase the Treatment Level.

Turning the dial a small amount counter-clockwise will decrement the Treatment Level by 0.5. Continuously turning dial will rapidly decrease the Treatment Level.

After turning the dial, the user will have 5 seconds to press the Confirm button, or the Treatment Level will revert to the previous value.

Selection of the proper Treatment Level depends upon both the intensity of the effect desired and the Treatment Tip's electrode configuration.

- The first digit of the Treatment Level indicates the Electrode Configuration. The first digit is automatically selected by the Generator upon Insert connection.
- The second and third digits indicate increasing quantities of energy and/or power, within the grouping for that Electrode.

9.4.1.1. The Treatment Level settings

Treatment Level	Electrode Used
0	All electrodes – Tuning Only
10.5-19.5	TT-1.50A Standard 1.0 cm^2
20.5-29.5	TT-1.00A Standard 0.5 cm^2
30.5-39.5	TT-0.50A Standard 0.25 cm^2
40.5-49.5	TT-0.25A Standard 1.50 cm^2
50.5-59.5	TT-1.00B Mode B 1.00 cm^2

Note that the system should be set to the lowest Treatment Level setting, within a particular group, necessary to achieve the desired effect.

Start at the lowest Treatment Level setting for the Electrode type and deliver RF energy to the treatment site. If the desired effect is

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achieved, continue delivering at the selected Treatment Level until the entire site has been treated.

If the Treatment Level is not satisfactory, increment the Treatment Level by 0.5 and deliver RF energy at this setting. Repeat this process until the desired level of treatment is achieved. Then continue at the selected Treatment Level until the entire site has been treated.

After each delivery of RF energy, evaluate the treated location to ensure the desired level of treatment is being achieved. If the selected Treatment Level results in excessive treatment, the Treatment Level should be decremented until a satisfactory result is achieved.

Prior to delivery of RF energy, a thin, even layer of Thermage ThermaCool TC Coupling Fluid shall be applied to the treatment site.

9.4.2. Prepare the System

Depress the START/STOP button to enter the System READY mode, which allows the Handpiece Assembly to cool to its preset temperature. When the Generator "Ready" light illuminates, the system is ready.

9.4.3. Position Handpiece Assembly as desired

Choose the treatment site. Hold the Handpiece Assembly slightly above the treatment site in a vertical position.

9.4.4. Enable the system

The Generator can be ARMED by either the FOOTSWITCH or the Handpiece Assembly Finger Switch.

9.4.5. Deliver RF energy

The Generator can now be activated with tissue contact. The system must be activated within 3 seconds or the ARMED state ends. Press lightly and evenly to ensure full contact of the Treatment Tip surface with the treatment zone. The treatment cycle begins immediately after the system determines that you are applying the appropriate amount of force to the tissue.

RF application occurs after the initial tissue "Pre-cool" phase.

The Generator begins "RF Energy Delivery" phase, and displays measured values for POWER, IMPEDANCE, ENERGY and elapsed TIME. The START/STOP button is illuminated, and an audible tone is activated.

To end the procedure before time has elapsed, depress the START/STOP button, release the foot switch or the Finger Switch on the Handpiece Assembly to "Dis-Arm" the system. Two short tones will indicate an

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incomplete delivery. Do not lift the Handpiece Assembly prior to the cessation of the "Active" tone.

9.4.6. Shutdown Conditions

During RF delivery, the following conditions will cause the software to cease RF output. Measured values will remain on screen for two seconds and/or an Error code may appear.

- The Footswitch is released ("Dis-Arming" the unit).
- The Handpiece Assembly Finger Switch is released ("Dis-Arming" the unit).
- Tissue Contact switch is disengaged.
- The START/STOP button is depressed again.
- ERROR or FAULT is encountered.

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10. Troubleshooting

10.1. Tuning – Optimization of System Performance

Due to differences in tissue properties, the System may not operate efficiently at high power and current levels without an adjustment. The Tuning Level is a very low power setting that will allow the Generator to adjust itself for optimum performance.

Upon system start-up, and occasionally during patient treatment, the unit may prompt the user that Tuning is necessary. If so, the user should deliver as normal, in an untreated area, following the prompts on the screen, while the Generator automatically adjusts its calibration.

The tuning cycle will require the user to arm the system and press the Treatment Tip to the patient. It may be necessary to perform more than one tuning cycle. When the system has made the necessary adjustments, it will prompt the user to select a Treatment Level and resume treatment. If it is desired to treat the area used for tuning, wait a few minutes for normal temperature to be restored to the site.

10.2. Generator Problems

10.2.1. No RF Output

- Broken instrument cable
- Cable(s) not connected
- Coolant Control Center is not connected or not ready
- Fault in accessory or footswitch
- Generator ARMED mode cycle timer "timed out" prior to ACTIVE mode initiation
- Generator in FAULT or ERROR mode
- Generator internal failure
- Generator is still in DONE mode
- Generator not in ACTIVE mode
- Generator not plugged in
- Generator not turned on
- Handpiece not connected
- Treatment Level parameter not set

10.2.2. Generator Error Codes

If a fault condition should occur, the Impedance display on the front panel will display an error code, and all others will be blank. The interpretation of the error code, as well as possible causes and solutions are listed in Tables 10-1A to 10-1G.

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Table 10-1A Generator POST Fault Codes		
Description	**Error Type / Solution**	**Error Code**
POST Flash Disk CRC	**FAULT - Un-Recoverable** **Problem persists, contact Thermage, Inc.**	**P01**
POST Measurement and Delivery Test Error	**FAULT - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**P02**
POST Watchdog Shutdown Test Error	**FAULT - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**P03**
POST System Clock Test Error	**FAULT - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**P04**

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Table 10-1B Generator Software/Hardware Error Codes		
Description	**Error Type / Solution**	**Error Code**
Reference Voltage Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U10**
Duplicate Variable Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U11**
Software Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U12**
Hardware Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U13**
THIM Communication Error	**ERROR - Un-Recoverable** • Check all connections, the Treatment Tip, return pad and cables for visible damage. • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U14**
RFG-THIM Periodic Timing Error	**ERROR - Un-Recoverable** • Check all connections, the Treatment Tip, return pad and cables for visible damage. • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U15**
Forward Power Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U16**
Reflected Power Offset Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U17**

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Table 10-1B Generator Software/Hardware Error Codes		
Description	**Error Type / Solution**	**Error Code**
Current Offset Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U18**
Standard Tip Current Offset Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U19**
Mode B Tip Current Offset Error	**ERROR - Un-Recoverable** • Try turning power off, then on. **If problem persists, contact Thermage, Inc.**	**U20**

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Table 10-1C Generator Application Error Codes		
Description	**Error Type / Solution**	**Error Code**
Output Current Limit Error	**ERROR - Recoverable.** Press START/STOP to clear. • Check all connections, the Treatment Tip, return pad and cables for visible damage.	**E30**
Measured Current Exceeds Max	**ERROR - Recoverable.** Press START/STOP to clear. • Check all connections, the Treatment Tip, return pad and cables for visible damage.	**E31**
Temperature Out Of Valid Range	**ERROR - Recoverable.** Press START/STOP to clear. • Check all connections, the Treatment Tip, and Temperature cable for visible damage. • Bad Thermistor: Replace Treatment Tip.	**E32**
Reflected Power Limit Error	**ERROR - Recoverable.** Press START/STOP to clear. • Ensure correct location for treatment. • Ensure Treatment Tip electrode is in contact with moist tissue.	**E33**
DC Power Limit Error	**ERROR - Recoverable.** Press START/STOP to clear. • Check all connections, the Treatment Tip, return pad and cables for visible damage. Replace damaged components.	**E34**
DC Voltage Limit Error	**ERROR - Recoverable.** Press START/STOP to clear. • Check all connections, the Treatment Tip, return pad and cables for visible damage. Replace damaged components.	**E35**
DC Current Limit Error	**ERROR - Recoverable.** Press START/STOP to clear. • Check all connections, the Treatment Tip, return pad and cables for visible damage. Replace damaged components.	**E36**

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Table 10-1C Generator Application Error Codes		
Description	**Error Type / Solution**	**Error Code**
Excessive Force Detected	**ERROR - Recoverable.** Press START/STOP to clear. • Apply less force to the Handpiece when activating treatment.	**E37**

Table 10-1D Generator Auto Tune Error Codes		
Description	**Error Type / Solution**	**Error Code**
Fine Tune Reflected Power Error	**ERROR - Recoverable.** Transitions back to AUTO TUNE. • Check all connections, the Treatment Tip, return pad and cables for visible damage. Replace damaged components. • Ensure Treatment Tip electrode is in contact with moist tissue.	**E50**
Fine Tune Incomplete Error	**ERROR - Recoverable.** Transitions back to AUTO TUNE. • Check all connections, the Treatment Tip, return pad and cables for visible damage. Replace damaged components. • Ensure Treatment Tip electrode is in contact with moist tissue.	**E51**
Nominal Tune Incomplete Error	**ERROR – Recoverable.** Transitions back to AUTO TUNE. • Check all connections, the Treatment Tip, return pad and cables for visible damage. Replace damaged components. • Ensure Treatment Tip electrode is in contact with moist tissue.	**E52**

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Table 10-1E Standby Application Alarms		
Description	**Error Type / Solution**	**Error Code**
Coolant Control Center Not Available	**ALARM.** System will timeout back to STAND-BY Mode. • Coolant Control Center (CCC) is not available – check CCC LEDs for problem • Connect CCC	**A60**
No Flow Detected	**ALARM.** System will timeout back to STAND-BY Mode. • Coolant flow is not detected • Check for coolant flow	**A61**

Table 10-1F Generator Ready Application Alarms		
Description	**Error Type / Solution**	**Error Code**
Cycle Timeout Error	**ERROR - Recoverable.** Transitions back to READY. • Cycle timeout – must activate treatment within 3 seconds of Arming • Restart the treatment	**A70**
Temperature Not Ready	**ERROR - Recoverable.** Transitions back to READY. • Temperature is not within ready limit – wait for green Handpiece LED to illuminate before Arming • Check for coolant flow	**A71**

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Table 10-1G Generator Connection Error Codes		
Description	**Error Type / Solution**	**Error Code**
Handpiece Flash CRC Error	**ALARM.** System will timeout back to Connection Error. • Handpiece memory corruption • Replace Handpiece	**A80**
Expired Handpiece Detected	**ALARM.** System will timeout back to Connection Error. • Handpiece expired • Replace handpiece	**A81**
Treatment Tip EPROM CRC Error	**ALARM.** System will timeout back to Connection Error. • Treatment tip memory corruption • Replace treatment tip	**A82**
TM1 Not Connected	**ALARM.** System will timeout back to Connection Error. • Treatment tip temperature sensor error • Replace treatment tip	**A83**
TM2 Not Connected	**ALARM.** System will timeout back to Connection Error. • Treatment tip temperature sensor error • Replace treatment tip	**A84**
TM3 Not Connected	**ALARM.** System will timeout back to Connection Error. • Treatment tip temperature sensor error • Replace treatment tip	**A85**
TM4 Not Connected	**ALARM.** System will timeout back to Connection Error. • Treatment tip temperature sensor error • Replace treatment tip	**A86**

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Table 10-1G Generator Connection Error Codes		
Description	**Error Type / Solution**	**Error Code**
Maximum Treatment Tip Count Exceeded	**ALARM.** System will timeout back to Connection Error. • Treatment tip has exceeded its useful life • Replace treatment tip	**A87**
Maximum Treatment Tip Usage Time Exceeded	**ALARM.** System will timeout back to Connection Error. • Treatment tip has exceeded its useful life • Replace treatment tip	**A88**
Expired Treatment Tip Detected	**ALARM.** System will timeout back to Connection Error. • Treatment tip shelf-life expired • Replace treatment tip	**A89**
Handpiece Not Connected	**ALARM.** System will timeout back to Connection Error. • No handpiece detected • Connect handpiece	**100**
Treatment Tip Not Connected	**ALARM.** System will timeout back to Connection Error. • No treatment tip detected • Connect the treatment tip	**101**

10.3. Coolant Control Center Problems

If the "System Fault" indicator illuminates, it is indicating that there is a problem with the System and will prevent RF delivery. When the problem is corrected, the indicator will turn off and the Coolant Control Center will be available for use.

No further action will be required to return the CCC to operation; however, the Generator may require an action to return it to normal operation (e.g. pressing the Start/Stop button to re-enter the READY mode).

If the "System Fault" indicator does not illuminate, then the Coolant Control Center will not prevent RF delivery.

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10.3.1. Coolant Control Center Error Codes

Table 10-2 CCC Error Codes

Indication	Possible cause	Solution
Coolant flows out of canister with the Manual Valve set to "Vent", even though "Replace Can" indicator is illuminated.	• Normal operation; • Or, system failure.	• The system is designed to ensure the proper availability of liquid coolant. It is necessary to discharge the coolant vapor during canister removal. • If excessive amounts of liquid coolant are available after "Replace Can" is illuminated, then the unit may need servicing.
"Coolant Low" indicator is on.	System is low on coolant	No action. Have replacement coolant can ready to replace existing can when "Replace Can" indicator illuminates.
Handpiece "Ready" indicator does not illuminate.	• Temp sensors not within range • Temp sensors not working	• Wait. Coolant delivery in progress will cool the Handpiece to an acceptable temperature. • Check cable for loose connections or replace Treatment Tip.
Hissing sound.	• System is performing a "self-vent" operation; • Or, it is leaking.	• If the "Please Wait" indicator is on, this is normal operation. • If the "Please Wait" indicator is off, and the hissing sound remains, the unit may need servicing. With power off, the hissing sound indicates a leak – **contact Thermage, Inc. for service.** Repetitive canister changes without use of coolant can also indicate that the unit may need servicing.
"Replace Can" indicator is on.	Out of Coolant	Check coolant supply. Vent vapor in can and replace, if necessary

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Table 10-2 CCC Error Codes		
Indication	**Possible cause**	**Solution**
"System Fault" indicator is on.	Indicates problem: • Handpiece signal cable not connected or Handpiece problem • CCC failure	• Check Handpiece, Coolant Control Center, and Generator for proper connection of cables. • Cycle Coolant Control Center power OFF then ON. **If problem persists, contact Thermage, Inc. for service.**
"Please Wait" indicator is on.	Normal operation: • System is performing a "self-vent" operation; hissing sound • System is raising coolant pressure; "Pressure Low" indicator is on	• Wait for "Self-Vent" operation to complete. • Wait for pressure to normalize
"Tilt Indicator" indicator is on; audible tone	CCC unit is not on a level surface or vertical.	Adjust position of unit until indicator is no longer illuminated.
Unit will not Power-on, or Powers off without User action.	CCC failure	**If the problem repeats, leave unit off and contact Thermage, Inc. for service.**

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

10.4. Handpiece Assembly Problems

10.4.1. Handpiece Assembly Error Codes

Table 10-3 HA Error Codes

Indication	Description	Possible Cause	Solution
Green indicator is OFF	Treatment Tip Temp. out of range		Recoverable. Press START/STOP on Generator to clear.
		• Treatment Tip temperature is too cold or too warm	• Wait for Treatment Tip temperature to reach acceptable range.
		• Generator not in READY mode	• Check the Generator to ensure it is in the READY mode.
		• CCC not "Ready"	• Check the Coolant Control Center to ensure it is available ("System Fault" LED is off).
		• Cable/tubing connections not tight	• Check to ensure all cables and tubing are connected.
		• Damaged cables	• Check to ensure all cables and tubing are not damaged, kinked or twisted.
		• Kink in coolant tubing	• Check to ensure all cables and tubing are not damaged, kinked or twisted.
		• Damaged Treatment Tip	• Replace Treatment Tip.
		• Treatment Tip Temperature out of range	• May NOT be a problem. Wait for system to cool to proper temperature

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

11. Technical specifications

11.1. RF Output

• RF energy:	6 MHz ± 2%.
• Maximum power:	330 W
• Maximum current:	2.25 ARMS

11.2. Settings

• Treatment Level:	19 Levels per Treatment Tip

11.3. Measurement Accuracy

• Power:	± 10% of reading ± 2.5 W up to 40 Watts nominal. ± 10% of reading ± 2% measurement range, above 50 Watts.
• Output Current.	± 10% of reading from 0.15 to 0.40 amps. ± 5% of reading above 0.40 amps
• Impedance:	± 10%, ±25 Ω over the impedance load range of 50 Ω to 200 Ω - except for Treatment Levels 31-49 and 71-99

11.4. Enclosure Material

• Generator:	Aluminum

11.5. Mechanical Specifications - Generator

• Size:	17.25"W x 22.5" L x 8"H (438mm x 571mm x 203mm) maximum.
• Weight:	40 lb. (9.1 kg) maximum.
• Moisture protection rating:	IPX1

11.6. Mechanical Specifications – Coolant Control Center

• Size:	8" W x 6" D x 20" H (203 mm x 152 mm x 508 mm) maximum.
• Weight:	30 lb. (13.6 kg) maximum.
• Moisture protection rating:	IPX1

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

11.7. Mechanical Specifications - Handpiece Assembly

- Size: 1.25" Diameter x 5" L x 6.5" H (31.8 mm x 127 mm x 165 mm) maximum.
- Weight: 300 g maximum.
- Moisture protection rating: IPX1

11.8. Environmental Specifications

- Operational temperature: 10° C to 40° C
  NOTE: Allow system to equilibrate to room temperature for a minimum of 4 hours if the system has been stored at temperatures below 10° C
- Storage temperature: -40° C to 70° C
- Humidity: 20% to 95% non-condensing

11.9. Fuses - Coolant Module

- 100-120 VAC @ 50/60 Hz configuration: Replace mains fuses as marked: **2A/250V, T-lag, 5x20mm.**
- 220-240 VAC @ 50/60 Hz configuration: Replace mains fuses as marked: **2A/250V, T-lag, 5x20mm.**

11.10. Fuses - Generator

- 90-132 VAC @ 50/60Hz configuration: Replace mains fuses as marked: **5A/250V, T-lag, 5x20mm.**
- 200-264 VAC @ 50Hz configuration: Replace mains fuses as marked: **2.5A/250V, T-lag, 5x20mm.**

11.11. Power Output Restrictions

The maximum output, 250 W, is available over the limited impedance range of 50 Ω - 200 Ω.

11.12. Footswitch Specifications

- Moisture protection rating: IPX8
- Electric

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

12. Labeling Symbols

Alternating Current	~
Attention: consult accompanying documents	
Dangerous Voltage	
Return Pad – for Standard Mode only	
Earth Ground	
Footswitch	
Fuses	
Power OFF	O
Power ON	|
STOP	
START	
Type "BF" Symbol	

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

ATTACHMENT D

PRODUCT LABELS

List of Contents in Attachment D:

1. **DTS LT Applicator Label**
2. **DTS LT Applicator – Disposable Head Label**

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Miramar Labs, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

DTS LT APPLICATOR

MODEL #: MN-DTSALT4

NON-STERILE

DO NOT STERILIZE

MADE IN USA

PATENTS PENDING

CAUTION: Federal law (USA) restricts the sale, distribution and use of this device to, by or on the lawful order of a health care professional

This package contains 1 DTS LT Applicator.

LOT XXXXXX

DRAFT

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Miramar Labs, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

DISPOSABLE HEAD – DTS LT APPLICATOR

MODEL #: MN-DTSHLT4

STERILE	EO

DO NOT RESTERILIZE

MADE IN USA
PATENTS PENDING

CAUTION: Federal law (USA) restricts the sale, distribution and use of this device to, by or on the lawful order of a health care professional

Instructions for Use:

1. Place the Disposable Head onto the DTS LT Applicator until it's fully seated against the face of the Applicator.
2. Use the latches on the Applicator to engage and lock the Disposable Head onto the Applicator
3. Connect the end of the Disposable Head vacuum tubing to the DTS Generator.

Important:

- Use only with Miramar Labs DTS LT Applicator.
- If the plastic film on the Disposable Head looks damaged, do not use.
- Product is sterile unless package has been damaged or opened

This package contains 1 Disposable Head for the DTS LT Applicator

LOT XXXXXX Use By: XX-XXXX

DRAFT

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

ATTACHMENT E

BIOCOMPATIBILITY INFORMATION

List of Contents in Attachment E:

1. 510(k) Summary for K071488 – example of use of polycarbonate in surgical instruments device
2. 510(k) Summary for FAS-CLEAN K073616 – example of use of polyethylene in electrosurgical device
3. 510(k) Summary for K052738 – example of use of UV adhesive in catheter device
4. Additional information for UV Adhesive Loctite 3311 and Loctite 3321

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

JUN 29 2007 K071488

510(k) Summary

General Information

Classification	Class II
Trade Name	RealHand™ High Dexterity (HD) Instruments.
Submitter	Novare Surgical Systems, Inc. 10440 Bubb Road Suite A Cupertino, CA 95014 Tel: 408-873-3161
Contact	Kerry Pope President & CEO

Intended Use

The RealHand™ High Dexterity (HD) Instruments are intended for grasping, mobilization, dissection, transection and / or suturing of tissue under direct and endoscopic visualization.

Predicate Devices

K043541	Endolink™ True Movement System™ Novare Surgical Systems, Inc.

Device Description

The RealHand Instruments are single use, sterile instruments that consist of a handle, jaws, and a shaft which includes distal and proximal articulating sections. The instruments are similar in size to other instruments and are designed for use through an incision or appropriately sized surgical trocars/ports. The instrument jaws (or scissor blades) are activated by compressing and releasing the handle. The handle can include a ratchet and ratchet release which allow the instrument jaws to be locked in place, a rotation control wheel and articulation lock.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Materials

All materials used in the manufacture of the RealHand Instruments are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included grasping, manipulating, cutting and suturing of tissue.

Testing comparing the RealHand Instruments to a commercially available predicate product was conducted. The products were used per their respective Instructions for Use. The results showed the RealHand Instruments were equivalent to the predicate device.

Summary of Substantial Equivalence

The RealHand Instruments are equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Novare Surgical Systems
% Regulatory Strategies, Inc.
Mr. Gregory Mathison
President
3924 Cascade Beach Road
Lutsen, Minnesota 55612

Re: K071488
Trade/Device Name: RealHand™ High Dexterity (HD) Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 24, 2007
Received: May 30, 2007

Dear Mr. Mathison:

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. 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.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anastacia M Bilk

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Indications for Use

510(k) Number (if known): This application

Device Name: RealHand™ High Dexterity (HD) Instruments

Indications for Use: The RealHand™ High Dexterity (HD) Instruments are intended for grasping, mobilization, dissection, transection and / or suturing of tissue under direct and endoscopic visualization.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X
Prescription Use ___ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Anastacia M Bilek
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071488

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

510(k) Summary

K073616

JUL 23 2008

General Information:

Submitter: ELECTROMEDICS Co. LTD.
55 Anderson Avenue
Moonachie, NJ 07074

Contact Person: John Scholz
Tel : 201-935-0770
Fax: 201-935-2812

Summary Date of Preparation: December 1, 2007

Names:

Proprietary Name: FAS-CLEAN Electrosurgical Coated Active Blade
Common Name: Electrosurgical Electrode
Classification Name: Electrosurgical cutting and coagulation device and accessories

Predicate Devices:

Unimed Coated Blade Electrode (K962935)
Valley Lab's EDGE (K962044)
ConMed's UltraClean (K052104)
Megadyne's EX Clean (K943055)

ELECTROMEDICS' FAS-CLEAN Electrosurgical Coated Active Blade is substantially equivalent to the Unimed Coated Blade Electrode, Valley Lab EDGE, ConMed's Ultra Clean and Megadyne's EZ Clean electrode. The FAS-CLEAN Electrosurgical Coated Active Blade shares the same intended uses, indications for use and the same or similar characteristics including: single use, non-stick properties, sterilization method, and various configurations.,

Device Description

ELECTROMEDICS' FAS-CLEAN Electrosurgical Coated Active Blade is a sterile, single use, coated stainless steel blade. The main parts of the device are the Emralon coated stainless steel blade and the insulated polyethylene sleeve.

Intended Use

The FAS-CLEAN Electrosurgical Coated Active Blade is intended for use by surgeons as an alternative to uncoated stainless steel blades or "non-stick" coated electrodes where monopolar electrosurgical cutting and coagulation blades are normally used.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K073616

Technological Characteristics

The FAS-CLEAN Electrosurgical Coated Active Blade is substantially equivalent in materials and operation to the predicate devices on the market. This device has been designed to comply with the Sterilization of health care products – Requirements for validation and routine control- radiation Sterilization, ISO 11137 and Biocompatibility ISO 10993. There are no new technological characteristics and therefore no new questions of safety and effectiveness.

Performance Data:

No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A database search has been conducted to evaluate any adverse effects of the device that is currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c)]. See attached documentation of adverse effects.

Conclusion:

The FAS-CLEAN Electrosurgical Coated Active Blade is substantially equivalent to Unimed's Coated Blade Electrode, Valley Lab's EDGE, ConMed's Ultra Clean and Megadyne's EZ Clean Electrodes. The FAS-CLEAN Electrosurgical Active Coated Blade shares the same intended use, indications for use and same or similar technological characteristics as the predicate electrosurgical electrodes.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Electromedics Co., Ltd.
% Mr. John Scholz
55 Anderson Avenue
Moonachie, New Jersey 07074

Re: K073616
Trade/Device Name: FAS-CLEAN Electrosurgical Coated Active Blade
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 10, 2008
Received: April 11, 2008

Dear Mr. Scholz:

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. 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.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Indications for Use

510(k) K073616

Device Name: FAS-CLEAN Electrosurgical Coated Active Blade

Indications for Use:

The FAS-CLEAN Electrosurgical Coated Active Blade, a single use, sterile, monopolar, Emralon coated electrode is intended for use:

- In surgical procedures (general, neurosurgical, laparoscopic, orthopedic, and gynecologic) where monopolar electrosurgical cutting and coagulation are normally used.
- As an alternative to uncoated stainless steel electrodes or "non-stick" coated electrodes, which are used for these indications.

Prescription Use X And/Or Over- The-Counter Use No

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073616

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K 052738

DEC 6 2005

510(k) Summary

General Information

Classification	Class II
Trade Name	InfusionCath™ Peripheral Infusion Catheter
Submitter	VeinRx Inc 8200 N.W. 27th Street Suite 102 Miami, FL 33122 305-716-7005
Contact	Gregory J. Mathison Vice President – Regulatory Affairs

Intended Use

The VeinRx Infusion Catheter is intended for the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Devices

InfusionCath Peripheral Infusion Catheter Manufactured by VeinRx, Inc.	K041517

Device Description

The VeinRx InfusionCath Peripheral Infusion Catheter is comprised of a distal occlusion balloon, a fixed infusion length catheter body with infusion holes, and a proximal trifurcated Luer connection hub. The trifurcated hub allows connection to three main systems of the device. The distal black marker indicates the proximal edge of the infusion length. The proximal black marker is used to properly align the device with the recommended introducer. The InfusionCath is packaged inside a protective tube mounted on a card and placed in a sealed protective pouch.

Materials

All materials used in the manufacture of the InfusionCath Peripheral Infusion Catheter are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The modified InfusionCath Peripheral Infusion Catheter was tested in the same manner as the original InfusionCath Peripheral Infusion Catheter. All components, subassemblies, and/or full devices met the required specifications for the completed tests.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Summary of Substantial Equivalence

The modified InfusionCath Peripheral Infusion Catheter is equivalent to the predicate product, the original InfusionCath Peripheral Infusion Catheter. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. VeinRx, Inc. believes the modified InfusionCath Peripheral Infusion Catheter is substantially equivalent to existing legally marketed devices

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

Mr. Gregory Mathison
Vice President
Vein RX, Inc.
8299 NW 27 St.
Suite 102
Miami, FL 33122

Re: K052738
Trade Name: Infusion Catl™
Regulation Number: 21 CFR 870.3470
Regulation Name: Infusion Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: November 08, 2005
Received: November 11, 2005

Dear Mr. Mathison:

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Diana R. Vachner

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

Enclosure

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Indications for Use

510(k) Number (if known): K052738

Device Name: InfusionCath Peripheral Infusion Catheter

Indications For Use: The InfusionCath Peripheral Infusion Catheter is intended for infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature

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

Anna R. Ledwich

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052738

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

TOXIKON
Leaders in Life Science and Technology

Loctite Corporation
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: November 11, 2004
Project Numbers: 04-3975
Page: 1 of 2

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: Loctite 3311 Medical Device Adhesive

Lot Number: 4F303

INTRACUTANEOUS INJECTION (ISO): The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater tissue reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 27, National Formulary 22, 2004; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant-conforms. *Reference: Biological Evaluation of Medical Devices - Part 10: Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002.*

ACUTE SYSTEMIC INJECTION (ISO): The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 27, National Formulary 22, 2004; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material-conforms.
Reference: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11:1993.

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-5:1999.

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www.toxikon.com

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

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TOXIKON
Leaders in Life Science and Technology

Project Number: 04-3975
Page: 2 of 2

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):
Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 2002.

***In Vitro* Hemocompatibility Assay**: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:2002.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.
Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 27, National Formulary 22, 2004.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

The adhesive bonded polycarbonate lap shears utilized to approximate typical medical device applications are disassembled prior to testing in order to maximize adhesive exposure during the respective tests. All test results reflect maximum exposure of the adhesive to the various test parameters and conditions. In this manner, the adhesive test results provide a higher margin of safety when compared to the tests involving only the bondline area and thickness.

Study Director

Quality Assurance

Date of Certificate: November 15, 2004

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Loctite Corporation
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: November 03, 2004
Project Numbers: 04-3974
Page: 1 of 2

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: Loctite 3321 Medical Device Adhesive

Lot Number: 4F337

INTRACUTANEOUS INJECTION (ISO): The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater tissue reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 27, National Formulary 22, 2004; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant-conforms. *Reference: Biological Evaluation of Medical Devices - Part 10: Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002.*

ACUTE SYSTEMIC INJECTION (ISO): The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 27, National Formulary 22, 2004; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material-conforms.
Reference: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11:1993.

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-5:1999.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

TOXIKON
Leaders in Life Science and Technology

Project Number: 04-3974
Page: 2 of 2

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):
Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 2002.

***In Vitro* Hemocompatibility Assay**: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:2002.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.
Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 27, National Formulary 22, 2004.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

The adhesive bonded polycarbonate lap shears utilized to approximate typical medical device applications are disassembled prior to testing in order to maximize adhesive exposure during the respective tests. All test results reflect maximum exposure of the adhesive to the various test parameters and conditions. In this manner, the adhesive test results provide a higher margin of safety when compared to the tests involving only the bondline area and thickness.

Study Director

Felice Randi La Madeleine
Quality Assurance

Date of Certificate: November 04, 2004

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

ATTACHMENT F

CLINICALTRIALS.GOV CERTIFICATION

List of Contents in Attachment F:

1. FDA Form 3674 – Certifcation of Compliance with Requirements of ClinicalTrials.gov

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

Records processed under FOIA Request # 2015-8801 Release Date: 09/09/2015 on 9/10/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Miramar Labs, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
09/23/08

3. ADDRESS *(Number, Street, State, and ZIP Code)*
199 Jefferson Drive
Menlo Park, CA 94025

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 650-326-2656
(Fax) 650-326-3108

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Tissue Coagulation System

DTS G2

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Kathy O'Shaughnessy

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Kathy O'Shaughnessy
(Title) VP, Clinical and Regulatory

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
199 Jefferson Drive
Menlo Park, CA 94025

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 650-326-2656
(Fax) 650-326-3108

15. DATE OF CERTIFICATION
09/22/2008

PSC Graphics: (301) 443-1090 EF

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K082819/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
[illegible]	[illegible]	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of* [illegible]			X
[illegible] contacted to obtain completed fo[illegible]			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Rev. 7/2/07

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Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
21 CFR 878.4400	II	NEY

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Neil M. Ogden (Branch Chief) GSDB (Branch Code) 3/20/09 (Date)

Final Review: [illegible] for MXM (Division Director) 3/20/09 (Date)

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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)] Review
Traditional

K082819/S2

Date: March 20, 2009
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: Miramar Labs, Inc., Menlo Park, CA
Device Name: **DTS G2 System**
Contact: Ms. Kathy O'Shaughnessy, VP Clinical and Regulatory Affairs
Phone: (650)-326-2656
Fax: (650)-326-3108
Email: kathyo@miramarlabs.com

I. Purpose

The 510(k) holder would like to introduce the subject DTS G2 into interstate commerce.

The DTS G2 is a microwave based device to interact using a surface contact applicator. It is designed for use for coagulation of soft tissue. It is noted that, in the previous supplements, the sponsor has modified the indications for use to be used for coagulation of soft tissue. The sponsor also changed the device name from Dermatologic Treatment System (DTS) G2 to DTS G2 to remove the "dermatologic treatment" language.

The DTS microwave generator operates at a frequency of 5800 MHz with a maximum power of 100 W and a limit of maximum time of 9.999 seconds using a surface contact applicator. The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The microwave energy is delivered through 4 microwave antennas embedded in the Applicator housing. There are 4 temperature sensors placed on the inside of the vacuum chamber to monitor the tissue surface temperature under each of the antennas. The cooling feature is provided using the chiller pump that circulates the sterile saline through the LT-DTS applicator.

In the original submission, the sponsor presented test data on in-vivo skin and ex-vivo liver, muscle, and kidney. However, the data was insufficient to support the substantial equivalence. Hence, it was put on hold on October 17, 2008 for deficiencies in substantial equivalence, DTS G2 system description, performance testing data, applicator temperature test, lesion size guidance, performance testing - electrical safety, control & display, and labeling.

The sponsor's 1st supplemental response to this AI (K082819/S1) was received on November 18, 2008. However, the response is not complete. The sponsor needs to describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly. In addition, the subject device will need to comply with the applicable clauses of the IEC 6061-2-2:2006 standard. The submission was put on hold again on December 2, 2008 for deficiencies in name of the device, maximum time setting, and performance testing data,

In this supplement (K082819/S2), together with the e-mail clarification on 3/20/2009, the sponsor has

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adequately addressed all the deficiencies identified in the telephone hold letter dated December 2, 2008. Therefore, an **SE** is recommended.

II. Administrative Requirements

	Yes	No	N/A
Revised Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary	x		
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x	x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x	x	

The DTS G2 System consists of a DTS G2 microwave generator (non-sterile), a DTS LT applicator with disposable head (sterile, single use), a NanoTerm chiller and recirculation (non-sterile) and an Isolation Transformer (non-sterile). The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has the surface cooling feature. There are four temperature sensors placed on the inside surface of the suction chamber to monitor the tissue surface temperature. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the NanoTherm with chiller pump that circulates the sterile saline through the DTS G2 applicator.

III. Revised Indications for Use

The revised indications for use statement for the subject device is as follows: "The DTS G2 System is indicated for use for coagulation of soft tissue." This revised indication statement is the same as that of the predicate, Foundry Newco X Microwave Tissue Coagulation System (MTCS) (K072870).

IV. Predicate Device Comparison

The proposed DTS G2 System is SE in design configuration, technological characteristics, functions and intended use, indications to its predicate, Foundry Newco X Microwave Tissue Coagulation System (MTCS) (K072870).

The sponsor has included in the revised substantial equivalence comparison table the following technological characteristics comparison: indications for use, manual setting or automatic, energy, maximum power, coagulation time, maximum coagulation cycle, frequency, vacuum source, maximum supplied vacuum, monitored parameters, displayed parameters, shutoff alarms, operation mode, output temperature, software, supplied sterile, antenna/applicator design, antenna/applicator size, expiration date for handpiece, maximum applicator surface temperature, antenna/applicator use, cooling mechanism, coolant, and cooling design.

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Major differences are in the microwave frequency, delivery power and delivery time. The subject DTS G2 system has a 5.8 GHz compared to 2.4 GHz of the MTCS predicate. The sponsor has provided the comparative ex-vivo vivo porcine tissue data of three types of tissue: liver, muscle and kidney, by the subject DTS G2 system and the MTCS predicate to demonstrate the equivalence of the thermal damage zone. Regarding the delivery power, the subject DTS G2 system delivers 100W which is higher than the 60W of the MTCS predicate. However, the maximum deliver time of 9.999 seconds is less than the 30 seconds of the MTCS. The maximum possible energy delivered (power x time) is 1000 Jules for the DTS G2 compared to 1800 Joules for the MTCS. Therefore, these differences do not affect the safety and effectiveness of the subject DTS G2 System.

V. Labeling

The sponsor has revised the user manuals for the DTS G2 Generator and LT-DTS applicator (Attachments K and C, K082819/S1). The package labels for the DTS LT- Applicator and DTS LT Applicator-Disposable Head are also provided (Attachment D, K082819). The revised labeling is acceptable.

VI. Sterilization/Shelf Life/Reuse

The disposable head of the DTS LT applicator will be supplied sterile. They will be sterilized by EtO. According to the sponsor, the sterilization process will be validated to a SAL of 10^{-6} in accordance with ANSI/AAMI/ISO 11135-1. The sponsor also stated that acceptable EtO residuals levels will be in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose). The DTS LT applicator is not labeled "pyrogen free".

The disposable head of the DTS LT applicator will be packaged in an industry standard heat sealed Tyvek and polyester sterile barrier pouch. The shelf life will be 6 month.

1. Sterilant:	**YES**	**NO**
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose).	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ANSI/AAMI/ISO 11135-1	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		x
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		

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

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5. A description of the packaging (not including package integrity test data):	industry standard heat sealed Tyvek and polyester sterile barrier pouch.

VII. Biocompatibility

The sponsor has identified the patient contact materials and the predicates as follows: polycarbonate (K071488), polyethylene (K073616), and UV adhesive (K052738). No biocompatibility issue here.

VIII. Software

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

According to the sponsor, all digital logic block in the microwave generator is embedded in two Complex Programmable Logic Devices (CPLDs). The logic is hardwired and there is no code that is executed inside the CPLD. The logic information for the control and display is provided (Attachment J, K082819/S1). The hazard Analysis for the subject DTS G2 system is also provided (Attachment L, K082819/S1).

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor stated the subject system is designed to comply with the electrical safety (IEC60601-1) and electromagnetic compatibility (IEC60601-1-2) standards. Test results are provided (Attachments H and I, K082819/S1).

The sponsor also provided a clause by clause analysis of the applicability of IEC 60601-2-2:2006 standard to the subject DTS G2 system (Attachment B, K082819/S2). The sponsor indicated that the DTS G2 system complies with all but one of the applicable requirements: clause 56.102 where alternative testing was done. Isaac Chang, Deputy Director, OSEL/DP, had discussions with sponsor's consultant, Mark Mirotznik, Associate Professor at the Catholic University of America and agreed with this approach.

IX. Performance Testing – Bench

The sponsor stated that clinical simulation tests were performed to demonstrate the following:

- Vacuum was sufficient to pull tissue into applicator

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

- No vacuum leaks observed
- Cooling system operated per specification
- No coolant leaks observed

In addition, bench tests were also conducted to record the temperature profile of the LT-DTS Applicator surface during simulation use for the maximum energy delivery duration (10 seconds) at the maximum power of 100 Watts, with and without cooling system (Attachment G, K082819/S1). The results showed that the maximum surface temperature was below 27.9 C under all tested configurations.

X. Performance Testing – Animal

The sponsor has provided comparative ex-vivo vivo porcine tissue data of three types of tissue: liver, muscle and kidney, by the subject DTS G2 system and the predicate, MTCS. The comparison of the sizes of lesions and the examples of gross pathology is provided in the response to question #3 (K082819/S1). The lesion sizes guideline for ex-vivo muscle tissue, liver tissue, and kidney tissue is also included in the revised LT-DTS Applicator Instruction for Use (Attachment C, K082819/S1). Overall, due to higher frequency (5.8 GHz vs. 2.45 GHz), the subject DTS G2 system creates smaller lesion sizes than those from the MTCS predicate.

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?		x	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		x	If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs 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:

Compared to the predicate, Foundry Newco X Microwave Tissue Coagulation System (MTCS) (K072870), the subject DTS G2 system has the following new characteristics: microwave frequency (5.8 GHz vs. 2.4 GHz), maximum power delivery (100W vs. 60W) and delivery time (10 seconds vs. 30 seconds).

6. Explain how new characteristics could or could not affect safety or effectiveness:

The new characteristics could not affect safety or effectiveness.

Although the subject DTS G2 system delivers 100W which is higher than the 60W of the MTCS. However, the maximum deliver time of 9.999 seconds is less than the 30 seconds of the MTCS. Therefore, the maximum possible energy delivered (power x time) is 1000 Jules for the DTS G2 compared to 1800 Joules for the MTCS.

The sponsor has provided comparative ex-vivo vivo porcine tissue data of three types of tissue: liver, muscle and kidney, by the subject DTS G2 system and the predicate, MTCS. Overall, the subject DTS G2 system creates smaller lesion sizes than those from the MTCS predicate.

In addition, bench tests were also conducted to record the temperature profile of the LT-DTS Applicator surface during simulation use for the maximum energy delivery duration (10 seconds) at the maximum power of 100 Watts, with and without cooling system. The results showed that the maximum surface temperature was below 27.9 C under all tested configurations.

Finally, testing results demonstrated that the subject device complies with the electrical safety (IEC60601-1:1995), electromagnetic compatibility (IEC60601-1-2:2004) and applicable clauses of High Frequency Safety (IEC60601-2-2:2006) standards.

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) 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:

XIII. Deficiencies

The sponsor has adequately addressed all the deficiencies in the AI letters dated October 17, 2008 and dated December 2, 2008 as follows:

Deficiencies in the AI letter dated October 17, 2008 were partially addressed as follows:

1) Substantial Equivalence
In the equivalence device comparison table (page 11), you include some of the technological characteristics such as: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, coolant, applicator design, and vacuum source. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator

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surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

Response:
The sponsor has revised the substantial equivalence comparison table that compares the subject DTS G2 system with the microwave device predicate, MTCS(K072870). Although the subject DTS G2 system delivers 100W which is higher than the 60W of the MTCS. However, the maximum deliver time of 9.999 seconds is less than the 30 seconds of the MTCS. Therefore, the maximum possible energy delivered (power x time) is 1000 Jules for the DTS G2 compared to 1800 Joules for the MTCS.
This revised comparison table is adequate.

2) DTS G2 System Description
The information you provided for DTS G2 system is not adequate. Please provide the following additional information:

a. Detailed design information and test results for the NanoTherm System and/or FDA clearance number.
b. Design information and test results for the integrated vacuum pump.

Response:
The sponsor stated that the Nano Therm chiller/circulator has been cleared in K061866. The integrated vacuum pump, on the other hand, is supplied by Clark Solution, Model 15988. It was tested as part of the overall Generator verification testing. This response is acceptable.

3) Performance Testing Data
The data from your in-vivo porcine skin model and ex-vivo porcine tissue models is inadequate. You did not compare the histological results of the subject DTS G2 system to the ThermaCool TC System (K013639) predicate device. Please provide comparative performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the ThermaCool TC System (K013639) predicate device.

Response:
The sponsor has modified the indications for use statement to remove the dermatologic indication. It is used only for coagulation of soft tissue, same as the predicate, MTCS (K072870). Therefore, the comparison of the sizes of lesions and the examples of gross pathology in this response is adequate. In general, due to higher frequency (5.8 GHz vs. 2.45 GHz), the subject DTS G2 system creates smaller lesion sizes than those from the MTCS predicate.

4) Applicator Temperature Test
You did not discuss the maximum surface temperatures of your Applicator LT during usage.

a. Please provide bench test results that record the temperature profiles of your DTS LT applicator and cable during simulation use for the maximum energy delivery duration (99.99 seconds) at the maximum power of 100 Watts, with and without cooling system, to demonstrate that your maximum applicator surface temperature and maximum cable surface temperature will be safe to the user and/or to the patient.
b. Please discuss your method for the mitigation of potential high applicator surface temperatures.

Response:

The sponsor stated that they have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in the original submission. A DTS LT Applicator-Device temperature measuring testing was conducted (Atachment G, K082819/S1) and the results were satisfactory. However, how the maximum time setting of 9.999 seconds was implemented was not described. See new deficiency #2.

5) Lesion Size Guideline
You have provided the lesion sizes created by the DTS LT applicator up to 14 seconds and up to 100 watts (Instructions for Use, DTS-LT Applicator). This data is inadequate considering your generator output is designed for a maximum duration of 99.99 seconds and at a maximum power output of 100 watts (DTS G2 Generator User Manual). Please provide the suggested lesion sizes for the whole operating range of the device and revise your DTS-LT Applicator Instructions for Use accordingly.

Response:
Based on the change made to limit the maximum time setting to 9.999 seconds, the sponsor has revised the proposed DTS-LT Applicator Instructions for Use to include the lesion sizes guideline for ex-vivo muscle tissue, liver tissue, and kidney tissue. (Attachment C, K082819/S1). This revised information is adequate.

6) Performance Testing- Electrical Safety
Please provide complete test results to demonstrate that your device including the DTS G2 generator, LT applicator, NanoTherm and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

Response:
The sponsor has conducted the IEC 60601-1:1995 and IEC 60601-1-2:2004 electrical testing. Test results are provided (Attachments H and I, K082819/S1).

The sponsor also indicated that their DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, the sponsor stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. The subject DTS G2 System will need to comply with applicable clauses of the IEC 6061-2-2 standard. See new deficiency #3.

7) Control & Display
You have provided the microwave generator controller diagram in Attachment A. However, the mechanism that is utilized for the control and display of the parameters such as skin temperature, power control, energy timer, start/stop, etc.., as shown in the DTS G2 Generator User Manual (page 5-6, Attachment B) is still not clear.

a. Please describe in detail how these functions are accomplished. Specifically, how the 10 antenna select switches are used to select the 4 antenna in the applicator? how the energy timer setting is used to control the energy delivery time? is there any mechanism to prevent the applicator surface temperature running too high?)
b. Please provide the logic information of your microwave generator controller diagram. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html.
c. Please provide the Device Hazard Analysis for the mitigation of potential hazards.

Response:
According to the sponsor, all digital logic block in the microwave generator is embedded in two Complex Programmable Logic Devices (CPLDs). The logic is hardwired and there is no code that is executed inside the CPLD. The logic information for the control and display is provided (Attachment J, K082819/S1). The hazard Analysis for the subject DTS G2 system is also provided (Attachment L, K082819/S1).

8) Labeling - User Manual for the DTS G2 Generator
Please revise your User manual for the DTS G2 Generator to include the following information:

a. description of vacuum pump
b. a consistent indications for use statement
c. provide data to substantiate your list of potential adverse events
d. detailed technical specifications to include, for example, energy durations, vacuum range, etc...

Response:
The sponsor has revised the proposed User Manual for the DTS G2 Generator (Attachment K, K082819/S1) to include a brief description of the vacuum pump, a consistent indications for use statement, and a revised technical specifications table product brochure. The sponsor also removed the potential adverse events section. This revised User Manual for the DTS G2 Generator is acceptable.

9) Labeling - DTS-LT Applicator Instructions for Use
Please revise your DTS-LT Applicator Instructions for Use to include the following information:

a. description and pictorial illustration of the assembly and disassembly of disposable applicator head.
b. technical specifications of the applicator

Response:
The sponsor has revised the proposed DTS-LT Applicator Instructions for Use to include the description and pictorial illustration of the disposable applicator head. The technical specification was also added (Attachment C, K082819/S1). This revision is acceptable.

10) Labeling - User Manual for the NanoTherm
Please revise your User manual for the DTS G2 Generator to include the intended use and/or indications for use statement.

Response:
The sponsor indicated that the NanoTherm is supplied by Thermo Tek, Inc and was cleared in K061866. The sponsor has included in the revised DTS G2 Generator Manual a description to the user that the NanoTherm User Manual should be consulted to set the chiler/circulator configuration. This revision is acceptable.

New deficiencies:
Deficiencies in the AI letter dated December 2, 2008 were fully addressed as follows:

1) Name of the Device
You have changed the device name from "Dermatologic Treatment System (DTS) G2" to "DTS G2" in this supplement. Please submit a letter to inform FDA such change together with your revised CDRH Premarket Review Submission Cover Sheet.

Response:
The sponsor agreed to remove "dermatologic treatment" language from the indications for use statement. Consequently, the sponsor also changed the name of the device from "Dermatologic Treatment System (DTS) G2" to "DTS G2 System". This change is acceptable.

2) Maximum Time Setting - Implementation and Verification
In your response to deficiency #4, you stated that you have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in your original submission. However, how the maximum time setting of 9.999 seconds was implemented to mitigate the potential risk of taking a time setting input that is higher than the maximum time setting has not been described. Please describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly.

Response:
The sponsor will change the maximum energy timer setting from 99.99 seconds to 9.999 seconds (e-mail 3/20/2009). The description of the implementation and validation process is adequate and acceptable.

3) Performance Testing- Electrical Safety
In your response to deficiency #6, you indicated that your DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, you stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. Furthermore, the generator cannot be evaluated for applicability to IEC 60601-2-2 by itself. The entire system, including DTS LT-Applicator, has to be evaluated as a whole. Please provide test results to demonstrate that your DTS G2 System complies with applicable clauses of the IEC 6061-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, 2006.

Response:
The sponsor has provided a clause by clause analysis of the applicability of IEC 60601-2-2:2006 standard to the subject DTS G2 system (Attachment B, K082819/S2). The sponsor indicated that the DTS G2 system complies with all but one of the applicable requirements: clause 56.102 where alternative testing was done. Isaac Chang, Deputy Director, OSEL/DP, had discussions with sponsor's consultant, Mark Mirotznik, Associate Professor at the Catholic University of America and agreed with this approach.

XIV. Contact History

A telephone conversation with the sponsor (Ms. Kathy O'Shaughnessy) followed up by an e-mail on 10/17/2008 asking for additional information.
An e-mail was sent to the sponsor (Ms. Kathy O'Shaughnessy) on 12/2/2008 asking for additional information.
A teleconference (Issac Chang and myself) with the sponsor (Ms. Kathy O'Shaughnessy) on 12/16/2008 to clarify the additional information request.
Further e-mail clarifications with the sponsor (Ms. Kathy O'Shaughnessy) on 1/22, 2/24, and 3/20/2009.

XV. Recommendation

SE is recommended.

Regulation Number: 21CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY

Long Chen
Lead Reviewer, GSDB/DGRND

3/20/09
Date

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Neil R P Ogden

Neil Ogden
Branch Chief, GSDB/DGRND

I concur with SE.

3/20/09
Date

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Chen, Long H

From: Kathy OShaughnessy [KathyO@miramarlabs.com]
Sent: Friday, March 20, 2009 3:05 PM
To: Chen, Long H
Cc: Steven Kim
Subject: RE: response for K082819 sent in (K082819/S1)
Attachments: Miramar SAR plot 20Mar09.doc

Long;
Please see our clarifications below. I hope that this meets your timing needs – we gathered the information as fast as we could!

Let me know if you need more information. Please call my cell phone 650-269-4770 as I will be out of the office from approximately 12:30 to 2:30 Pacific time.

Regards,
Kathy

From: Chen, Long H [mailto:Long.Chen@fda.hhs.gov]
Sent: Friday, March 20, 2009 5:33 AM
To: Kathy OShaughnessy
Subject: RE: response for K082819 sent in (K082819/S1)

Kathy,

I would appreciate your clarifications for the following:

1) In your response to deficiency #2, you have changed the position of the decimal place to limit the maximum time to 9.999 seconds instead of 99.99 seconds. However, we believe that this new display implies that the temporal accuracy of monitoring and energy delivery is 0.001 seconds. Since you have not provided testing that demonstrates that your device is capable of that level of precision, we strongly recommend that you modify your display to a reasonable number of decimal places.
The timer modules used in the DTS G2 System Instrumentation are off the shelf components that display 4 digits and a decimal point. The only control over the display that is available to be set during the manufacturing process is where the decimal point is located. We cannot eliminate digits from the display.

The time accuracy from the timer manufacturer's specification is ± 20.5 ms (± 0.0205 seconds) for the 9.999 second timer range setting. (For the 99.99 sec range, the accuracy was ± 25 ms.) The settings that are described in the treatment guidance section of the DTS-LT Applicator IFU are whole second settings. Having the additional digits available on the timer provides additional resolution to allow the user to see the time countdown to indicate temporal energy delivery progress. We will add a clarification to the DTS G2 User Manual that states that the timer displays to a resolution of 0.001 second, but that the accuracy of the timer display is ± 0.0205 second.

2) In Figure 4 of your response to deficiency #3, you show that the Normalized SAR does not effectly exceed 6 mm depth. However, this data is somewhat misleading as it does not indicate how much power is actually being delivered – or what the expected temperature distribution would look like. Please specify this figure in absolute SAR.
Please see the attached document for the SAR plot in absolute units for the maximum power setting of 0W. Note that the plot shows the "point" SAR and that volume averaging was not applied in this calculation.

3) In response to our Jan 22 Question Clause 6.8.2, Section bb, paragraph 2-4:section ff, kk, your reply mentions that all surfaces of the applicator that may contact the patient or user (i.e. cable bundle, plastic handle, dielectric antenna

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cradle, and patient contact surface) are non-conductive and well isolated rom any high frequency or low frequency voltage source or ground. You did not specifically mention whether this was also true of the connectors, where excessive leakage current have been known to occur. Please clarify.

All surfaces of the "DTS-LT Applicator-to-DTS G2 Instrumentation" connectors that may contact the atient or user are non-conductive and well isolated from any voltage source or ground.

4) Feb 24 Question c), we asked you to describe the control you have implemented to mitigate against potential hazardous events should a loss of target coolant temperature occur. You specify that "If a failure mode such as a significant loss of coolant or a loss of target coolant temperature within the Nanotherm chiller were to occur, the user would be able to see the rise in coolant temperature on the front panel." It is not clear whether there is an audible alarm in case the physician is not looking. Please clarify.

The integrated NanoTherm chiller does have warning notifications that combine the use of a flashing description on the upper line of the display and a fast audible beeping noise that indicate that an unsafe condition could or is about to occur. The NanoTherm chiller does have alarm notifications that combine the use of "alarm active" text on the upper line and an alarm description on the lower line of the display and a slow audible beeping noise that indicate that an unsafe condition is currently present and halts all current NanoTherm operations to protect the user. The alarm state must be corrected before the chiller can be restarted. The NanoTherm constantly monitors the internal temperature at the heat sink and coolant manifold. If the temperature of the heat sink or the coolant manifold is hotter or colder than a safe level, the alarm is activated.

These warnings and alarms are described in the NanoTherm User Manual (submitted as Attachment B of the original submission dated Sept 23, 2008). In addition, to facilitate user awareness, we will add the following text to the DTS G2 User Manual, section 7 Warnings and Precautions:

- During energy delivery, monitor the coolant temperature on the front panel of the DTS G2 System and/or the NanoTherm Chiller display to ensure that the temperature remains within the acceptable range for the required clinical effect.

ɔng
Long Chen, Ph.D.
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GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Kathy OShaughnessy [mailto:KathyO@miramarlabs.com]
Sent: Monday, March 02, 2009 2:20 PM
To: Chen, Long H
Subject: response for K082819 sent in

Long;
I wanted to let you know that our response to all questions on K082819 was sent in on Friday; I received word this morning that it was delivered to the Document Mail Center today.

I'm not sure how long it takes to get to you. I'm attaching the electronic copy of the submission for your reference (one of the two copies was sent in as an electronic copy). I have placed bookmarks in the file to help in navigating to the different sections.

Please let me know if you have any further questions.

Regards, Kathy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
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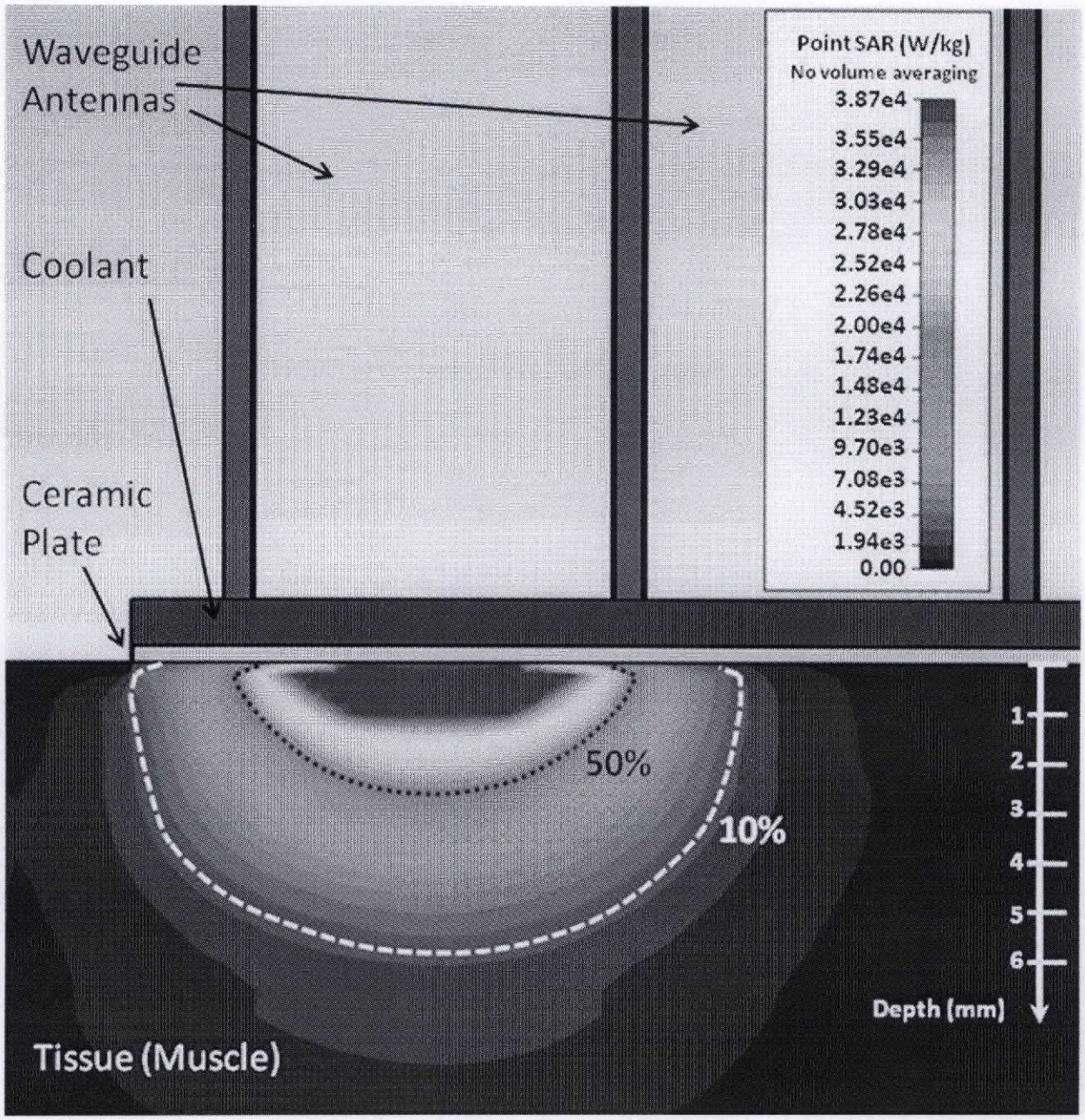

Figure 1. Point SAR profile for a 100W generator set power (assumes a muscle tissue density of 1270 kg/m^3).

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

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Chen, Long H

From: Chen, Long H
Sent: Tuesday, February 24, 2009 2:22 PM
To: 'Kathy OShaughnessy'
Subject: RE: K082819 - draft response to questions from Dec 2

Kathy,

Here are comments for your consideration:
1) ok
2) ok
3) please address the questions in my e-mail dated Jan 22, 2009. Please also clarify whether you have taken into consideration the coolant effect in developing your SAR distribution diagram in Figure 4.

In addition,
a) please describe the effect of coolant temperature on the lesion size.
b) please describe the mechanism to maintain the coolant temperature at the proposed 10 C
c) please describe the control you have implemented to mitigate the potential hazardous events such as temperature deviation from the target coolant temperature, loss of coolant, etc...

Thanks.

Long
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long.chen@fda.hhs.gov

From: Kathy OShaughnessy [mailto:KathyO@miramarlabs.com]
Sent: Thursday, February 19, 2009 6:25 PM
To: Chen, Long H
Subject: K082819 - draft response to questions from Dec 2

Long;
Please find attached our draft response to your questions of December 2, 2008. The meeting last week between our consultant, Dr. Mirotznik and Dr. Chang was very helpful to us to clarify where any misunderstandings have occurred with the language we used to discuss the IEC 60601-2-2 standard. We have changed the language in our draft response accordingly. In addition, we have revised several of the clause discussions to more accurately describe our device.

In the process of this review, we did revise our analysis of one clause, 56.102, which relates to cable testing. The exact test specified for 56.102 was not done, however other testing was done. Therefore we are no longer stating that all applicable clauses have been shown to pass. However, we do not feel that this affects the safety of the DTS G2 System. Also, we decided to clarify the warnings in the User Manual to more explicitly meet the requirement of clause 6.8.2 (gg) and so a revised User Manual will be submitted with the formal response (not included here).

I'm attaching:
- Our draft response to all 3 questions that were asked on December 2. I did not track changes relative to our prior informal draft responses because there have been substantial changes. I am not including all attachments – those will come in the formal response (e.g. the revised Form FDA 3514, the Submission Cover Sheet).
- A revised clause-by-clause analysis of the 60601-2-2 standard that would be attached to our formal response (clean copy).
- A redlined copy of the clause-by-clause analysis compared to the draft we submitted to you on 05Jan09 to aid in this informal review.

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Please note that I did not explicitly address the six questions that were sent to us on Jan 22, 2009. I can certainly do that, but we feel that the revised discussion in the main body of the response (in particular the clarifying figures) and the changes in the table itself address the issues that were raised. If you would prefer I list those questions and address them please let me know and I can do that quickly.

As you know our extension to submit our formal response was extended to March 2. I would hope to hear back from you at least a few days before then, if possible, so that I can get our response submitted.

As always, please let me know if you have questions or need anything.

Regards, Kathy

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Chen, Long H

From: Chen, Long H
Sent: Thursday, January 22, 2009 8:34 AM
To: 'Kathy OShaughnessy'
Subject: RE: K082819 - draft response re 60601-2-2 standard

Kathy,

Here are our comments for your consideration:

1) Clause 6.8.2. section aa: You need to specify output voltage. We do not accept your assertion that there is no output voltage for the device. While we are willing to accept that energy transfer is not in the traditional monopolar or bipolar modes, an output voltage certainly exists to drive current through their antenna – this should be stated so that it is clear what the voltage potential is in case of accidental grounding.
2) Clause 6.8.2. section bb, paragraph 2-4; section ff, kk. You indicated that your device is incapable of causing burns since the device does not have a neutral ground electrode and does not have a patient path to ground. We do not agree as we believe that it is possible for accidental grounding to occur. (For example, if the isolation transformer is not used for any reason; or if equipment comes into contact with other pathway to ground.) Should the patient become accidentally grounded there is potential risk of significant leakage current – which may cause injury. We request that (1) please provide an analysis of how you mitigate against this hazard; (2) please describe what injury would occur should this hazard occur. (Patient auxillary leakage current)
3) Clause 19.2 – You specified that single fault testing is not necessary as no failure of circuits in the device can cause elevated leakage current since there is no conductive patient connection. However, we believe that single fault testing is still applicable since accidental grounding may cause elevated leakage current.
4) Clause 20.3 – We believe that dielectric withstand testing is applicable regardless of mode of operation. This test is inter-related to our comments for Clauses 6.8.2 and 19.2 since dielectric failure will elevate patient leakage currents.
5) Clause 46.104, section a. It is not clear from the diagrams of the disposable head whether the connectors to the generator are unique enough as to avoid confusion when connecting to the generator.
6) Clause 51.5 – In your response to this clause, you indicate that the maximum output power of your device is 100 W. If the detected power is over 13 W away from the front panel set power, an error LED illuminates and the energy cycle is terminated. Please provide justification for the selection of 13 W as the maximum allowable deviation from set power.

Let me know if you have more questions. Thanks.

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Kathy OShaughnessy [mailto:KathyO@miramarlabs.com]
Sent: Monday, January 05, 2009 8:57 PM
To: Chen, Long H
Cc: Steven Kim
Subject: K082819 - draft response re 60601-2-2 standard

Dear Long;
Happy New Year! I hope you were able to enjoy some time off. As we were closed for several days in December, we were not able to complete our response to your questions sent on December 2. On Dec 31, I sent a letter to the Document Mail Center formally requesting an extension to respond to your additional information request. I received the acknowledgement today.

Now an update. After our call on December 16, we have been working to understand the applicability of the IEC60601-2-2 (2006) standard to our device. We have worked with Mr. Schmidt who also talked with Mr. Eggleston of the IEC/Subcommittee 62D/MT 17 who was mentioned during our call. We still feel that the scope

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of the standard does not apply as explained below.

However, as you and Dr. Chang suggested, we did conduct a clause by clause analysis of the standard to see which clauses might apply to our device. The result is attached. As expected there are many clauses (e.g. the ones with active electrodes or monopolar/bipolar testing) that do not apply (n=76). For the clauses that could apply to our device (e.g. 44.6.aa regarding footswitch design) (n=17) we have determined that we comply with those requirements. Given that the majority of the clauses do not apply to our device, we do not feel that it would be possible to claim compliance with this standard. However, we feel that we have done a thorough job in addressing your concerns.

Therefore we propose to respond to question #3 in the manner stated below. Please let us know if this is a satisfactory response to your request.

As always, please contact me if you have any questions.

Regards, Kathy

3) Performance Testing- Electrical Safety
In your response to deficiency #6, you indicated that your DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, you stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. Furthermore, the generator cannot be evaluated for applicability to IEC 60601-2-2 by itself. The entire system, including DTS LT-Applicator, has to be evaluated as a whole. Please provide test results to demonstrate that your DTS G2 System complies with applicable clauses of the IEC 6061-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, 2006.

As explained in our prior response, we still believe that the scope of the standard does not apply to our device, but have completed the clause-by-clause analysis that was requested during our call on December16, 2008. We reiterate our concern with the interpretation of the scope of the standard that is being applied.

A key point regarding the applicability of the standard is your assertion that the scope of IEC 60601-2-2 and definition of "HIGH FREQUENCY SURGICAL EQUIPMENT" includes any device incorporating frequencies above 20 kHz. We do not agree with this view for the following reason. While HIGH FREQUENCY is defined as "frequencies above 20 kHz", the germane definition is the one for HF SURGICAL EQUIPMENT - *not* the definition of HIGH FREQUENCY alone. The definition of HF SURGICAL EQUIPMENT is as follows:

"MEDICAL ELECTRICAL EQUIPMENT including its associated ACCESSORIES intended for the performance of surgical operations, such as the CUTTING or COAGULATION of biological tissue by means of HIGH FREQUENCY (HF) currents."

This definition clearly indicates the scope of the standard is limited to devices that utilize HF current in order to perform surgical operations (such as cutting and coagulating) by means of those currents. As we discussed, any current associated with our device is ancillary to its intended use/purpose. We conferred with other experts and confirmed that the current generated by our device would be insignificant in terms of generating physiological affects and, in fact, occurs only at the very surface of the tissue and is always below the 10 mA threshold set in the Rationale of 60601-2-2.

However, we do want to provide information that you have requested. In our call of December 16, 2008 we confirmed that you were looking to see a clause-by-clause analysis of the IEC 60601-2-2 standard and its applicability to our device, with the expectation that some clauses

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wouldn't apply.

See Attachment X for the result. The table shows each clause listed in the standard, a brief summary of the requirement for that clause and the last column shows either "N/A" (and a justification) or "Pass" (with the appropriate data or information). The DTS G2 System passes all applicable clauses from this standard. Please note that test data provided was measured internally.

Finally, to your last point regarding evaluating the system as a whole when considering the applicability of a standard or testing to a standard, we confirm that all standards review and testing has been done with the full system (generator and applicator) in consideration. Perhaps our wording in our prior response was not clear.

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park, CA 94025
(phone) 650-326-2656 x152
(fax) 650-326-3108
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Engineering Consult - IEC 60601-2-2 (3/19/09)

Chen, Long H

From: Chang, Isaac A.
Sent: Thursday, March 19, 2009 10:04 PM
To: Chen, Long H
Subject: K082819 - Chang Review

Attachments: K082819.doc

Hi Long,

Here you go. Please give me a call if you have questions.

Isaac

K082819.doc
(30 KB)

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

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To: Long Chen, Ph.D.
From: Isaac Chang, Ph.D
Date: March 18, 2009

RE: K082819 – Miramar Labs – Microwave Tissue Coagulation System

I have reviewed the responses to our deficiency letter dated Dec 2, 2008. The device is a microwave ablation device that consists of 4 components: a microwave generator, a disposable ablation head that uses a vacuum chamber to insure good contact with skin and other general soft tissue, a chiller/recirculator unit that is incorporated as part of the deivice, and an isolation transformer which isolates the entire ablation unit from ground. The device operates at 5.8 GHz and has been clarified to most closely resemble a radiated waveguide.

Question 1: Name of the Device
We asked: You have changed the device name from "Dermatologic Treatment System (DTS) G2" to "DTS G2" in this supplement. Please submit a letter to inform FDA such change together with your revised CDRH Premarket Review Submission Cover Sheet.

They specified: the sponsor removed language from the Indications for use statement regarding "dermatologic treatment". The name of the device has been changed to DTS G2 System.

Recommendations: I am unsure whether this minor change really resolves the issue. DTS G2 still looks a lot like (DTS) G2. The change in the device to Microwave Tissue Coagulation represents a broader claim of use for the device that is technically inclusive for "dermatologic treatment". I don't have any recommendations – judgment call by lead reviewer.

Question 2: Maximum Time Setting – Implementation and Verification.
We asked: In your response to deficiency #4, you stated that you have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in your original submission. However, how the maximum time setting of 9.999 seconds was implemented to mitigate the potential risk of taking a time setting input that is higher than the maximum time setting has not been described. Please describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly.

They specified: The company made changes by using different dip switch settings in the timer module to change the decimal point location.

\Recommendations: Apart from the logistics and testing necessary to demonstrate that the display can be changed to limit the length of the procedure to 9.999 seconds, I have an issue with the claim that a company can (a) monitor; (b) respond; and (c) limit energy delivery down to a 0.001 second precision. There is no evidence that the company has measured or performed testing to warrant display of this level of temporal accuracy.

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

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Since there does not appear to be a good rationale for what the additional decimal places add in clinical use, I strongly recommend that the sponsor remove the extra digits. **In response to deficiency #4, you have changed the position of the decimal place to limit the maximum time to 9.999 seconds instead of 99.99 seconds. However, we believe that this new display implies that the temporal accuracy of monitoring and energy delivery is 0.001 seconds. Since you have not provided testing that demonstrates that your device is capable of that level of precision, we strongly recommend that you modify your display to a reasonable number of decimal places.**

Question 3: Performance testing – Electrical Safety

We asked: In your response to deficiency #6, you indicated that your DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, you stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic deifintion of high frequency device, as it applies to IEC 60601-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC60601-2-2 standard is an applicable standard to the subject microwave coagulation system. Furthermore, the generator cannot be evaluated for applicability to IEC60601-2-2 by itself. The entire system including DTS LT-Applicator, has to be evaluated as a whole. Please provide test results to demonstrate that your DTS G2 System complies with applicable clauses of the IEC60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, 2006.

They Specified: The company recognized that they did not provide an adequate description of their device. They consulted with Dr. Mark Mirotznik at the Catholic University of America, an experot on the interaction microwaves with tissues. The response to this question provided additional information in 4 areas:

a) More detailed explanation of the DTS G2 Applicator and a general explanation of concepts that have arisen during our discussion of how the IEC60601-2-2 standard applies to the DTS G2 System.
b) Clause-by-clause analysis that was requested during the December 16,2008 call with the expectation that some of the clauses wouldn't apply. The DTS G2 System complies with all but one of the applicable requirements, which the company does not believe this affects the safety of the device.
c) Additional questions submitted via email on Jan 22, 2009.
d) Additional questions submitted via email to Miramar Labs on February 24, 2009.

Recommendations:

- In Figure 4, the sponsor shows that the Normalized SAR does not effectly exceed 6 mm depth. However, this data is somewhat misleading as it does not indicate how much power is actually being delivered – or what the expected temperature distribution would look like. The sponsor should specify this figure in absolute SAR.

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

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- In response to our Jan 22 Question Clause 6.8.2, Section bb, paragraph 2-4:section ff, kk, the sponsor replies mentions that all surfaces of the applicator that may contact the patient or user (i.e. cable bundle, plastic handle, dielectric antenna cradle, and patient contact surface) are non-conductive and well isolated rom any high frequency or low frequency voltage source or ground. The sponsor did not specifically mention whether this was also true of the connectors, where excessive leakage current have been known to occur.

- Feb 24 Question c), we asked the sponsor to describe the control they have implemented to mitigate against potential hazardous events should a loss of target coolant temperature occur. The sponsor specifis that "If a failure mode such as a significant loss of coolant or a loss of target coolant temperature within the Nanotherm chiller were to occur, the user would be able to see the rise in coolant temperature on the front panel. It is not clear whether there is an audible alarm in case the physician is not looking.

If I can be of further assistance, please feel free to contact me.

Isaac Chang, Ph.D.
Deputy Director
Division of Physics
Office of Science and Engineering Laboratories

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Chen, Long H

From: Kathy OShaughnessy [KathyO@miramarlabs.com]
Sent: Friday, January 30, 2009 11:27 AM
To: Chen, Long H
Cc: mirotznik@cua.edu; Chang, Isaac A.
Subject: authorization for consultant - K082819

Long;
I am writing this email to authorize that FDA staff can discuss our 510(k) submission K082819 with Mark Mirotznik, Associate Professor at The Catholic University of America.

Dr. Mirotznik has worked with our engineers on prior projects and we would like to use his expertise to address some of the questions that have arisen in our review.

Thanks, Kathy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
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Engineering Concept TEC 6 0001-2-2 (1/16/09)

Chen, Long H

From: Chang, Isaac A.
Sent: Friday, January 16, 2009 7:43 PM
To: Chen, Long H
Subject: FW: K082819.doc

Attachments: K082819.doc

K082819.doc
(35 KB)

Hi Long,

Here is my review. Can you modify the date and long me out? Thanks!

Isaac

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

To: Long Chen, Ph.D.
From: Isaac Chang, Ph.D.
Date: January 16, 2009

RE: K082819 – MiramarLab - Dermatologic treatment System (DTS) G2

Per your instruction, I have reviewed the 510(k) focusing on questions related to the device description and the applicability of IEC60601-2-2. The device is the Dermatologic Treatment System (DTS) G2 which is a microwave ablation device that has 4 components: a microwave generator, a disposable ablation head that uses a vacuum chamber to insure good contact with skin and other general soft tissue, a chiller/recirculator unit that is incorporated as part of the device, and an isolation transformer which isolates the entire ablation unit from ground.

With regards to the device description, I have several concerns. On Page 11 of 22 in the device description, the sponsor compares their device to two predicate devices: K072870 – MTCS device used for coagulation of soft tissue; and the K013639 device which is indicated for "Dermatologic and general surgical procedures for electrocoagulation and hemostasis." The MTCS device is a microwave ablation device that operates at 2.4 GHz with an output power of 60 Watts The K013639 device is a radiofrequency ablation device which operates at 6.0 MHz with an output power of 250 Watts and is used for comparison because it has the same indications as the study device. These two devices are not appropriate predicate devices to the study device. Table 1 shows a comparison of the penetration depth of a variety of tissues at the various frequencies.

Table 1: Penetration Depth of Electromagnetic Energy as a Function of Frequency

Tissue Type	**6 MHz**	**2.4 GHz**	**5.8 GHz**
Blood	22 cm	1.6 cm	6.0 mm
Muscle	29 cm	2.3 cm	7.5 mm
Skin (Dry)	97 cm	2.3 cm	8.6 mm
Skin (Wet)	42 cm	2.2 cm	7.7 mm

Clearly the depth of penetration at 6.0 MHz is at least an 2 orders of magnitude larger than at 5.8 GHz. This is likely to result in substantial differences in lesion dimensions generated by the two devices. At 2.4 GHz, there is also a 3 fold difference in the depth of penetration. Thus, for the same power, we anticipate that comparable levels of tissue injury would result if the power is reduced by nearly a factor of 3 at 5.8 GHz. The sponsor, has specified an output power of 100 W for their device, *which is a 40% increase* from what was previously in the predicate device. I am concerned that increasing the allowable power by 40% when the energy is confined to roughly 1/3 the distance may result in excessive tissue injury should the cooling system fail. I have not seen any testing to demonstrate that the device shuts off in such an event. It is also unclear whether the thermocouple that is on the head will adequately monitor the temperature should thermal necrosis occurs, since no information has been presented to its location relative to the antennas.

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

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With regards to the performance testing in animal tissues, the sponsor presents data on Page 18 of 22 (Table 3) that specifies lesion sizes created in In-Vivo porcine skin. The data listed in the table does not give any indication of the amount of variation in lesion size. As a number of factors may influence the dimensions of lesions, the sponsor should provide mean and standard deviation data to substantiate the robustness of these numbers.

With regards to the IEC60601-2-2 requirements, we support the applicability of the standard for microwave ablation devices and recognize that there are limitations to the various subclauses. We do not agree with the assertion that the standard is not applicable to microwave devices since it is nearly impossible to distinguish between "conductive" and "radiative" energy modes. Theoretically, both exist for any specific situation and the properties of the antenna, as well as the surrounding geometry, often determine which of these two modes dominates for a specific situation. The sponsor has provided a clause-by-clause analysis of IEC60601-2-2 as requested. Below are my comments:

- Clause 6.8.2. section aa: The sponsor needs to specify output voltage. We do not accept the sponsor's assertion that there is no output voltage for the device. While we are willing to accept that energy transfer is not in the traditional monopolar or bipolar modes, an output voltage certainly exists to drive current through their antenna – this should be stated so that it is clear what the voltage potential is in case of accidental grounding.

- Clause 6.8.2. section bb, paragraph 2-4; section ff, kk. The sponsor has indicated that their device is incapable of causing burns since the device does not have a neutral ground electrode and does not have a patient path to ground. We do not agree as we believe that it is possible for accidental grounding to occur. (For example, if the isolation transformer is not used for any reason; or if equipment comes into contact with other pathway to ground.) Should the patient become accidentally grounded there is potential risk of significant leakage current – which may cause injury. We request that the sponsor (1) provide an analysis of how they mitigate against this hazard; (2) describe what injury would occur should this hazard occur. (Patient auxillary leakage current)

- Clause 19.2 – The sponsor has specified that single fault testing is not necessary as no failure of circuits in the device can cause elevated leakage current since there is no conductive patient connection. However, we believe that single fault testing is still applicable since accidental grounding may cause elevated leakage current.

- Clause 20.3 – We believe that dielectric withstand testing is applicable regardless of mode of operation. This test is inter-related to our comments for Clauses 6.8.2 and 19.2 since dielectric failure will elevate patient leakage currents.

- Clause 46.104, section a. It is not clear from the diagrams of the disposable head whether the connectors to the generator are unique enough as to avoid confusion when connecting to the generator.

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

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- Clause 51.5 – In your response to this clause, you indicate that the maximum output power of your device is 100 W. If the detected power is over 13 W away from the front panel set power, an error LED illuminates and the energy cycle is terminated. Please provide justification for the selection of 13 W as the maximum allowable deviation from set power.

Please feel free to contact me should further clarification be needed.

Isaac Chang, Ph.D.
Deputy Director
OSEL/DP

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K082819/S1

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold)

☐ Final Decision (SE, SE with ~~Limitations~~, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Rev. 7/2/07

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

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Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	

Regulation Number	**Class***	**Product Code**
21 CFR 878.4400	II	NEY

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Review:_____
(Branch Chief) (Branch Code) (Date)

Final Review:_____
(Division Director) (Date)

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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)] Review
Traditional

K082819/S1

Date: December 2, 2008
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: Miramar Labs, Inc., Menlo Park, CA
Device Name: **DTS G2**
Contact: Ms. Kathy O'Shaughessy, VP Clinical and Regulatory Affairs
Phone: (650)-326-2656
Fax: (650)-326-3108
Email: kathyo@miramarlabs.com

I. Purpose

The 510(k) holder would like to introduce the subject DTS G2 into interstate commerce.

The sponsor has modified the indications for use to be used for coagulation of soft tissue. Thus, the sponsor also changed the device name from Dermatologic Treatment System (DTS) G2 to DTS G2 to remove the dermatologic language. The DTS G2 is a microwave based device to interact using a surface contact applicator. It is designed for use for coagulation of soft tissue.

The DTS microwave generator operates at a frequency of 5800 MHz with a maximum power of 100 W and a limit of maximum time of 9.999 seconds using a surface contact applicator. The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The microwave energy is delivered through 4 microwave antennas embedded in the Applicator housing. There are 4 temperature sensors placed on the inside of the vacuum chamber to monitor the tissue surface temperature under each of the antennas. The cooling feature is provided using the chiller pump that circulates the sterile saline through the LT-DTS applicator.

In the original submission, the sponsor presented test data on in-vivo skin and ex-vivo liver, muscle, and kidney. However, the data was insufficient to support the substantial equivalence. Hence, it was put on hold on October 17, 2008 for deficiencies in substantial equivalence, DTS G2 system description, performance testing data, applicator temperature test, lesion size guidance, performance testing - electrical safety, control & display, and labeling.

The sponsor's supplemental response to this AI (K082819/S1) was received on November 18, 2008. However, the response is not complete. The sponsor needs to describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly. In addition, the subject device will need to comply with the applicable clauses of the IEC 6061-2-2:2006 standard. As a result, new deficiencies are identified in section XIII and need to be clarified.

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

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II. Administrative Requirements

	Yes	No	N/A
Revised Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary	x		
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x	x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x	x	

The DTS G2 System consists of a DTS G2 microwave generator (non-sterile), a DTS LT applicator with disposable head (sterile, single use), a NanoTerm chiller and recirculation (non-sterile) and an Isolation Transformer (non-sterile). The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has the surface cooling feature. There are four temperature sensors placed on the inside surface of the suction chamber to monitor the tissue surface temperature. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the NanoTherm with chiller pump that circulates the sterile saline through the DTS G2 applicator.

III. Revised Indications for Use

The sponsor has revised the indications for use statement in this supplement.
The DTS G2 System is indicated for coagulation of soft tissue. This revised indication statement is the same as that of the predicate, Foundry Newco X Microwave Tissue Coagulation System (MTCS) (K072870).

IV. Predicate Device Comparison

The sponsor proposed Foundry Newco X Microwave Tissue Coagulation System (MTCS) (K072870) as the predicate device.

The sponsor has included in the revised substantial equivalence comparison table the following technological characteristics comparison: indications for use, manual setting or automatic, energy, maximum power, coagulation time, maximum coagulation cycle, frequency, vacuum source, maximum supplied vacuum, monitored parameters, displayed parameters, shutoff alarms, operation mode, output temperature, software, supplied sterile, antenna/applicator design, antenna/applicator size, expiration date for handpiece, maximum applicator surface temperature, antenna/applicator use, cooling mechanism, coolant, and cooling design.

The subject DTS G2 system delivers 100W which is higher than the 60W of the predicate, MTCS. However, the maximum deliver time of 9.999 seconds is less than the 30 seconds of the MTCS. Therefore, the maximum possible energy delivered (power x time) is 1000 Jules for the DTS G2

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

compared to 1800 Joules for the MTCS. Therefore, this difference does not affect the safety of the subject DTS G2 System.

V. Labeling

The sponsor has revised the user manuals for the DTS G2 Generator and LT-DTS applicator (Attachments K and C, K082819/S1). The package labels for the DTS LT- Applicator and DTS LT Applicator-Disposable Head were also provided (Attachment D, K082819). Te revised labeling is acceptable.

VI. Sterilization/Shelf Life/Reuse

The disposable head of the DTS LT applicator will be supplied sterile. They will be sterilized by EtO. According to the sponsor, the sterilization process will be validated to a SAL of 10^{-6} in accordance with ANSI/AAMI/ISO 11135-1. The sponsor also stated that acceptable EtO residuals levels will be in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose). The DTS LT applicator is not labeled "pyrogen free".

The disposable head of the DTS LT applicator will be packaged in an industry standard heat sealed Tyvek and polyester sterile barrier pouch. The shelf life will be 6 month.

	YES	NO
1. Sterilant: a. **Sterilization method** description (e.g., Steam, EtO, Radiation): b. **Dose**, for radiation (e.g., 25 – 50 kGy): c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	EtO in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose).	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ANSI/AAMI/ISO 11135-1	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"? If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		x
5. A description of the packaging (not including package integrity test data):	industry standard heat sealed Tyvek and polyester sterile barrier pouch.	

VII. Biocompatibility

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The sponsor has identified the patient contact materials and the predicates as follows: polycarbonate (K071488), polyethylene (K073616), and UV adhesive (K052738).

VIII. Software

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

According to the sponsor, all digital logic block in the microwave generator is embedded in two Complex Programmable Logic Devices (CPLDs). The logic is hardwired and there is no code that is executed inside the CPLD. The logic information for the control and display is provided (Attachment J, K082819/S1). The hazard Analysis for the subject DTS G2 system is also provided (Attachment L, K082819/S1).

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor stated the subject system is designed to comply with the electrical safety (IEC60601-1) and electromagnetic compatibility (IEC60601-1-2) standards. Test results are provided (Attachments H and I, K082819/S1).

The sponsor also indicated that their DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, the sponsor stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. The subject DTS G2 System will need to comply with applicable causes of the IEC 6061-2-2 standard. See new deficiency #3.

IX. Performance Testing – Bench

The sponsor stated that clinical simulation tests were performed to demonstrate the following:

- Vacuum was sufficient to pull tissue into applicator
- No vacuum leaks observed
- Cooling system operated per specification
- No coolant leaks observed

In addition, bench tests were also conducted to record the temperature profile of the LT-DTS Applicator

surface during simulation use for the maximum energy delivery duration (10 seconds) at the maximum power of 100 Watts, with and without cooling system (Attachment G, K082819/S1). The results showed that the maximum surface temperature was below 27.9 C under all tested configurations.

X. Performance Testing – Animal

The sponsor has provided comparative ex-vivo vivo porcine tissue data of three types of tissue: liver, muscle and kidney, by the subject DTS G2 system and the predicate, MTCS. The comparison of the sizes of lesions and the examples of gross pathology is provided in the response to question #3 (K082819/S1). The lesion sizes guideline for ex-vivo muscle tissue, liver tissue, and kidney tissue is also included in the revised LT-DTS Applicator Instruction for Use (Attachment C, K082819/S1). Overall, due to higher frequency (5.8 GHz vs. 2.45 GHz), the subject DTS G2 system creates smaller lesion sizes than those from the MTCS predicate.

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs 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 question(s) raised or why the question(s) 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:

XIII. Deficiencies

1) Substantial Equivalence
In the equivalence device comparison table (page 11), you include some of the technological characteristics such as: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, coolant, applicator design, and vacuum source. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

Response:
The sponsor has revised the substantial equivalence comparison table that compares the subject DTS G2 system with the microwave device predicate, MTCS(K072870). Although the subject DTS G2 system delivers 100W which is higher than the 60W of the MTCS. However, the maximum deliver time of 9.999 seconds is less than the 30 seconds of the MTCS. Therefore, the maximum possible energy delivered (power x time) is 1000 Jules for the DTS G2 compared to 1800 Joules for the MTCS.
This revised comparison table is adequate.

2) DTS G2 System Description
The information you provided for DTS G2 system is not adequate. Please provide the following additional information:

a. Detailed design information and test results for the NanoTherm System and/or FDA clearance number.
b. Design information and test results for the integrated vacuum pump.

Response:
The sponsor stated that the Nano Therm chiller/circulator has been cleared in K061866. The integrated vacuum pump, on the other hand, is supplied by Clark Solution, Model 15988. It was tested as part of the overall Generator verification testing. This response is acceptable.

3) Performance Testing Data
The data from your in-vivo porcine skin model and ex-vivo porcine tissue models is inadequate. You did not compare the histological results of the subject DTS G2 system to the ThermaCool TC System

(K013639) predicate device. Please provide comparative performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the ThermaCool TC System (K013639) predicate device.

Response:
The sponsor has modified the indications for use statement to remove the dermatologic indication. It is used only for coagulation of soft tissue, same as the predicate, MTCS (K072870). Therefore, the comparison of the sizes of lesions and the examples of gross pathology in this response is adequate. In general, due to higher frequency (5.8 GHz vs. 2.45 GHz), the subject DTS G2 system creates smaller lesion sizes than those from the MTCS predicate.

4) Applicator Temperature Test
You did not discuss the maximum surface temperatures of your Applicator LT during usage.

a. Please provide bench test results that record the temperature profiles of your DTS LT applicator and cable during simulation use for the maximum energy delivery duration (99.99 seconds) at the maximum power of 100 Watts, with and without cooling system, to demonstrate that your maximum applicator surface temperature and maximum cable surface temperature will be safe to the user and/or to the patient.
b. Please discuss your method for the mitigation of potential high applicator surface temperatures.

Response:
The sponsor stated that they have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in the original submission. A DTS LT Applicator-Device temperature measuring testing was conducted (Atachment G, K082819/S1) and the results were satisfactory. However, how the maximum time setting of 9.999 seconds was implemented was not described. See new deficiency #2.

5) Lesion Size Guideline
You have provided the lesion sizes created by the DTS LT applicator up to 14 seconds and up to 100 watts (Instructions for Use, DTS-LT Applicator). This data is inadequate considering your generator output is designed for a maximum duration of 99.99 seconds and at a maximum power output of 100 watts (DTS G2 Generator User Manual). Please provide the suggested lesion sizes for the whole operating range of the device and revise your DTS-LT Applicator Instructions for Use accordingly.

Response:
Based on the change made to limit the maximum time setting to 9.999 seconds, the sponsor has revised the proposed DTS-LT Applicator Instructions for Use to include the lesion sizes guideline for ex-vivo muscle tissue, liver tissue, and kidney tissue. (Attachment C, K082819/S1). This revised information is adequate.

6) Performance Testing- Electrical Safety
Please provide complete test results to demonstrate that your device including the DTS G2 generator, LT applicator, NanoTherm and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

Response:
The sponsor has conducted the IEC 60601-1:1995 and IEC 60601-1-2:2004 electrical testing. Test results are provided (Attachments H and I, K082819/S1).

The sponsor also indicated that their DTS G2 system utilizes microwave energy which does not send any

electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, the sponsor stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. The subject DTS G2 System will need to comply with applicable clauses of the IEC 6061-2-2 standard. See new deficiency #3.

7) Control & Display
You have provided the microwave generator controller diagram in Attachment A. However, the mechanism that is utilized for the control and display of the parameters such as skin temperature, power control, energy timer, start/stop, etc.., as shown in the DTS G2 Generator User Manual (page 5-6, Attachment B) is still not clear.

a. Please describe in detail how these functions are accomplished. Specifically, how the 10 antenna select switches are used to select the 4 antenna in the applicator? how the energy timer setting is used to control the energy delivery time? is there any mechanism to prevent the applicator surface temperature running too high?)
b. Please provide the logic information of your microwave generator controller diagram. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html.
c. Please provide the Device Hazard Analysis for the mitigation of potential hazards.

Response:
According to the sponsor, all digital logic block in the microwave generator is embedded in two Complex Programmable Logic Devices (CPLDs). The logic is hardwired and there is no code that is executed inside the CPLD. The logic information for the control and display is provided (Attachment J, K082819/S1). The hazard Analysis for the subject DTS G2 system is also provided (Attachment L, K082819/S1).

8) Labeling - User Manual for the DTS G2 Generator
Please revise your User manual for the DTS G2 Generator to include the following information:

a. description of vacuum pump
b. a consistent indications for use statement
c. provide data to substantiate your list of potential adverse events
d. detailed technical specifications to include, for example, energy durations, vacuum range, etc...

Response:
The sponsor has revised the proposed User Manual for the DTS G2 Generator (Attachment K, K082819/S1) to include a brief description of the vacuum pump, a consistent indications for use statement, and a revised technical specifications table product brochure. The sponsor also removed the potential adverse events section. This revised User Manual for the DTS G2 Generator is acceptable.

9) Labeling - DTS-LT Applicator Instructions for Use
Please revise your DTS-LT Applicator Instructions for Use to include the following information:

a. description and pictorial illustration of the assembly and disassembly of disposable applicator head.
b. technical specifications of the applicator

Response:
The sponsor has revised the proposed DTS-LT Applicator Instructions for Use to include the description and pictorial illustration of the disposable applicator head. The technical specification was also added (Attachment C, K082819/S1). This revision is acceptable.

10) Labeling - User Manual for the NanoTherm
Please revise your User manual for the DTS G2 Generator to include the intended use and/or indications for use statement.

Response:
The sponsor indicated that the NanoTherm is supplied by Thermo Tek, Inc and was cleared in K061866. The sponsor has included in the revised DTS G2 Generator Manual a description to the user that the NanoTherm User Manual should be consulted to set the chiler/circulator configuration. This revision is acceptable.

New deficiencies:
Consequently, new deficiencies will need to be clarified by the sponsor. They are summarized as follows:

1) Name of the Device
You have changed the device name from "Dermatologic Treatment System (DTS) G2" to "DTS G2" in this supplement. Please submit a letter to inform FDA such change together with your revised CDRH Premarket Review Submission Cover Sheet.

2) Maximum Time Setting - Implementation and Verification
In your response to deficiency #4, you stated that you have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in your original submission. However, how the maximum time setting of 9.999 seconds was implemented to mitigate the potential risk of taking a time setting input that is higher than the maximum time setting has not been described. Please describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly.

3) Performance Testing- Electrical Safety
In your response to deficiency #6, you indicated that your DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, you stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. Furthermore, the generator cannot be evaluated for applicability to IEC 60601-2-2 by itself. The entire system, including DTS LT-Applicator, has to be evaluated as a whole. Please provide test results to demonstrate that your DTS G2 System complies with applicable clauses of the IEC 6061-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, 2006.

XIV. Contact History

A telephone conversation with the sponsor (Ms. Kathy O'Shaughessy) followed up by an e-mail on 10/17/2008 asking for additional information.
An e-mail was sent to the sponsor (Ms. Kathy O'Shaughessy on 12/2/2008 asking for additional information.

XV. Recommendation

I recommend that this submission be placed on hold again pending receipt of the response to the above questions.

Regulation Number: 21CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY

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Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Long Chen
Lead Reviewer, GSDB/DGRND

12/2/08
Date

Neil Ogden
Branch Chief, GSDB/DGRND

12/2/08
Date

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Chen, Long H

From: Chen, Long H
Sent: Tuesday, December 02, 2008 8:45 AM
To: 'kathyo@miramarlabs.com'
Subject: 510(k) Supplement - DTS G2 (K082819/S1)

Attachments: k082819.s1_email.1.doc

Kathy,

I have enclosed a copy of the additional information request for the subject 510 (k) supplement. Feel free to contact me for any further clarification. Thanks.

k082819.s1_
il.1.doc (61 K

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

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

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December 2, 2008

Ms. Kathy O'Shaughessy
VP, Clinical and Regulatory Affairs
Miramar Labs, Inc., Menlo Park, CA
Ph#: (650)-326-2656
Fax#: (650)-326-3108
e-mail: kathyo@miramarlabs.com

Re: 510(k) Supplement - DTS G2 (K082819/S1)

Dear Ms. O'Shaughessy,

In reviewing the subject supplement, we have the following additional questions that need to be clarified to facilitate our review process:

1) Name of the Device
You have changed the device name from "Dermatologic Treatment System (DTS) G2" to "DTS G2" in this supplement. Please submit a letter to inform FDA such change together with your revised CDRH Premarket Review Submission Cover Sheet.

2) Maximum Time Setting - Implementation and Verification
In your response to deficiency #4, you stated that you have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in your original submission. However, how the maximum time setting of 9.999 seconds was implemented to mitigate the potential risk of taking a time setting input that is higher than the maximum time setting has not been described. Please describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly.

3) Performance Testing- Electrical Safety
In your response to deficiency #6, you indicated that your DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, you stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 6061-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 6061-2-2 standard is an applicable standard to the subject microwave coagulation system. Furthermore, the generator cannot be evaluated for applicability to IEC 60601-2-2 by itself. The entire system, including DTS LT-Applicator, has to be evaluated as a whole. Please provide test results to demonstrate that your DTS G2 System complies with applicable clauses of the IEC 6061-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, 2006.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

The subject supplement will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at:
http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K082819

To: The Record

Please list CTS decision code AI

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)
- ☒ Hold (Additional Information or Telephone Hold)
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 -<21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Rev. 7/2/07

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Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number	Class*	Product Code
21 CFR 878.4400	II	NEY

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [signature] (Branch Chief) GSOB (Branch Code) 10/12/08 (Date)

Final Review: _____ (Division Director) _____ (Date)

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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)] Review
Traditional

K082819

Date: October 17, 2007
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: Miramar Labs, Inc., Menlo Park, CA
Device Name: **Dermatologic Treatment System (DTS) G2**
Contact: Ms. Kathy O'Shaughessy, VP Clinical and Regulatory Affairs
Phone: (650)-326-2656
Fax: (650)-326-3108
Email: kathyo@miramarlabs.com

I. Purpose

The 510(k) holder would like to introduce the subject Dermatologic Treatment System (DTS) G2 into interstate commerce.

The Dermatologic Treatment System (DTS) G2 is a microwave based device to interact using a surface contact applicator. It is designed for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis.

The DTS microwave generator operates at a frequency of 5800 MHz with a maximum power of 100 W using a surface contact applicator. The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The microwave energy is delivered through 4 microwave antennas embedded in the Applicator housing. There are 4 temperature sensors placed on the inside of the vacuum chamber to monitor the tissue surface temperature under each of the antennas. The cooling feature is provided using the chiller pump that circulates the sterile saline through the DTS applicator.

The sponsor performed tests on in-vivo skin and ex-vivo liver, muscle, and kidney. However, without confirming the similarity of the technology characteristics with the predicate(s) (5800 MHz vs. 6MHz), these data is insufficient to support the substantial equivalence for the dermatologic and general surgery use. Furthermore, the sponsor stated that DTS G2 does not contain any software. However, the sponsor did not clearly address the underlined technology used for the control and display functions and features described in the DTS G2 Generator User Manual (page 5-6, Attachment B).

As a result, new deficiencies are identified in section XIII and need to be clarified.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		

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	Yes	No	N/A
Truthful and Accuracy Statement	x		
510(k) Summary	x		
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x	x	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?	x	x	

The Dermatologic Treatment System (DTS) G2 consists of a DTS G2 microwave generator (non-sterile), a DTS LT applicator with disposable head (sterile, single use), a NanoTerm chiller and recirculation (non-sterile) and an Isolation Transformer (non-sterile). The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has the surface cooling feature. There are four temperature sensors placed on the inside surface of the suction chamber to monitor the tissue surface temperature. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the NanoTherm with chiller pump that circulates the sterile saline through the DTS G2 applicator.

III. Indications for Use

The Dermatologic Treatment System (DTS) G2 is indicated for use in dermatologic and general surgery procedures for electrocoagulation and hemostasis. This indication statement is same as that of the predicate, ThermaCool TC System (K013639). However, the fundamental technology between these two devices are different. ThermaCool TC System is based on RF technology while the subject DTS G2 is based on microwave technology. Comparative performance data will be needed to demonstrate the similarity of the clinical and pathological characteristics between your device and the ThermaCool TC System (K013639) predicate device. See deficiency #3.

IV. Predicate Device Comparison

The sponsor proposed following devices as the predicates: ThermaCool TC System (K013639) and Foundry Newco X Microwave Tissue Coagulation System (MTCS) (K072870).

Although the sponsor has included in the substantial equivalence comparison table the following technological characteristics: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, coolant, applicator design, and vacuum source. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum, and heating/cooling design, etc... See deficiency #1.

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Furthermore, the information provided for the electronic heating and cooling system (NanoTherm) is not adequate. The sponsor needs to provide the FDA clearance number or provide detailed design information and test results for the NanoTherm System. See deficiency #2.

V. Labeling

The sponsor has provided the user manuals for the DTS G2 Generator, DTS applicator, and NanoTherm Chiller/Circulator (Attachment B, K082819). In addition, the package labels for the DTS LT Applicator and DTS LT Applicator-Disposable Head were also provided (Attachment D, K082819). However, the sponsor needs to provide the following additional information:

- the User Manual for the DTS G2 Generator
  a. description of vacuum pump
  b. a consistent indications for use statement
  c. provide data to substantiate your list of potential adverse events
  d. detailed technical specifications to include, for example, energy durations, vacuum range, etc...

- DTS-LT Applicator Instructions for Use
  a. description and pictorial illustration of the assembly and disassembly of disposable applicator head.
  b. technical specifications of the applicator

- User Manual for the NanoTherm
  a. include the intended use and/or indications for use statement.

See deficiencies #8, 9, and 10.

VI. Sterilization/Shelf Life/Reuse

The disposable head of the DTS LT applicator will be supplied sterile. They will be sterilized by EtO. According to the sponsor, the sterilization process will be validated to a SAL of 10^{-6} in accordance with ANSI/AAMI/ISO 11135-1. The sponsor also stated that acceptable EtO residuals levels will be in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose). The DTS LT applicator is not labeled "pyrogen free".

The disposable head of the DTS LT applicator will be packaged in an industry standard heat sealed Tyvek and polyester sterile barrier pouch. The shelf life will be 6 month.

1. Sterilant:	**YES**	**NO**
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose).	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is	ANSI/AAMI/ISO 11135-1	

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recommended (e.g., ANSI/AAMI/ISO 11135))		
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		x
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	industry standard heat sealed Tyvek and polyester sterile barrier pouch.	

VII. Biocompatibility

The sponsor has identified the patient contact materials and the predicates as follows: polycarbonate (K071488), polyethylene (K073616), and UV adhesive (K052738).

VIII. Software

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

The sponsor stated that DTS G2 generator does not contain any software. Although the sponsor has provided a microwave generator controller diagram in Attachment A (K082819). However, the mechanism that is utilized for the control and display of the parameters such as skin temperature, power control, energy timer, start/stop, etc.., as shown in the DTS G2 Generator User Manual (page 5-6, Attachment B) is still not clear. See deficiency #7.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor stated the subject system is designed to comply with the electrical safety (IEC60601-1) and electromagnetic compatibility (IEC60601-1-2) standards. However, the sponsor did not provide test results for IEC 60601-1, and IEC 601-1-2. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

See deficiency #6.

IX. Performance Testing – Bench

The sponsor stated that clinical simulation tests were performed to demonstrate the following:

- Vacuum was sufficient to pull tissue into applicator
- No vacuum leaks observed
- Cooling system operated per specification
- No coolant leaks observed

However, the sponsor needs to provide bench test results that record the temperature profile of the DTS LT applicator surface during simulation use for the maximum energy delivery duration (99.99 seconds) at the maximum power of 100 Watts, with and without cooling system, to demonstrate that the maximum applicator surface temperature and maximum cable surface temperature will be safe to the user and/or to the patient. See deficiencies #4 and 5.

X. Performance Testing – Animal

The sponsor has provided in-vivo porcine skin data and ex-vivo vivo porcine tissue data of three types of tissue: liver, muscle and kidney, by the subject DTS G2 system. However, due to the great difference in the microwave frequency, the sponsor needs to provide comparative performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the predicate(s). See deficiency #3.

XI. Performance Testing – Clinical

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

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?		x	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs 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 question(s) raised or why the question(s) 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:

XIII. Deficiencies

1) Substantial Equivalence
In the equivalence device comparison table (page 11), you include some of the technological

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characteristics such as: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, coolant, applicator design, and vacuum source. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

2) DTS G2 System Description

The information you provided for DTS G2 system is not adequate. Please provide the following additional information:

a. Detailed design information and test results for the NanoTherm System and/or FDA clearance number.
b. Design information and test results for the integrated vacuum pump.

3) Performance Testing Data

The data from your in-vivo porcine skin model and ex-vivo porcine tissue models is inadequate. You did not compare the histological results of the subject DTS G2 system to the ThermaCool TC System (K013639) predicate device. Please provide comparative performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the ThermaCool TC System (K013639) predicate device.

4) Applicator Temperature Test

You did not discuss the maximum surface temperatures of your Applicator LT during usage.

a. Please provide bench test results that record the temperature profiles of your DTS LT applicator and cable during simulation use for the maximum energy delivery duration (99.99 seconds) at the maximum power of 100 Watts, with and without cooling system, to demonstrate that your maximum applicator surface temperature and maximum cable surface temperature will be safe to the user and/or to the patient.
b. Please discuss your method for the mitigation of potential high applicator surface temperatures.

5) Lesion Size Guideline

You have provided the lesion sizes created by the DTS LT applicator up to 14 seconds and up to 100 watts (Instructions for Use, DTS-LT Applicator). This data is inadequate considering your generator output is designed for a maximum duration of 99.99 seconds and at a maximum power output of 100 watts (DTS G2 Generator User Manual). Please provide the suggested lesion sizes for the whole operating range of the device and revise your DTS-LT Applicator Instructions for Use accordingly.

6) Performance Testing- Electrical Safety

Please provide complete test results to demonstrate that your device including the DTS G2 generator, LT applicator, NanoTherm and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)

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- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

7) Control & Display
You have provided the microwave generator controller diagram in Attachment A. However, the mechanism that is utilized for the control and display of the parameters such as skin temperature, power control, energy timer, start/stop, etc.., as shown in the DTS G2 Generator User Manual (page 5-6, Attachment B) is still not clear.

a. Please describe in detail how these functions are accomplished. Specifically, how the 10 antenna select switches are used to select the 4 antenna in the applicator? how the energy timer setting is used to control the energy delivery time? is there any mechanism to prevent the applicator surface temperature running too high?)
b. Please provide the logic information of your microwave generator controller diagram. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html.
c. Please provide the Device Hazard Analysis for the mitigation of potential hazards.

8) Labeling - User Manual for the DTS G2 Generator
Please revise your User manual for the DTS G2 Generator to include the following information:

b. description of vacuum pump
c. a consistent indications for use statement
d. provide data to substantiate your list of potential adverse events
e. detailed technical specifications to include, for example, energy durations, vacuum range, etc...

9) Labeling - DTS-LT Applicator Instructions for Use
Please revise your DTS-LT Applicator Instructions for Use to include the following information:

c. description and pictorial illustration of the assembly and disassembly of disposable applicator head.
d. technical specifications of the applicator

10) Labeling - User Manual for the NanoTherm
Please revise your User manual for the DTS G2 Generator to include the intended use and/or indications for use statement.

XIV. Contact History

A telephone conversation with the sponsor (Ms. Kathy O'Shaughessy) followed up by an e-mail on 10/17/2008 asking for additional information.

XV. Recommendation

I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Regulation Number: 21CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY

Long Chen
Lead Reviewer, GSDB/DGRND

10/17/08
Date

I concur with AI.

Neil Ogden
Branch Chief, GSDB/DGRND

10/17/08
Date

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

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Chen, Long H

From: Chen, Long H
Sent: Friday, October 17, 2008 1:24 PM
To: 'kathyo@miramarlabs.com'
Subject: 510(k) Submission - Dermatologic Treatment System (DTS) G2 (K082819)

Attachments: k082819_email.1.doc

Kathy,

I have enclosed a copy of the additional information request for the subject 510 (k) submission. Feel free to contact me for any further clarification.

k082819_em
l.1.doc (71 KE

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

307

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

October 17, 2007

Ms. Kathy O'Shaughessy
VP, Clinical and Regulatory Affairs
Miramar Labs, Inc., Menlo Park, CA
Ph#: (650)-326-2656
Fax#: (650)-326-3108
e-mail: kathyo@miramarlabs.com

Re: 510(k) Submission - Dermatologic Treatment System (DTS) G2 (K082819)

Dear Ms. O'Shaughessy,

In reviewing the subject submission, we have the following additional questions that need to be clarified to facilitate our review process:

1) Substantial Equivalence

In the equivalence device comparison table (page 11), you include some of the technological characteristics such as: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, coolant, applicator design, and vacuum source. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc…

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc…
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

2) DTS G2 System Description

The information you provided for DTS G2 system is not adequate. Please provide the following additional information:

a. Detailed design information and test results for the NanoTherm System and/or FDA clearance number.
b. Design information and test results for the integrated vacuum pump.

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

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3) Performance Testing Data

The data from your in-vivo porcine skin model and ex-vivo porcine tissue models is inadequate. You did not compare the histological results of the subject DTS G2 system to the ThermaCool TC System (K013639) predicate device. Please provide comparative performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the ThermaCool TC System (K013639) predicate device.

4) Applicator Temperature Test

You did not discuss the maximum surface temperatures of your Applicator LT during usage.

a. Please provide bench test results that record the temperature profiles of your DTS LT applicator and cable during simulation use for the maximum energy delivery duration (99.99 seconds) at the maximum power of 100 Watts, with and without cooling system, to demonstrate that your maximum applicator surface temperature and maximum cable surface temperature will be safe to the user and/or to the patient.
b. Please discuss your method for the mitigation of potential high applicator surface temperatures.

5) Lesion Size Guideline

You have provided the lesion sizes created by the DTS LT applicator up to 14 seconds and up to 100 watts (Instructions for Use, DTS-LT Applicator). This data is inadequate considering your generator output is designed for a maximum duration of 99.99 seconds and at a maximum power output of 100 watts (DTS G2 Generator User Manual). Please provide the suggested lesion sizes for the whole operating range of the device and revise your DTS-LT Applicator Instructions for Use accordingly.

6) Performance Testing- Electrical Safety

Please provide complete test results to demonstrate that your device including the DTS G2 generator, LT applicator, NanoTherm and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

7) Control & Display

You have provided the microwave generator controller diagram in Attachment A. However, the mechanism that is utilized for the control and display of the parameters such as skin temperature, power control, energy timer, start/stop, etc.., as shown in the DTS G2 Generator User Manual (page 5-6, Attachment B) is still not clear.

a. Please describe in detail how these functions are accomplished. Specifically, how

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

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the 10 antenna select switches are used to select the 4 antenna in the applicator? how the energy timer setting is used to control the energy delivery time? is there any mechanism to prevent the applicator surface temperature running too high?)

b. Please provide the logic information of your microwave generator controller diagram. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html.
c. Please provide the Device Hazard Analysis for the mitigation of potential hazards.

8) Labeling - User Manual for the DTS G2 Generator
Please revise your User manual for the DTS G2 Generator to include the following information:

a. description of vacuum pump
b. a consistent indications for use statement
c. provide data to substantiate your list of potential adverse events
d. detailed technical specifications to include, for example, energy durations, vacuum range, etc…

9) Labeling - DTS-LT Applicator Instructions for Use
Please revise your DTS-LT Applicator Instructions for Use to include the following information:

a. description and pictorial illustration of the assembly and disassembly of disposable applicator head.
b. technical specifications of the applicator

10) Labeling - User Manual for the NanoTherm
Please revise your User manual for the DTS G2 Generator to include the intended use and/or indications for use statement.

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at:
http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE

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

THIS MESSAGE IS INTENDED 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
9200 Corporate Boulevard
Rockville, Maryland 20850

November 18, 2008

MIRAMAR LABS, INC.
199 JEFFERSON DR.
MENLO PARK, CALIFORNIA 94025
UNITED STATES
ATTN: KATHY O'SHAUGHNESSY

510k Number: K082819

Product: DERMATOLOGIC TREATMENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

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

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K082819/S1

FDA CDRH DMC

NOV 18 2008

Received

K-18

November 17, 2008

Long Chen, PhD
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) Submission - DTS G2 System (**K082819**)

Dear Dr. Chen,

Please see the following for our responses to the additional questions regarding the submission for the subject device.

Before responding to the questions, we would like to note that in accordance with our email and telephone conversations, we have modified the Indications for Use for the DTS G2 System to remove the dermatologic language. The revised Indications for Use statement can be found in Attachment A. (The accompanying labeling has also been revised in this regard and is provided.) In addition, the revision of the Indications for Use has meant that we no longer require the Thermage ThermaCool TC system (K013639) as a predicate device. A revised 510(k) Summary including both these changes is included as Attachment B. The changes to the substantial equivalence table and description are included as the response to question 1 below.

If you have any further questions, feel free to contact me.

Regards,

Kathy O'Shaughnessy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs

Email: kathyo@miramarlabs.com
Phone: 650-326-2656 x152

miramarlabs
199 Jefferson Drive
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

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

FDA's questions are in italics, with Miramar's response in normal font.

1) Substantial Equivalence

In the equivalence device comparison table (page 11), you include some of the technological characteristics such as: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, coolant, applicator design, and vacuum source. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...

a. *Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, operation mode, coagulation time, system output power, output temperature, maximum applicator surface temperature, maximum coagulation cycle, maximum vacuum and heating/cooling design, etc...*

Please see the revised Substantial Equivalence table below, including the removal of the ThermaCool TC predicate. We have added additional information based on your request. Changes are not tracked because of the amount of information that was added.

Feature	MTCS (cleared)	DTS G2 (subject of this submission)	SE?
General Information			
510(k) Number	K072870	K082819	NA
Product Code	NEY	NEY	Yes
CFR Reference	21CFR§878.4400	21CFR§878.4400	Yes
Manufacturer	Foundry Newco X, Inc.	Miramar Labs, Inc. (formerly Foundry Newco X)	NA
Indications for Use	The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.	The DTS G2 System is indicated for use for coagulation of soft tissue.	Yes – same
Electrical Safety and EMC	Compliance to IEC 60601-1 and 60601-1-2	Compliance to IEC 60601-1 and 60601-1-2	Yes – same
Generator/System			
Manual or automatic	Manual setting	Manual setting	Yes – same
Energy	Microwave	Microwave	Yes – same
System output Power - maximum	60 Watts in 5 Watt increments	100 Watts in 5 Watt increments	Yes – similar*
Coagulation Time	1-30 seconds set by user in 1 second increments	0.001 to 9.999 seconds set by user in 0.001 second increments	Yes – similar*
Maximum coagulation cycle	60 W for 30 sec (1800 Joules)	100 W for 9.999** sec (1000 Joules)	Yes – similar*

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Feature	MTCS (cleared)	DTS G2 (subject of this submission)	SE?
Frequency	2.45 GHz	5.8 GHz	Yes – similar*
Vacuum Source	Medela Basic 30 Vacuum Pump	Off-the-shelf component built into the Generator	Yes – same
Maximum supplied vacuum	-27.5 inches Hg	-28 inches Hg	Yes – same
Monitored parameters	Target tissue surface temperature; vacuum	Target tissue surface temperature; coolant temperature; vacuum	Yes – similar*
Displayed parameters	Target tissue surface temperature (°C) Set power (Watt) Set time (sec)	Target tissue surface temperature (°C) Coolant temperature (°C) Set power (Watt) Set pre-cool time (sec) Set Energy time (sec) Set post-cool time (sec)	Yes – similar*
Shutoff/alarms	Shut-offs: - Broken applicator - Microwave connector not securely connected - Thermocouple connector not securely connected - Faulty fuse - Internal generator overtemp condition	Shut-offs: - Broken applicator - Microwave connector not securely connected - Thermocouple connector not securely connected - Faulty fuse - Internal generator overtemp condition	Yes - same
Operation Mode	Single mode: Manually set power and time	Single mode: Manually set power and time	Yes – same
Output temperature	Temperature monitored on tissue contact surface	Temperature monitored on tissue contact surface	Yes – same
Software	None	None	Yes – same
Patient Contact			
Patient Contacting Part Supplied Sterile	Disposable hand piece is ETO sterilized	Disposable hand piece cover is ETO sterilized	Yes – same
Antenna /Applicator Design	Dual antenna with vacuum and surface cooling feature	Up to four antennas with vacuum and surface cooling feature	Yes – similar*
Applicator size (footprint of applicator head)	Approximately 6cm x 3cm	Approximately 7cm x 5cm	Yes – similar*
Expiration Dating for handpiece	6 months	6 months	Yes – same
Max Applicator Surface Temperature [non-active areas]	< 30 °C	< 30 °C	Yes – same
Antenna/Applicator use	Soft tissue coagulation	Soft tissue coagulation	Yes – same
Cooling System			
Cooling mechanism	Peristaltic pump	Chiller/circulator pump	Yes – similar*
Coolant	Saline	Water/saline	Yes – same
Cooling design	Coolant flows in channel	Closed system: coolant flows	Yes – same

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Feature	MTCS (cleared)	DTS G2 (subject of this submission)	SE?
	between antenna and cooling plate. Does not directly contact patient.	in channel between antenna and cooling plate. Does not directly contact patient.	

* - Differences are discussed in the response to item 1d below.
** - This is a change for the DTS G2 System compared to the original submission. Please see the response to question 4 for more details.

b. *Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.*

See the prior response. The expanded table is above. The degree to which the subject device and the predicate device are the same or similar is indicated in the last column of the table.

c. *Please provide additional predicate(s) for some of the different features, or*

No additional predicate devices were added to the table, and, consistent with our email and phone discussions and the revised Indications for Use, the Thermage ThermaCool predicate device was removed as a predicate.

d. *Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.*

A discussion of the differences between the subject device and the predicate device is given below for all items identified as "similar" in the above table. It should be noted first that the DTS G2 system was designed to target a smaller range of lesion sizes compared to the MTCS device, but allow the physician to create more lesions in a single applicator placement (i.e. one lesion for each of the four antennas). Several of the differences relate to these different design goals.

<u>System output power – maximum, coagulation time and maximum coagulation cycle</u>

The relevant parameter to examine is the maximum coagulation cycle, which is the maximum possible energy (energy = power x time) that the system can deliver. The highest power setting available is 100W in the DTS G2 system, which is higher than the maximum power setting (60 W) for the MTCS system. However, the maximum time setting of 9.999 sec is less than the 30 seconds for the MTCS system. The maximum energy delivered for the DTS G2 System is 1000 Joules compared to 1800 Joules for the MTCS. This difference does not affect the safety of the device. For efficacy, the appropriate power and time settings to use with this device for the clinical application is chosen by the user, based on the lesion size guidelines provided in the Applicator IFU (see Attachment C).

<u>Frequency of energy delivery</u>

The frequency of the microwave energy delivered by the DTS G2 system is 5.8 GHz, as compared to 2.45 GHz for the MTCS predicate device. In general, the frequency of the device determines the target depth of the energy (higher frequency penetrates less). The higher frequency of the DTS G2 device is a

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better match for the smaller lesions desired for this device, while still allowing the user flexibility to reach the tissue depths of the predicate device. The user is provided with example data (see the Applicator IFU in Attachment C) to indicate the approximate target depths. The data provided from ex vivo animal testing demonstrates that there are no effects on safety or effectiveness of the device with the different frequency.

Monitored and Displayed parameters

Both systems monitor and display similar parameters (e.g. target tissue surface temperature and display the power and time settings, and vacuum). For the MTCS, the vacuum display was on a separate component (the Medela unit), whereas for the DTS G2 system the vacuum display is integrated into the front panel of the Generator. The DTS G2 system provides more information to the user in terms of showing coolant system temperature. This additional information makes the system safer to use and does not affect the efficacy. (For more information on the monitored and displayed parameters for the DTS G2 system, see the response to question 7.)

Antenna/Applicator Design

The primary difference between the DTS G2 device applicator and the MTCS applicator is that the DTS G2 device has up to four antennas mounted in the applicator head, whereas the MTCS had just two. The use of four antennas allows creation of up to four lesions with a single placement of the applicator. (Each of the antennas is powered in turn, but there is not a separate pre-cool and post-cool cycle). This design change was a result of feedback from clinicians to allow for creation of multiple small lesions to provide an overall faster procedure. It does not have an affect on the safety or effectiveness of the device.

Applicator size

Due to doubling the number of antennas housed in the applicator, the footprint of the patient contacting surface is about double the size (6cm x 3cm for the MTCS device and 7cm x 5cm for the DTS G2 device). This does not affect the safety or efficacy of the device.

Cooling System

The subject device and the predicate device have slightly different cooling mechanisms. The DTS G2 system is very similar to the MTCS system, where cool water is circulated in a channel next to the skin. The difference comes from the type of pump that is used to circulate the water. The chiller/circulator pump in the DTS G2 system is a medical grade subsystem that provides a more regulated coolant temperature. The user manual for the pump was provided in the original submission in Attachment B. The use of a different pump has no effect on the safety or effectiveness of the DTS G2 system.

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The analysis shows that there are no differences that adversely affect the safety and effectiveness of the DTS G2 device and therefore it is substantially equivalent to the predicate device.

2) DTS G2 System Description

The information you provided for DTS G2 system is not adequate. Please provide the following additional information:

a. Detailed design information and test results for the NanoTherm System and/or FDA clearance number.

The NanoTherm chiller/circulator is manufactured by ThermoTek, Inc and is a component that was cleared as part of the NanoTherm System in K061866. The component used by Miramar Labs in the DTS G2 system is the component referred to as the "NanoTherm unit" in the 510(k) summary. See Attachment D for the 510(k) Summary for K061866. The description of how the NanoTherm chiller/circulator is integrated into the DTS G2 system is reproduced here from page 10 of the original submission:

The NanoTherm Chiller/Circulator is a solid-state chiller designed to chill the fluid in its reservoir and pump the chilled fluid at a fixed pressure through inlet and outlet ports on the back of the unit. The NanoTherm is used to create fluid flow through the Applicator cooling chamber to cool the surface of the target tissue. The Applicator has integrated inlet and outlet tubing to be used with the NanoTherm Chiller/Circulator. This is a closed loop system where the chilled fluid is circulated through the applicator and back to the NanoTherm Chiller/Circulator fluid reservoir.

b. Design information and test results for the integrated vacuum pump.

The vacuum pump that is integrated into the DTS G2 Generator is a component currently supplied by Clark Solutions, Model 15988. It is a variable voltage (up to 12V) powered rotary vane pump. See Attachment E for the currently released part specification. The amount of vacuum supplied by the pump is controlled by the user via a rotary knob on the front face of the DTS G2 Generator (see the response to question 7 for more information about user control).

The integrated vacuum pump was tested as part of the overall Generator verification testing. The relevant sections of the Test Protocol and Test Report are included in Attachment E. The testing showed that all requirements were met.

3) Performance Testing Data

The data from your in-vivo porcine skin model and ex-vivo porcine tissue models is inadequate. You did not compare the histological results of the subject DTS G2 system to the ThermaCool TC System (K013639) predicate device. Please provide comparative performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the ThermaCool TC System (K013639) predicate device.

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Modification of predicate device for comparison: As discussed with the reviewer via email and telephone (on 11/3/08), the company was not able to find published data or find a ThermaCool TC predicate system that could be used to generate the requested performance data. With the proposed revised Indications for Use that removes the dermatologic indication, Miramar Labs proposed and the reviewer accepted that providing comparative performance data for the subject device (the DTS G2 System) and the predicate microwave device (K072870, the MTCS system) would meet the requirements for this question.

Comparative data. As explained in the response to Question 1 above, the two devices being compared are both microwave energy devices with surface cooling. They both create lesions by focusing the microwave energy to cause thermal tissue coagulation. We compare below the sizes of lesions that are created by the devices as well as show examples of gross pathology to demonstrate that the appearance of the lesions in the same type of tissue is the same. This information is the same as that supplied in the cleared 510(k) for the MTCS predicate device (K072870).

The systems, however, have different power and time setting ranges and a different frequency. One goal of the DTS G2 system was to allow the physicians to create smaller lesions than those from the MTCS system, and this is illustrated by the overall lesion sizes that are provided in the respective IFUs. (See Attachment C for the DTS LT Applicator IFU and Attachment F for the MTCS Applicator IFU cleared as part of K072870.) For example, in muscle tissue the provided range of lesion sizes (max dimension) was 9-22 mm for the MTCS device. For the DTS G2 device it is 6 – 10mm.

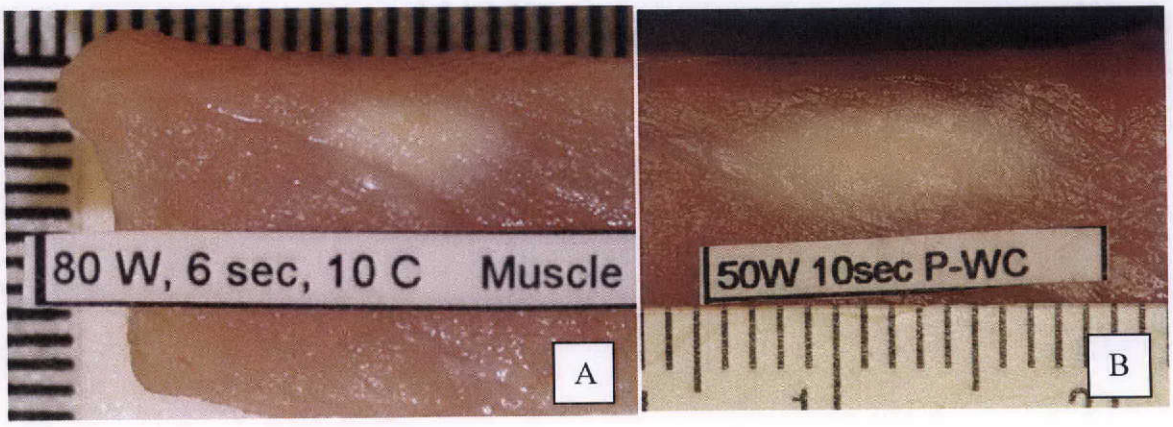

Figure 1. Comparison of lesions created in ex-vivo muscle tissue by (A) the subject device (DTS G2 System) and (B) the predicate device (MTCS system). The scale for both photos is in mm. The size of the lesion created with the DTS G2 system for approximately the same energy setting (80W x 6 sec compared to 50 W x 10 sec) is smaller, but the lesion and surrounding tissue are qualitatively the same.

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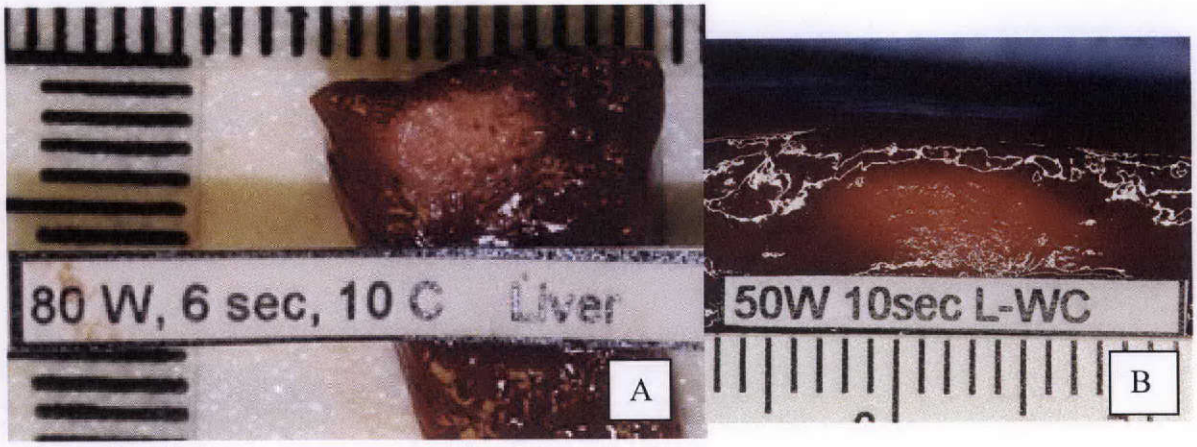

Figure 2. Comparison of lesions created in ex-vivo liver tissue by (A) the subject device (DTS G2 System) and (B) the predicate device (MTCS system). The scale for both photos is in mm. The size of the lesion created with the DTS G2 system for approximately the same energy setting is smaller, but the lesion and surrounding tissue are qualitatively the same.

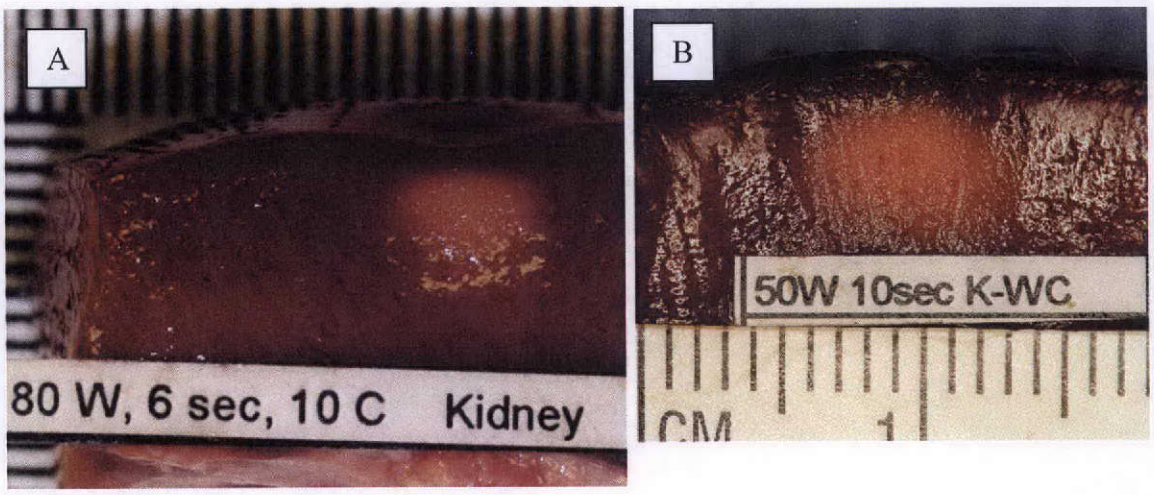

Figure 3. Comparison of lesions created in ex-vivo kidney tissue by (A) the subject device (DTS G2 System) and (B) the predicate device (MTCS system). The scale for both photos is in mm. The size of the lesion created with the DTS G2 system for approximately the same energy setting is smaller, but the lesion and surrounding tissue are qualitatively the same.

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4) <u>Applicator Temperature Test</u>

You did not discuss the maximum surface temperatures of your Applicator LT during usage.

a. *Please provide bench test results that record the temperature profiles of your DTS LT applicator and cable during simulation use for the maximum energy delivery duration (99.99 seconds) at the maximum power of 100 Watts, with and without cooling system, to demonstrate that your maximum applicator surface temperature and maximum cable surface temperature will be safe to the user and/or to the patient.*

As is common with energy delivery devices that are designed to coagulate tissue, these devices are often capable of being operated at conditions that provide high heat in the active region of the applicator/probe. However, the non-active areas of the applicator should be designed not to injure the user or patient with heat generated in unintended areas like the handle and cable.

Users are trained to use the system and the IFUs provide guidance for recommended settings and expected results. However, Miramar Labs recognizes that the DTS G2 system design did allow for a substantially longer energy duration time compared to the times shown in the IFU and in testing. Initially the intent was to provide a very flexible system that the physician could use for a range of soft tissue coagulation needs. Further market research has narrowed the need to creating smaller lesions.

Therefore, the company has implemented a change to the system that will limit the maximum time setting to 9.999 seconds. (The maximum power setting remains at 100W.) This maximum time setting is adequate for the lesions sizes desired. The DTS G2 Generator User Manual has been revised to reflect the different time ranges and the DTS LT Applicator IFU has been revised to report different lesion creation parameters that are consistent with this new maximum time. (See Attachment C).

Additional temperature testing was conducted to demonstrate that the maximum applicator surface temperature and the maximum cable surface temperature would be safe to the user and/or patient when used at the maximum power of 100W for 9.999 seconds in conditions with the cooling system active and without the cooling system. See Attachment G for a description of the testing and the results. In summary, the maximum temperature that was reached under all tested configurations was 27.9°C, therefore the system has been shown to be safe to the user and patient.

b. *Please discuss your method for the mitigation of potential high applicator surface temperatures.*

As demonstrated in the response to item 4a above, the temperature on the surfaces contacted by the user remains within acceptable limits and therefore no further mitigations are required.

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5) Lesion Size Guideline
You have provided the lesion sizes created by the DTS LT applicator up to 14 seconds and up to 100 watts (Instructions for Use, DTS-LT Applicator). This data is inadequate considering your generator output is designed for a maximum duration of 99.99 seconds and at a maximum power output of 100 watts (DTS G2 Generator User Manual). Please provide the suggested lesion sizes for the whole operating range of the device and revise your DTS-LT Applicator Instructions for Use accordingly.

As discussed in the response to question 4a, the system has been changed to limit the maximum energy duration time to 9.999 seconds. The lesion size guidelines contained in the IFU have been revised accordingly.

Also, the DTS-LT Applicator IFU has been revised to include a warning specifically to recommend against using parameters outside the listed matrix of power/time settings.

6) Performance Testing- Electrical Safety
Please provide complete test results to demonstrate that your device including the DTS G2 generator, LT applicator, NanoTherm and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- *IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)*
- *IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)*
- *IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).*

The electrical safety and electromagnetic compatibility testing for the device has been completed and the DTS G2 system has been shown to meet the applicable test requirements of the IEC 60601-1 and IEC 60601-1-2 standard. See the test reports in Attachments H and I which include device tested, test configurations, acceptance parameters and test results. Final steps for certification to the standard will require a review of the final labeling; therefore complete compliance certificates are not provided.

Miramar Labs certifies that the DTS G2 system will conform to the requirements of the following safety standards prior to distribution:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)

Miramar Labs' DTS G2 System is not tested to one of the standards listed in the question: *IEC 60601-2-2 Particular requirements for the safety of high frequency surgical equipment.* This standard applies to high frequency surgical equipment that utilizes either monopolar or bipolar RADIOFREQUENCY technology. Radiofrequency technology uses the patient's body to close the electric circuit, which sends electric CURRENT through the body either between a relatively small active electrode and a

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relatively large return electrode (monopolar) or between two similarly sized electrodes (bipolar).

Miramar Labs' DTS G2 System utilizes microwave energy which does not send any electric current through the body. The electromagnetic fields are broadcast to the nearby target tissue which causes the water molecules near the vicinity of the applicator to oscillate, thereby causing local tissue heating. In fact, the active part of the applicator, the microwave antenna, is never in contact with the body. It is completely insulated from the body by a layer of cooling fluid, a ceramic plate, and a polymer film. There is no possibility of even getting electric current to the body with this set-up, unlike radiofrequency devices which have an electric conductor on both the active electrode and the return electrode that have to make good electrical contact with the body tissue to adequately close that electric circuit to effectively send current through the body.

In summary, we firmly believe that the IEC 60601-2-2 standard is not applicable to our device and we have performed the applicable electrical safety and EMC testing on our system as summarized in the reports contained in Attachments H and I.

7) <u>Control & Display</u>
You have provided the microwave generator controller diagram in Attachment A. However, the mechanism that is utilized for the control and display of the parameters such as skin temperature, power control, energy timer, start/stop, etc.., as shown in the DTS G2 Generator User Manual (page 5-6, Attachment B) is still not clear.

a. *Please describe in detail how these functions are accomplished. Specifically, how the 10 antenna select switches are used to select the 4 antenna in the applicator? how the energy timer setting is used to control the energy delivery time? is there any mechanism to prevent the applicator surface temperature running too high?*

To answer this question, here we review the information on the indicated pages and differentiate between panel components that the user controls versus display indicators and connectors. A description of how the controls are then implemented inside the generator can be found in the logic information provided to address question 7b (see Attachment J). We also describe the fault mechanisms that are built into the generator.

See Figure 4 for a photo of the front panel of the DTS G2 Generator (reproduced from page 5 of the DTS G2 Generator User Manual in Attachment K). All system control is provided by the user using the switches and knobs on this front panel. Items controlled by the user are indicated in bold in the figure. Displays of system values and system connectors are in normal font.

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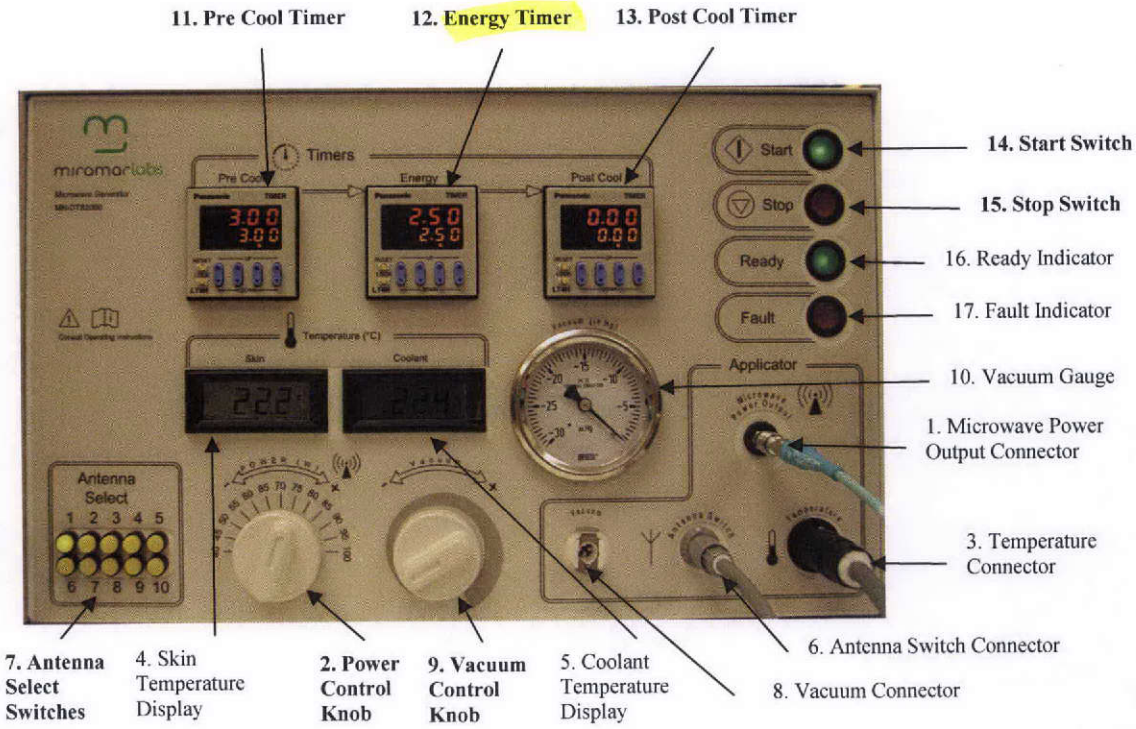

Figure 4. Front Panel for the DTS G2 generator. Knobs and switches used to control settings or device operation are shown in bold. The remaining labeled items are displays and/or connectors. See the text for further description.

More detail regarding each of these items can be found in the DTS G2 Generator User Manual. To specifically address the items above:

Antenna switches:
The DTS G2 Generator was designed to accommodate potential future applicators that may have up to 10 antennae, thus 10 toggle switches are provided (the switches light up when toggled "on"). Verification testing has confirmed that when the DTS LT applicator is connected to the Generator, only antenna switches 1 through 4 operate the device. That is, the Antenna Select switches directly correlate to the correct antenna in the applicator.

Timers:
All three timers (Pre Cool, Energy, and Post Cool) are all set using the blue rocker switches below the digital display. The switches are pressed (either up or down) until the smaller number on the bottom reaches the desired setting. Then the yellow Reset switch is pressed to activate the settings. The timer settings are used by the logic circuitry to control the vacuum activation and the microwave generation.

Fault mechanisms:
The situations that generate faults are described in the DTS G2 Generator User Manual in the Trouble-Shooting section. These listed faults include: intermittent connector contacts, lack of coolant flow, internal equipment over-temperature.

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In terms of the specific fault that was listed in the question (protection for the applicator surface temperature running too high), the indication for use for general soft tissue coagulation will at times necessitate high temperatures on the tissue surface. This is controlled and monitored by the trained user. Thus no specific cutoff is provided.

b. *Please provide the logic information of your microwave generator controller diagram. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html.*

See Attachment J for further information on the logic of the microwave generator. There is no software or firmware in the device that falls within the scope of the FDA guidance document mentioned or the IEC 60601-1-4 standard for programmable electrical medical systems. No software documentation is provided.

c. *Please provide the Device Hazard Analysis for the mitigation of potential hazards.*

The Hazard Analysis for the DTS G2 system can be found in Attachment L. The Hazard Analysis is based on the analysis that was done for the MTCS predicate device. Additional hazards added after the initial 510(k) was cleared and hazards identified due to design changes to make the DTS G2 System are added at the bottom (see shaded rows). All hazards are controlled to be at or below ALARP (as low as reasonably possible) levels.

8) Labeling - User Manual for the DTS G2 Generator
Please revise your User manual for the DTS G2 Generator to include the following information:

a. *description of vacuum pump*
The User Manual for the DTS G2 Generator has been revised to provide a brief description of the vacuum pump. See Attachment K.

b. *a consistent indications for use statement*
The User Manual for the DTS G2 Generator has been revised to give a consistent Indications for Use statement. See Attachment K. The version that was inadvertently submitted had been created to support a non-significant risk clinical study.

c. *provide data to substantiate your list of potential adverse events*
Again, a version of the User Manual that was created to support a non-significant risk clinical study was inadvertently used in the submission; the IRB submission included theoretical adverse events based on other types of energy-delivery devices. This section has been removed as it is not applicable to this device. See Attachment K.

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d. detailed technical specifications to include, for example, energy durations, vacuum range, etc...

A revised technical specifications table has been added to the User Manual for the DTS G2 Generator. See page 17 in Attachment K.

9) Labeling - DTS-LT Applicator Instructions for Use

Please revise your DTS-LT Applicator Instructions for Use to include the following information:

a. description and pictorial illustration of the assembly and disassembly of disposable applicator head.

A revised DTS-LT Applicator IFU is provided in Attachment C. The description and pictorial illustration of how to attach the disposable applicator head can be found on page 3. Instructions for disassembly and disposal are also included.

b. technical specifications of the applicator

Additional technical specifications for the DTS LT Applicator have been added to the IFU, see page 7 in Attachment C.

10) Labeling - User Manual for the NanoTherm

Please revise your User manual for the DTS G2 Generator to include the intended use and/or indications for use statement.

We believe this request is to revise the NanoTherm User Manual. As explained in the response to question 2a, the NanoTherm User Manual is supplied by an outside vendor, ThermoTek, Inc. Therefore we do not have the ability to modify that manual. We believe that the user will not be confused about the role of the NanoTherm unit or manual. However, to make it clearer, the DTS G2 Generator Manual has been modified to describe to the user that the NanoTherm User Manual should be consulted to set the chiller/circulator configuration (see Attachment K, page 4). The DTS-LT Applicator Instructions for Use already contained that language (page 2).

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List of Attachments:

Attachment A - Revised Indications for Use Statement
Attachment B - Revised 510(k) Summary
Attachment C - Revised DTS-LT Applicator IFU
Attachment D - 510(k) for NanoTherm System K061866
Attachment E - Vacuum Pump information
Parts spec for the Vacuum Pump
Test Protocol and Test Report (sections) for the Vacuum Pump
Attachment F - Applicator IFU for MTCS predicate device (K072870)
Attachment G - Applicator and Cable Temperature testing results
Attachment H - IEC 60601-1 test report
Attachment I - IEC 60601-1-2 test report
Attachment J - Further information for logic circuitry for DTS G2 Generator
Attachment K - Revised DTS G2 Generator User Manual
Attachment L - DTS G2 System Hazard Analysis

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

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K082819

Indications for Use

510(k) Number (if known): K082819

Device Name: DTS G2 System

Indications for Use: The DTS G2 System is indicated for use for coagulation of soft tissue.

X		
Prescription Use (Per 21 CFR 801 Subpart D)	OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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K082819

510(k) Summary

General Information

Classification	Class II
Trade Name	DTS G2 System
Submitter	Miramar Labs, Inc. 199 Jefferson Drive Menlo Park, CA 94025 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Kathy O'Shaughnessy, PhD VP, Clinical and Regulatory Affairs

Intended Use

The DTS G2 System is indicated for use for coagulation of soft tissue.

Predicate Devices

K072870 Foundry Newco X Microwave Tissue Coagulation System

Device Description

The DTS G2 System is designed to interact using a surface contact applicator. The system consists of an applicator; external microwave generator with integrated vacuum pump; and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, integrated vacuum pump, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator. The distal end has a sterile, disposable applicator head that contacts the patient.

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Materials

All materials used in the manufacture of the DTS G2 System are suitable for this use and have been used in numerous previously cleared products.

Testing

Product and animal testing was conducted to evaluate conformance to product specification and equivalence to predicate devices.

The results showed the system met specification.

Summary of Substantial Equivalence

The DTS G2 System is equivalent to the predicate product. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

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

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ATTACHMENT C

Revised DTS-LT Applicator Instructions for Use

List of Contents in Attachment C:

1. Clean copy of revised IFU

2. Redline copy showing changes from original version. Note: Tracked changes do not flag the columns deleted from the former Tables 2, 3 and 4 (showing lesions created for times larger than 10 sec); Microsoft Word is not able to track deleted columns.

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

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INSTRUCTIONS FOR USE

DTS-LT APPLICATOR

DRAFT 11/14/08

Miramar Labs, Inc.

199 Jefferson Dr.
Menlo Park, CA 94025
Phone: 650-326-2656
Fax: 650-326-3108

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

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DTS-LT APPLICATOR INSTRUCTIONS FOR USE

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

BEFORE USING THE SYSTEM:

Please refer to DTS G2 Generator User Manual for detailed instructions on connecting and operating the entire system. Components of the DTS G2 System are designed to be used together as a single unit.

Failure to understand and follow provided instructions may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

- The DTS G2 System is indicated for use for coagulation of soft tissue.

IMPORTANT:

- The procedures should only be performed by physicians and operating room staff familiar with the equipment and techniques involved.

WARNINGS AND CAUTIONS:

- ONLY use power/time settings that are within the bounds listed in the guidance tables below. Using higher power/time settings could cause injury to the patient.
- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
- DO NOT apply power with Applicator not in contact with the target tissue
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

- Refer to DTS G2 Generator User Manual for detailed instructions on how to activate system generator and properly connect associated components.
- Refer to the NanoTherm Chiller/Circulator User Manual for detailed instructions on how to set chiller temperature and activate the flow.
- Connect the Applicator Disposable Head to the DTS Applicator LT (see Figure 1 below)
- Inspect the film on the Applicator Disposable Head to ensure no rips/tears/holes are present.

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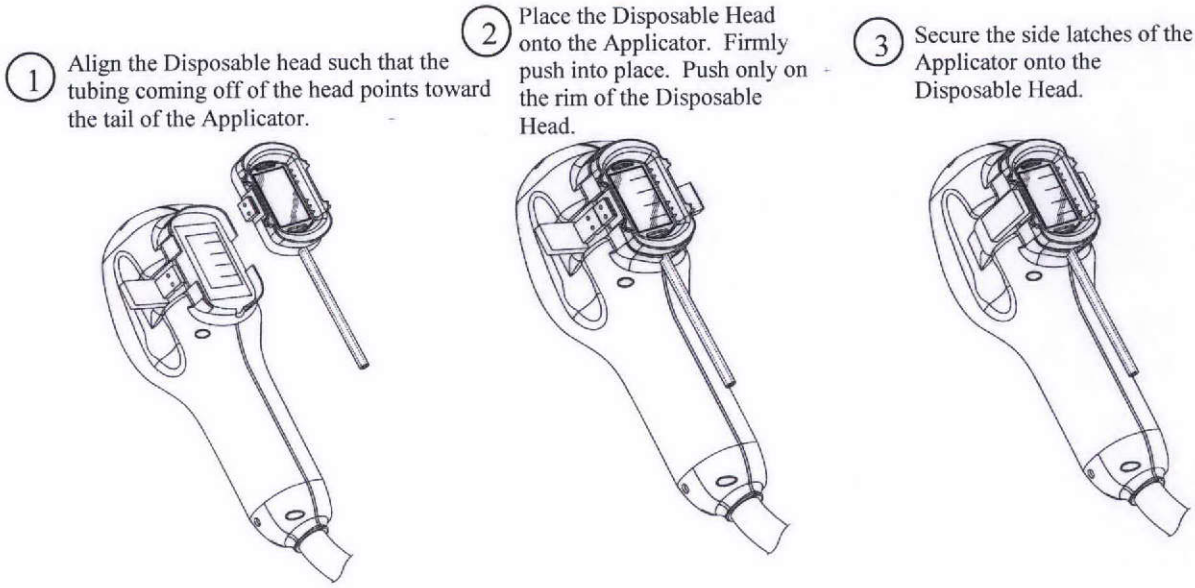

Figure 1. Connecting the Disposable Head onto the Applicator

STARTING THE PROCEDURE

- Activate the cooling flow for surface cooling.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level.
- Set power and durations of pre-cool, energy delivery, and post cool to desired levels.
  - Energy delivery times can be chosen based on the tables below and the desired lesion size.
  - Recommended setting for Pre-cool time is 3.0 sec and post-cool time is 20.0 sec. Settings can be varied if more surface cooling is desired.
- Place the Applicator on the target tissue (see Figure 2 below for proper technique of holding the handle).
- Confirm the generator settings before proceeding with the procedure.

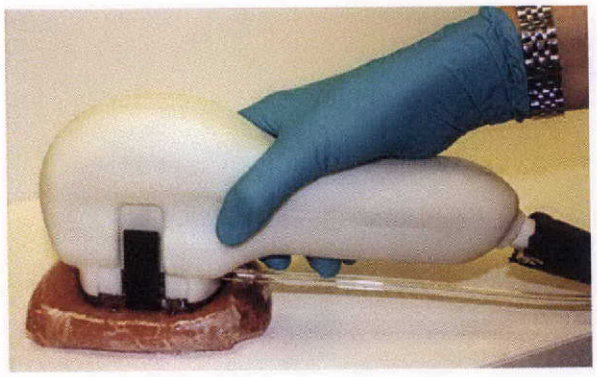

Figure 2. Proper technique for holding the handle of the Applicator

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ANTENNA SELECTION

The DTS Applicator LT contains four antenna that are arranged in a row along the Applicator body (see Figure 3 for the location and numbering scheme). The antenna are spaced 9 mm apart.

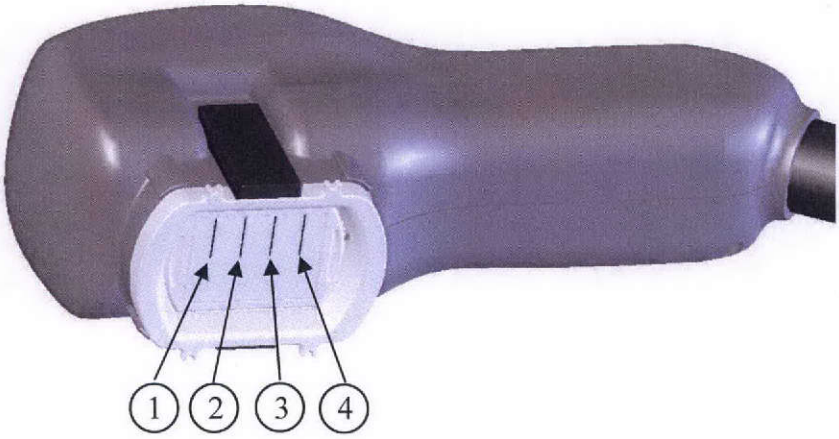

Figure 3. Location and numbering of antenna for the DTS Applicator LT.

Figure 4 shows a comparison between single antenna activation (4A) compared to having four antennas activated (Figure 4B). The DTS G2 Generator sends power to only one antenna at a time. Similar lesions are created under each antenna.

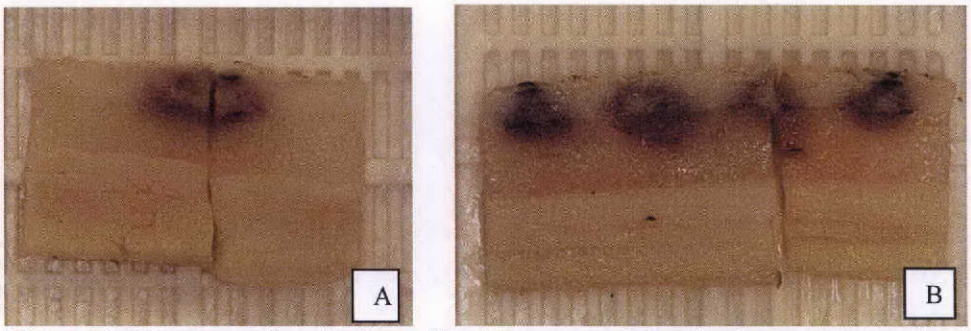

Figure 4. Cross-sectional view of lesions created by single antenna activation (A) versus lesions created with 4 antennas activated (B) in an In-Vivo porcine skin model.

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

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GENERAL SOFT TISSUE

NOTE:
The following tables show the approximate lesion size created by the DTS LT Applicator at various power and energy time settings with a single antenna activated for different tissues. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 4 with a skin model. The results below are from Ex-Vivo porcine tissue models. Lesion sizes may vary in clinical setting.

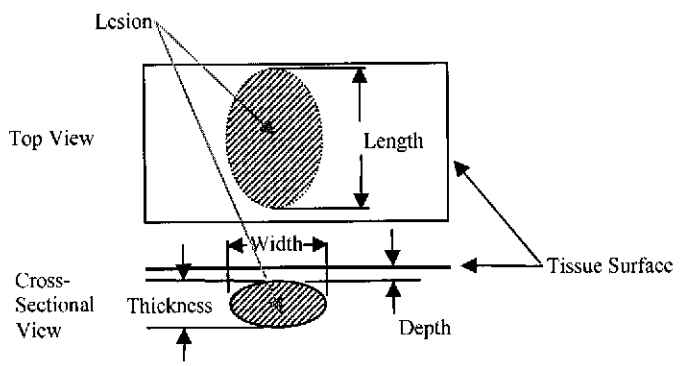

Figure 5. Lesion size and depth nomenclature.

Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length**	—	—	—	—	**6.1**
	Width					2.8
	Thickness					**1.8**
	Depth					0.6
60	**Length**	—	—	**7.6**	**7.6**	**8.8**
	Width			3.8	4.8	5.3
	Thickness			**1.9**	**3.0**	**3.1**
	Depth			0.3	0.6	0.4
80	**Length**	—	**7.8**	**8.4**	**9.5**	—
	Width		4.1	5.9	6.6	
	Thickness		**2.5**	**2.9**	**3.1**	
	Depth		0.5	0.3	0.3	
100	**Length**	**8.1**	**9.3**	**10.0**	—	—
	Width	5.4	6.6	7.4		
	Thickness	**2.5**	**2.9**	**3.4**		
	Depth	0.3	0.3	0.0		

Table 2. Approximate lesion sizes created in Ex-Vivo muscle tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length** Width **Thickness** Depth	—	—	—	—	**7.4** 2.6 **1.8** 0.9
60	**Length** Width **Thickness** Depth	—	—	**7.5** 2.5 **1.6** 0.8	**7.8** 3.3 **2.6** 0.6	**9.4** 3.8 **2.9** 0.6
80	**Length** Width **Thickness** Depth	—	**7.1** 3.3 **2.0** 0.5	**8.5** 3.9 **2.5** 0.5	**8.8** 5.4 **2.9** 0.3	—
100	**Length** Width **Thickness** Depth	**7.6** 3.8 **1.5** 0.6	**8.9** 5.0 **2.9** 0.3	**9.3** 5.5 **2.6** 0.3	—	—

Table 3. Approximate lesion sizes created in Ex-Vivo liver tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length** Width **Thickness** Depth	—	—	—	—	**7.1** 2.3 **2.1** 1.0
60	**Length** Width **Thickness** Depth	—	—	**8.1** 2.3 **2.3** 0.8	**8.4** 3.0 **2.6** 0.8	**9.0** 4.1 **3.6** 0.3
80	**Length** Width **Thickness** Depth	—	**8.9** 4.2 **2.5** 0.5	**9.0** 4.3 **3.0** 0.6	**9.5** 5.4 **4.0** 0.3	—
100	**Length** Width **Thickness** Depth	**8.9** 3.7 **3.1** 0.5	**9.5** 5.6 **3.9** 0.3	**10.1** 6.1 **3.9** 0.4	—	—

Table 4. Approximate lesion sizes created in Ex-Vivo kidney tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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PROCEDURE NOTES

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to DTS Generator User Manual for troubleshooting.

AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from Generator and Chiller/Circulator.
- Open the side latches on the Applicator and remove the Disposable Head. Discard the Disposable Head and the attached vacuum tubing. Do not re-use the Disposable Head.
- Turn off Generator after procedure.

STORAGE:

- Store Applicator away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:

⚠.....**Read Instructions**

Applicator Technical Specifications

Energy Modality:	Microwave
Frequency of Operation:	5.8GHz
Power Handling Capability:	0-100 Watts
Number of Active Antennas:	1-4
Applicator Head Footprint:	5cm x 7cm

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INSTRUCTIONS FOR USE

DTS-LT APPLICATOR

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Miramar Labs, Inc.

199 Jefferson Dr.
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Failure to understand and follow provided instructions may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

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IMPORTANT:

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WARNINGS AND CAUTIONS:

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- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
- DO NOT apply power with Applicator not in contact with the target tissue
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

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- Connect the Applicator Disposable Head to the DTS Applicator LT (see Figure 1 below)
- Inspect the film on the Applicator Disposable Head to ensure no rips/tears/holes are present.

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1 Align the Disposable head such that the tubing coming off of the head points toward the tail of the Applicator.

2 Place the Disposable Head onto the Applicator. Firmly push into place. Push only on the rim of the Disposable Head.

3 Secure the side latches of the Applicator onto the Disposable Head.

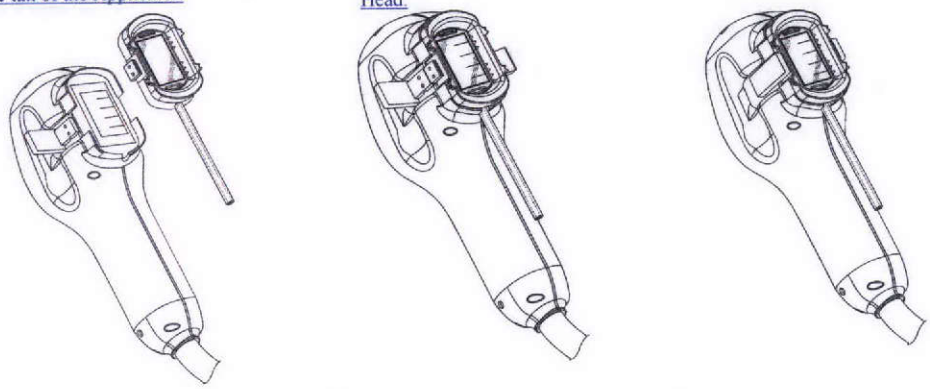

Figure 1. Connecting the Disposable Head onto the Applicator

STARTING THE PROCEDURE

- Activate the cooling flow for surface cooling.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level.
- Set power and durations of pre-cool, energy delivery, and post cool to desired levels.
  - Energy delivery times can be chosen based on the tables below and the desired lesion size.
  - Recommended setting for Pre-cool time is 3.0 sec and post-cool time is 20.0 sec. Settings can be varied if more surface cooling is desired.
- Place the Applicator on the target tissue (see Figure 2 below for proper technique of holding the handle).
- Confirm the generator settings before proceeding with the procedure.

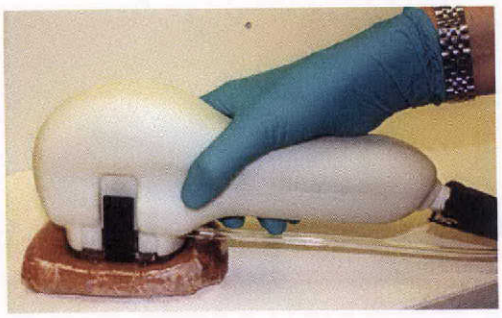

Figure 2. Proper technique for holding the handle of the Applicator

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NOTE:¶
The following tables show the approximate lesion size created by the DTS LT Applicator at various power/time settings with a single antenna activated. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 3. The results are from In-Vivo porcine skin model. Lesion sizes may vary in clinical setting. ¶
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Figure 2. Lesion size and depth nomenclature.¶
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Table 1. Approximate lesion sizes created in In-Vivo porcine skin. Coolant set at 10°C. All lesion size dimensions are in **millimeters**. The numbers are in the following sequence A / B / C / D (see Figure 2 for definition).¶
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ANTENNA SELECTION

The DTS Applicator LT contains four antenna that are arranged in a row along the Applicator body (see Figure 3 for the location and numbering scheme). The antenna are spaced 9 mm apart.

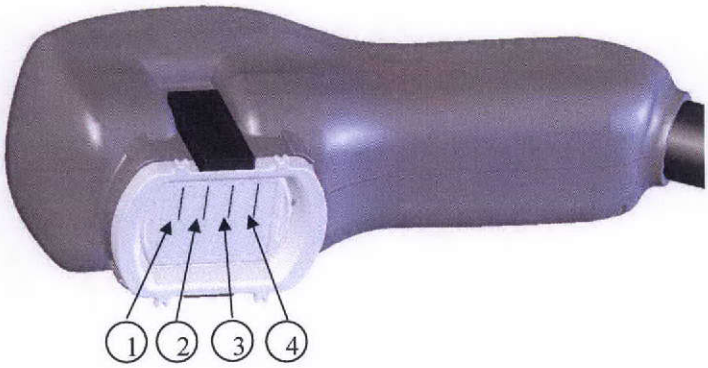

Figure 3. Location and numbering of antenna for the DTS Applicator LT.

Figure 4 shows a comparison between single antenna activation (4A) compared to having four antennas activated (Figure 4B). The DTS G2 Generator sends power to only one antenna at a time. Similar lesions are created under each antenna.

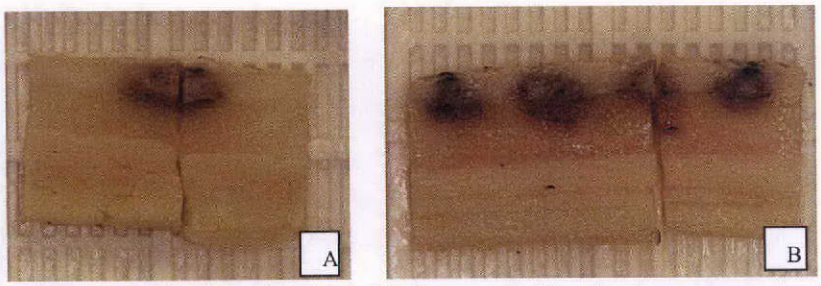

Figure 4. Cross-sectional view of lesions created by single antenna activation (A) versus lesions created with 4 antennas activated (B) in an In-Vivo porcine skin model.

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GENERAL SOFT TISSUE

NOTE:
The following tables show the approximate lesion size created by the DTS LT Applicator at various power and energy time settings with a single antenna activated for different tissues. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 4 with a skin model. The results below are from Ex-Vivo porcine tissue models. Lesion sizes may vary in clinical setting.

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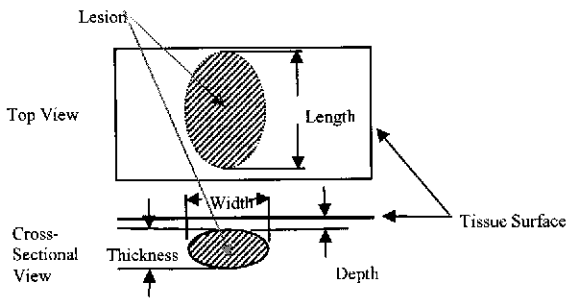

Figure 5. Lesion size and depth nomenclature.

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Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length**	–	–	–	–	**6.1**
	Width					2.8
	Thickness					**1.8**
	Depth					0.6
60	**Length**	–	–	**7.6**	**7.6**	**8.8**
	Width			3.8	4.8	5.3
	Thickness			**1.9**	**3.0**	**3.1**
	Depth			0.3	0.6	0.4
80	**Length**	–	**7.8**	**8.4**	**9.5**	–
	Width		4.1	5.9	6.6	
	Thickness		**2.5**	**2.9**	**3.1**	
	Depth		0.5	0.3	0.3	
100	**Length**	**8.1**	**9.3**	**10.0**	–	–
	Width	5.4	6.6	7.4		
	Thickness	**2.5**	**2.9**	**3.4**		
	Depth	0.3	0.3	0.0		

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Table 2. Approximate lesion sizes created in Ex-Vivo muscle tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length**	—	—	—	—	**7.4**
	Width					2.6
	Thickness					**1.8**
	Depth					0.9
60	**Length**	—	—	**7.5**	**7.8**	**9.4**
	Width			2.5	3.3	3.8
	Thickness			**1.6**	**2.6**	**2.9**
	Depth			0.8	0.6	0.6
80	**Length**	—	**7.1**	**8.5**	**8.8**	—
	Width		3.3	3.9	5.4	
	Thickness		**2.0**	**2.5**	**2.9**	
	Depth		0.5	0.5	0.3	
100	**Length**	**7.6**	**8.9**	**9.3**	—	—
	Width	3.8	5.0	5.5		
	Thickness	**1.5**	**2.9**	**2.6**		
	Depth	0.6	0.3	0.3		

Table 3. Approximate lesion sizes created in Ex-Vivo liver tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length**	—	—	—	—	**7.1**
	Width					2.3
	Thickness					**2.1**
	Depth					1.0
60	**Length**	—	—	**8.1**	**8.4**	**9.0**
	Width			2.3	3.0	4.1
	Thickness			**2.3**	**2.6**	**3.6**
	Depth			0.8	0.8	0.3
80	**Length**	—	**8.9**	**9.0**	**9.5**	—
	Width		4.2	4.3	5.4	
	Thickness		**2.5**	**3.0**	**4.0**	
	Depth		0.5	0.6	0.3	
100	**Length**	**8.9**	**9.5**	**10.1**	—	—
	Width	3.7	5.6	6.1		
	Thickness	**3.1**	**3.9**	**3.9**		
	Depth	0.5	0.3	0.4		

Table 4. Approximate lesion sizes created in Ex-Vivo kidney tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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PROCEDURE NOTES

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to DTS Generator User Manual for troubleshooting.

AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from Generator and Chiller/Circulator.
- Open the side latches on the Applicator and remove the Disposable Head. Discard the Disposable Head and the attached vacuum tubing. Do not re-use the Disposable Head.
- Turn off Generator after procedure.

Deleted: and d

STORAGE:

- Store Applicator away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:

⚠ .....**Read Instructions**

Applicator Technical Specifications

Energy Modality:	Microwave
Frequency of Operation:	5.8GHz
Power Handling Capability:	0-100 Watts
Number of Active Antennas:	1-4
Applicator Head Footprint:	5cm x 7cm

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2014

Section 5. 510(k) Summary

AUG 2 2 2006

APPLICANT
[As Required by 21 CFR 807.92 a(1)]

Applicant:	ThermoTek, Inc.
Address:	1454 Halsey Way Carrollton, TX 75007
Telephone Number:	972-242-3232 972-446-1195 (fax)
Company Contact:	Tony Quisenberry President
Date:	June 21, 2006

DEVICE NAME
[As Required by 21 CFR 807.92 a(2)]

Proprietary Name:	NanoTherm™ and VascuTherm™
Common Name:	Intermittent, External Pneumatic Compression Device
Classification Name:	Compressible Limb Sleeve (per 21 CFR section 870.5800)

IDENTIFICATION OF PREDICATE DEVICES
[As Required by 21 CFR 807.92 a(3)]

▪ Chattanooga Group, Inc. PresSsion S III	K942796
▪ KCI PlexiPulse® All-in-1 System	K981311
▪ Aircast VenaFlow System Disposable Cuffs as bundled	K023800
▪ Bio Compression Systems BioComfort Garments	K043423
▪ MicroTek Medical Holdings, Inc. Venodyne DVT Advantage Plus+	K011318
▪ Ormed Artrotherm Cryotherapy and Thermotherapy	K964799 sited and currently exempt Class II, per 21 CFR 890.5720

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

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DEVICE DESCRIPTION
[As Required by 21 CFR 807.92 a(4)]

Intended Use
The NanoTherm and VascuTherm systems are new devices that are intended to function as intermittent, external pneumatic compression devices. The intended therapy of the NanoTherm device is to aid in the reduction and control of edema including lymphedema of the upper and lower extremities and venous stasis ulcers. The intended therapy of the new VascuTherm device is to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding in blood flow back to the heart via lower extremity limb compression in addition to the intended uses of the NanoTherm device.

Physical Description
The NanoTherm device is comprised of a reusable pump (NanoTherm unit) and various single-patient use inflatable wraps (NanoTherm Wraps). The VascuTherm device consists of a reusable pump (VascuTherm unit) and various single-patient use inflatable wraps (VascuTherm Wraps). The VascuTherm unit has additional equipment installed and specially designed wraps specifically for the preventive treatment of DVT.

Therapy Modality Used
The NanoTherm unit thermal control therapy provides chilled fluid and heated fluid to the wrap affixed on an extremity therapy site to reduce pain and swelling and compresses the treatment site for optimum performance and fluid transfer and treatment of edema and lymphedema.
The VascuTherm unit contains a DVT mode that is not present on the NanoTherm unit. This therapy mode is for air-only DVT compression therapy using air-only DVT wraps.

Safety Features
The NanoTherm and VascuTherm systems utilize microprocessor control with multiple sensors to ensure patient safety and system functionality, and to provide consistent and repeatable therapy modalities. Alarms are both visual on the unit display and audible. Alarms are in place to detect a potentially unsafe situation and to terminate therapy to protect the patient and the system. Potentially unsafe situations are listed in the risk and hazard analysis covered in Appendices 16.3.A and 16.3.B.

STATEMENT OF INTENDED USE
[As Required by 21 CFR 807.92 a(5)]

Patient Population
The NanoTherm and VascuTherm devices' intended patient population is a non-ambulatory adult.

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

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NanoTherm Indications:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.
- Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

NanoTherm Contraindications

- Presumptive evidence of congestive heart failure
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Suspected/observed patient has Raynaud's Disease
- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Patient therapy contact on extremity containing a fracture
- Extremities that are not sensitive to pain

VascuTherm Indications:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.
- Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.
- Decrease the risk of deep venous thrombosis (DVT).
- Aids the blood flow back to the heart.
- Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

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

- Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

VascuTherm Contraindications

- Presumptive evidence of congestive heart failure
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Suspected/observed patient has Raynaud's Disease
- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Patient therapy contact on extremity containing a fracture
- Extremities that are not sensitive to pain

The following patients must use the NanoTherm or VascuTherm therapy systems for temperature contact therapy under the supervision of a physician if they are:

- Individuals with extremities not sensitive to pain
- Individuals with extremely low blood pressure
- Individuals with Raynaud's Disease
- Hypersensitive to cold
- Children
- Diabetics

Differences in Indications

The indications for NanoTherm and VascuTherm devices are the same as those for the predicate devices listed in the Tables 1, 3 and 5 below.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

TECHNOLOGICAL CHARACTERISTICS
[As Required by 21 CFR 807.92 a(6)]

The NanoTherm and VascuTherm devices have the same performance characteristics as the predicate devices.
The pneumatic control circuitry is a microprocessor-controlled system. Multiple safety redundancies are built into the system including: high and low temperature alarms, alarms for unit malfunction situations, and system malfunction overpressure safety via a pressure vent switch. Power is supplied via 110 VAC line current.
The surface contact temperature range is microprocessor controlled in cooling from 43°F to 49° and to 105°F in heating mode.

Comparison of features and principles of operation between the NanoTherm and VascuTherm devices and the predicate devices per Section 510(k) of the Act.

Table 1. Summary of Edema/Lymphedema Therapy Modality Comparison for the Units

Parameter	NanoTherm and VascuTherm for edema/lymphedema only	Chatttanooga Group, Inc. PresSsion S III (K942796)
Pump Pressure Range	30 mm Hg. ±5 mm Hg.	30-100 mm Hg. ±5 mm Hg.
Default Pressure	30 mm Hg.	User Selectable
Cycle Time	Inflation: 20 seconds Deflation: 40 seconds	Inflation: 5-120 seconds Deflation: 5-60 seconds
Indications for Use	Compression therapy is indicated for the following: Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains. (K942796)	Compression therapy is indicated for the following: Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains. Decrease the risk of deep venous thrombosis (DVT).
UL Mark	UL 60601 Class II, Type B	Class I, Type BF
CE Mark	IEC 60601-1 (safety) IEC 60601-1-1 (Emissions, Class A) IEC 60601-1-2 (Immunity)	Not known

Table 2. Summary of Edema/Lymphedema Biocompatibility Comparison for the Wraps

Parameter	Therapy wraps for edema/lymphedema only	BioCompression Systems, Inc. BioComfort Garments (K043423)
Material in Skin Contact	200 Denier Nylon Oxford	200 Denier Nylon Oxford
Sterile/Non-Sterile	Sterile and Non-Sterile	Sterile and Non-Sterile
Single Patient Use	Yes	Yes

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

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Table 3. Summary of DVT Therapy Modality Comparison for the Unit

Parameter	VascuTherm	Chatttanooga Group, Inc. PresSsion S III (K942796)	MicroTek Medical Venodyne DVT Advantage Plus+ (K011318)	KCI PlexiPulse All-in-1 System (K981311)
Pump Pressure Range	45-100 mm Hg. ±5 mm Hg.	30-100 mm Hg. ±5 mm Hg. (calf therapy only)	40-45 mm Hg. (calf and foot therapy)	140-180 mm Hg. ±5 mm Hg. (foot therapy only)
Default Pressure	45 mm Hg. (calf) 100 mm Hg. (foot)	User Selectable	45 mm Hg.	160 mm Hg. (foot therapy only)
Cycle Time	Inflation: 30 seconds Deflation: 30 seconds	Inflation: 5-120 seconds Deflation: 5-60 seconds	Inflation: 12 seconds Deflation: 48 seconds	Inflation: 1-5 seconds Deflation 20-60 seconds
Indications for Use	Decrease the risk of deep venous thrombosis, **DVT.** (K942796, K011318, K981311) Aids the blood flow back to the heart. (K011318) Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications. (K981311)	Compression therapy is indicated for the following: Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains. Decrease the risk of deep venous thrombosis (DVT).	The Venodyne DVT Advantage model 620 is designed to compress the lower limbs aiding the blood flow back toward the heart to prevent deep vein thrombosis in patients at risk.	The Cowboy XV is intended for patients in the home who would benefit from increased blood flow to: Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant medications (medications that thin the blood), and prevent deep venous thrombosis (DVT) (blood clots in deep veins).
UL Mark	UL 60601 Class II, Type B	UL - Type BF, Class I	Not Known	UL
CE Mark	IEC 60601-1 (safety) IEC 60601-1-1 (Emissions, Class A) IEC 60601-1-2 (Immunity)	Not Known	Yes	Not Known

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Table 4.Summary of DVT Biocompatibility Comparison for the Wraps

Parameter	VascuTherm air-only therapy wraps for DVT prevention only	Aircast Vena Flow Sterile Disposable Cuffs (K023800)
Material in Skin Contact	DuPont Softesse® Medical Fabric (non-latex, non-woven)	DuPont Softesse® Medical Fabric (non-latex, non-woven)
Sterile/Non-Sterile	Non-Sterile	Non-Sterile and Sterile
Single Patient Use	Yes	Yes

Table 5. Summary of Water Circulating Thermal Therapy

Parameter	NanoTherm and VascuTherm devices	Artrotherm Cryotherapy and Thermotherapy (K964799)
Therapy Type	Heat/Cool	Heat/Cool
Therapy Temperature Range	Heat: 105°F Cold: 43°F to 49°F	Heat: 122°F Cold: 43°F
Indications for Use	Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions. (K964799)	Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

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
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2006

ThermoTek, Inc.
C/O Mr. Jay Kogoma
Senior Staff Engineer
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K061866
Trade/Device Name: NanoTherm and VascuTherm Systems
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW, ILO
Dated: August 4, 2006
Received: August 7, 2006

Dear Mr. Kogoma:

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.

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

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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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

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

Enclosure

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Indications for Use

510(k) Number (if known): K061866

Device Name: NanoTherm

Indications for Use:

Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.

Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.

Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

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

Device Name: VascuTherm

Indications for Use:

Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.

Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.

Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

Decrease the risk of deep venous thrombosis (DVT).

Aids the blood flow back to the heart.

Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061866

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

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Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

ATTACHMENT E

DTS G2 System Vacuum Pump Information

List of Contents in Attachment E:

1. Currently released parts specification for the off-the-shelf component.

2. Sections of the released Test Protocol and Test Report for the DTS G2 Generator that relate to the performance of the integrated vacuum pump.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Rev.	EO #	Release Date	Originators Name & Signature	Description of Change
A	08-0076	03/18/08	Dan Hallock	Initial Release

Part number:	Revision:	Part Name:
PN0302	**A**	**Pump, Vacuum, Rotary Vane**

VENDOR(S): **Clark Solutions** 10 Brent Drive Hudson, MA 01749

DESCRIPTION: **15988** Pump, Vacuum, Rotary Vane

SPECIFICATION(S):

MFG: Furgut GmbH
MFG P/N: 15988

CLARK

Pressure/Vacuum Pump Model Series 15000

12VDC Powered Rotary Vane Pumps

Model 15980

Model 159(50, 83,85,86,88)

DESCRIPTION

These rotary vane pumps are an excellent pressure/vacuum source for gas analyzers, medical devices, process samplers and other analytical instrument applications. They are also useful for material handling and many general automation applications.

The pumps are quiet, reliable and mount in any position. The units operate oil free. The pump vanes have a service life of 1,000 hours and are easily field replaced without special tools.

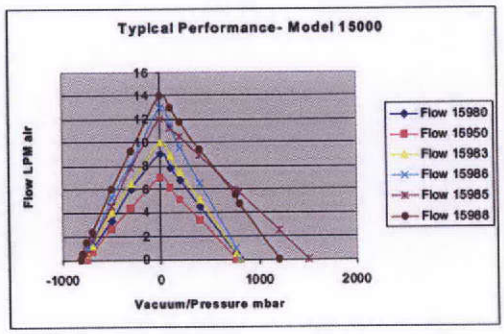
SPECIFICATIONS

Maximum Differential Pressure- 1500 mbar
Maximum Flow- 14 LPM
Vane Material- Carbon
Media- Inert gases

NOTE

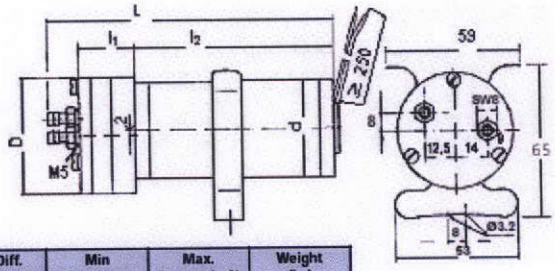
Operation at a somewhat lower than pump design voltage will yield a significantly longer life of the motor and the pump while also decreasing the current draw and operating noise of the unit.

If used for continuous operation, please note that the electrical current will be at least 10% below the specified design current draw. Consequently, we recommend that you select a pump that has a slightly higher pumping capacity than needed during normal operation.



DIMENSIONS (MM)

Model	D	d	L	L1	L2
15950	50	42	106	20.5	72
15980	50	35.5	95	22.3	57
15983	50	42	109	23.5	72
15985	50	42	132	23.5	85
15986	50	42	109	23.5	72
15988	50	42	132	23.5	85



ORDERING INFORMATION

Model	Voltage	Max. Flow(L/min)	Max. Diff. Pressure (mbar)	Min Current (mA)	Max. Current (mA)	Weight (kg)
15950	**12**	**7**	**±760**	**0.8**	**1.7**	**0.65**
15988	**12**	**14**	**+1200/-820**	**1.6**	****4.4**	**0.78**
15980	12	9	±800	1.8	3.2	0.49
15983	12	10	±800	1.2	2.2	0.67
15985	12	12	+1500/-800	1.6	*6.0	0.78
15986	12	13	±800	1.6	2.7	0.67

Bold Items Typically Ship From Stock *2.7 Amps at -800 mbar **2.8 Amps at -820 mbar

INSPECTION: Visually verify that the vendor part number on the component packaging or vendor packing list are correct.

Special Handling Instructions: ☒ No ☐ Yes, as listed below:

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

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Summary of Testing performed on the integrated vacuum pump for the DTS G2 Generator

Contents:

- Relevant sections from the released test protocol
- Relevant sections from the released test report (test deviations and final results)
- Completed test data sheets

Note: The internal project name for the DTS G2 Generator was the DTS2000 Instrumentation and therefore the released documents use the internal project name. The device name referred to in the regulatory submission was selected after this testing was complete.

Extracted sections from the Test Protocol TP-0013 Rev A,
DTS2000 Instrumentation Verification Protocol

The sections listed below are all sections that test the vacuum pump functionality of the DTS G2 Generator.

7.2 Generator Vacuum Control Valve Operate and Standby Mode Control Testing

7.2.1 Test Setup

7.2.1.1 Connect the High Power Termination to the Microwave Power Output port on the DTS2000.

7.2.1.2 Connect the Pressure Transducer through the Pressure Transducer Coupler Fixture to the vacuum port on front panel.

7.2.1.3 Power up the DTS2000 and allow the system to complete self-test.

7.2.1.4 Program the following times on the DTS2000: Pre-Cool = 3 s, Energy = 3 s, Post-Cool = 3 s.

7.2.1.5 Rotate the power control rotary knob to command the microwave power to maximum.

7.2.1.6 Rotate the vacuum control rotary knob to command the vacuum to maximum.

7.2.1.7 Select antenna 1.

7.2.2 Test Protocol

7.2.2.1 Press the "start" switch and on the front panel of the DTS2000 and allow the treatment to complete the post-cool. Note the value of pressure before the pre-cool, during the pre-cool, during energy, during post-cool, and after the post-cool. Confirm the value is between 0 and -1 inches Hg before pre-cool and after post-cool and between -20 and -30 inches Hg during pre-cool, energy, and post-cool.

7.2.2.2 Rotate the vacuum control rotary knob to command the vacuum to minimum. Press the "start" switch and on the front panel of the DTS2000 and allow the treatment to complete the post-cool. Note the value of pressure before the pre-cool, during the pre-cool, during energy, during post-cool, and after the post-cool. Confirm the value is between 0 and -1 inches Hg before pre-cool and after post-cool and between -1 and -10 inches Hg during pre-cool, energy, and post-cool.

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

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7.3 Generator Timer Mode Control Testing

7.3.1 Test Setup

7.3.1.1 Connect the High Power Termination to the Microwave Power Output port on the DTS2000.

7.3.1.2 Connect a power meter to the forward power output of the Microwave Coupler Fixture.

7.3.1.3 Connect recorder output of power meter to channel 1 of the oscilloscope with the following settings: 10mV/div, 20MHz Bandwidth Limiting, 1 sec/div, trigger on rising edge of channel 1 set to middle of the display.

7.3.1.4 Connect pressure transducer to the vacuum port of the DTS2000 and channel 2 of the oscilloscope. Set channel 2 scale to 2mV/div.

7.3.1.5 Power up the DTS2000 and allow the system to complete self-test.

7.3.1.6 Program the following times on the DTS2000: Pre-Cool = 2 s, Energy = 2 s, Post-Cool = 2 s.

7.3.1.7 Rotate the power control rotary knob to command the microwave power to maximum.

7.3.1.8 Rotate the vacuum control rotary knob to command the vacuum to maximum.

7.3.1.9 Select antenna 1.

7.3.1.10 Press the "start" switch and on the front panel of the DTS2000 and allow the treatment to complete the post-cool.

[..redacted: other timing test steps....]

7.3.2.10 Confirm vacuum valve connection is activated after START and immediately deactivated upon pressing the STOP button. This is done by observing that the vacuum gage on front panel reads between -20 and -30 inches Hg after START and before STOP.

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

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Extracted sections from the Test Report TR-0013 Rev A,
DTS2000 Instrumentation Verification Test Report

Test Report – Deviations:

4.3 In response to a requested change to have the vacuum pressure gage display the pressure in the vacuum reservoir, lines 7.2.1.2 and 7.3.2.10 in the TP0013-A, DTS2000 System Instrumentation Verification Protocol were modified as follows:

7.2.1.2 Connect the Pressure Transducer through the Pressure Transducer Coupler Fixture to the vacuum port on front panel and then to a DMM set to mV where 1 mV = 1 in Hg.

7.3.2.10 Confirm vacuum valve connection is activated after START and immediately deactivated upon pressing the STOP button. This is done by observing the magnitude of channel 2 on the oscilloscope where -20 to -30 mV corresponds to -20 and -30 inches Hg after START and before STOP.

These sections were re-tested and the results are shown in the test summary.

Test Report – Test Summary and Acceptance Criteria:

Test	Description	Acceptance Criteria	Pass/Fail
7.2.2.1	Confirm vacuum pressure attains appropriate value during pre-cool, energy, and post-cool cycles for maximum vacuum command.	The pressure measures between 0 and -1 in Hg before pre and after post-cool and between -20 and -30 in Hg during pre-cool, energy, and post-cool cycles.	Pass
7.2.2.2	Confirm vacuum pressure attains appropriate value during pre-cool, energy, and post-cool cycles for minimum vacuum command.	The pressure measures between 0 and -1 in Hg before pre and after post-cool and between -1 and -10 in Hg during pre-cool, energy, and post-cool cycles.	Pass
7.3.2.10	Confirm vacuum valve connection is activated after START and immediately deactivated upon pressing the STOP button.	The pressure is between -20 and -30 in Hg after pressing the "Start" button and between 0 and -1 in Hg upon pressing the "Stop" button.	Pass

Completed test data sheets for the two tested systems are on the following pages.

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

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Data Sheet 2: Generator Vacuum Control Valve Operate and Standby Mode Control Testing

Test operator: W. Segalla Date: 7-29-08 Location: Miramar Labs
DTS2000 S/N #08H0108 CONTROLLER S/N # 08R0800-1

Test Equipment Description/Model Number	Serial Number	Calibration Due Date
EQ0055-01 Fluke PV350 Pressure Transducer	94990075	NA
EQ0056-01 Pressure Transducer Coupler Fixture	NA	NA
EQ0053-01 High Power Termination Fixture	NA	NA

Maximum Pressure Test

Step/Test #	Pressure Before Pre-Cool and After Post-Cool (in HG)	0 to -1 in Hg Pass/Fail	Pressure During Pre-Cool, Energy, Post-Cool (in HG)	Between -20 in Hg and -30 in Hg Pass/Fail	Comments
7.2.2.1	0	PASS	-23	PASS	

Minimum Pressure Test

Step/Test #	Pressure Before Pre-Cool and After Post-Cool (in HG)	0 to -1 in Hg Pass/Fail	Pressure During Pre-Cool, Energy, Post-Cool (in HG)	Between -1 in Hg and -10 in Hg Pass/Fail	Comments
7.2.2.2	0	PASS	-7	PASS	

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Data Sheet 2: Generator Vacuum Control Valve Operate and Standby Mode Control Testing

Test operator: W. Segalla Date: 7-29-08 Location: Miramar Labs

DTS2000 S/N # 08H0109 CONTROLLER S/N # 08R0800-2

Test Equipment Description/Model Number	Serial Number	Calibration Due Date
EQ0053-01 High Power Termination Fixture	094890076	NA
EQ0055-01 Fluke PV350 Pressure Transducer	NA	NA
EQ0056-01 Pressure Transducer Coupler Fixture	NA	NA

Maximum Pressure Test

Step/Test #	Pressure Before Pre-Cool and After Post-Cool (in HG)	0 to -1 in Hg Pass/Fail	Pressure During Pre-Cool, Energy, Post-Cool (in HG)	Between -20 in Hg and -30 in Hg Pass/Fail	Comments
7.2.2.1	0	Pass	-23	Pass	

Minimum Pressure Test

Step/Test #	Pressure Before Pre-Cool and After Post-Cool (in HG)	0 to -1 in Hg Pass/Fail	Pressure During Pre-Cool, Energy, Post-Cool (in HG)	Between -1 in Hg and -10 in Hg Pass/Fail	Comments
7.2.2.2	0	Pass	-6	Pass	

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INSTRUCTIONS FOR USE

MTCS APPLICATOR

Foundry Newco X, Inc.

199 Jefferson Dr.
Menlo Park, CA 94025
Phone: 650-326-2656
Fax: 650-326-3108

DRAFT

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

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MTCS APPLICATOR INSTRUCTIONS FOR USE

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

BEFORE USING THE SYSTEM:

Please refer to Microwave Tissue Coagulation System (MTCS) Generator User Manual for detailed instructions on connecting and operating the entire system. Components of the MTCS System are designed to be used together as a single unit.

Failure to understand and follow provided instructions, may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

- The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

IMPORTANT:

- The procedures should only be performed by physicians and operating room staff familiar with the equipment and techniques involved.
- The MTCS Applicators are shipped as sterile products and are intended to be used one time only. Please discard after one use. Do not attempt to resterilize.
- Product is sterile unless package has been damaged or opened.

WARNINGS AND CAUTIONS:

- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to high possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
  DO NOT apply power with Applicator not in contact with the target tissue
- Localized burns to patient or physician may result from electric currents being carried through conductive objects or from metal objects in close proximity to Probe.
- DO NOT allow patient to come in contact with grounded metal objects.
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

- Refer to MTCS Generator User Manual for detailed instructions on how to activate system generator and properly connect associated components.
- Refer to the Vacuum Pump User Manual for detailed instructions on how to activate and adjust the vacuum level.
- Refer to the Chiller User Manual for detailed instructions on how to set chiller temperature and activate the flow.
- Place the Applicator on the target tissue (see figure below for proper technique of holding the handle.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level.
- Activate the cooling flow for surface cooling, if desired.
- Set power and duration of treatment to desired levels.
- Confirm the generator settings before proceeding with the procedure.

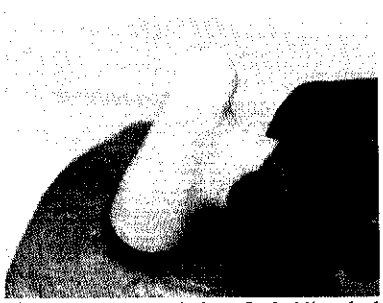
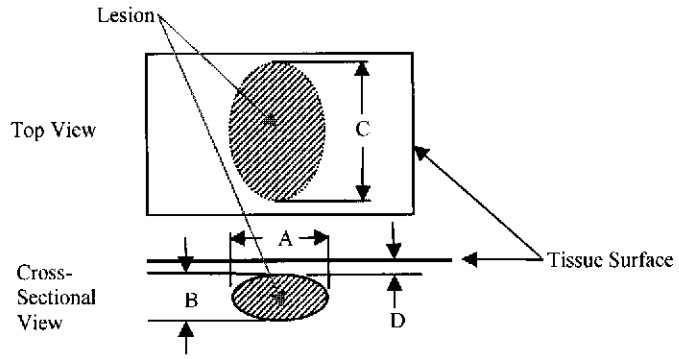


Figure 1. Proper technique for holding the handle of the Applicator

NOTE:
The following tables show the approximate lesion size created by the MTCS Applicator at various power/time settings. The results are from ex-vivo liver, muscle, and kidney animal tissue models, respectively. **Lesion size may vary in clinical setting.**



All lesion size dimensions are in **millimeters**. There are 2 sets of numbers in each box. The top set is created using chilled saline at 10 degrees Celsius and flow turned on. The bottom set is without cooling flow. (AxBxC – D See figure above for details of the dimensions)

Liver	10 seconds	15 seconds	20 seconds
40 Watts	5x2x2 – 2 5x2.5x2 – 1.5	10x2.5x3 – 1.5 10x4.5x7 – 1	15x4x5 – .5 15x5x9.5 – 0
50 Watts	7.5x3x3.5 – 1.5 8.5x4x3.5 – 1	13x3.5x5.5 – .5 14x6x9 – 0	14x5.5x6.5 – .5 16x7x11 – 0
60 Watts	11x4.5x4 – 1 14x3x8 – .5	15x5x5.5 – .5 15x6x10 – 0	16x6x7 – .5 17x7x11 – 0
For the maximum energy delivery (60Watts for 30 seconds), the following lesion sizes were created 20x8x10 – 0 (with cooling) and 22x9x11.5 – 0 (without cooling).			

Muscle	10 seconds	15 seconds	20 seconds
40 Watts	9x2.5x2.5 – 2.5 10x4x5 – 0	12x5x5 – .5 15x7x6 – 0	17x6x5.5 – .5 18x6x7 – 0
50 Watts	11x4x3.5 – 1 15x6x6 – 0	14x6x5 – 0 16x6.5x7.5 – 0	16x6.5x6.5 – 0 19x7x9 – 0
60 Watts	12x5x5 – .5 14.5x6x7 – 0	16x6.5x6 – 0 18x7x8 – 0	22x8x7.5 – 0 21x9x9 – 0
For the maximum energy delivery (60Watts for 30 seconds), the following lesion sizes were created 22x9x7.5 – 0 (with cooling) and 23x10x9 – 0 (without cooling).			

Kidney	10 seconds	15 seconds	20 seconds
40 Watts	6x3x3 – 1.5 8x4x4 – 1	9x5x6 – 2 13x6.5x8.5 – 0	12x6x6 – 1 13x6x9 – 0
50 Watts	6.5x4x4 – 1 10x4x6 – .5	12x6x7 – .5 13x5x8.5 – 0	14.5x6.5x7 – .5 15x8x9.5 – 0
60 Watts	10x4.5x5.5 – 1 10x5.5x7.5 – 0	12x6.5x7.5 – 0 15x6.5x8.5 – 0	17x7x7 – 0 18x7.5x9.5 – 0
For the maximum energy delivery (60Watts for 30 seconds), the following lesion sizes were created 17.5x8.5x8.5 – 0 (with cooling) and 19x9.5x10 – 0 (without cooling).			

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to MTCS Generator User Manual for troubleshooting.

AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from generator, vacuum pump, and chiller pump and discard.
- Turn off generator after procedure.

STORAGE:

- Store Probe away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:

(2) .....**Single Use**

⚠ .....**Read Instructions**

STERILE EO ..... **Sterilized by EtO**

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

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ATTACHMENT K

Revised DTS G2 Generator User Manual

List of Contents in Attachment K:

1. Clean copy of revised User Manual
2. Redline copy showing changes from original version.

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

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miramarlabs

DTS G2 Generator

User Manual

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

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1. CONTACT INFORMATION

Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park
CA 94025
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

1.1. EXPLANATION OF SYMBOLS

	Attention: See user manual for additional information Service By Qualified Personnel Only
	Fuse
	Type BF (Body Floating) Applied Part
LOT	Serial Number
	On (Main Power)
	Off (Main Power)
	Start
	Stop
	Non-Ionizing Radiation
	Timer
	Temperature
	Equipotential ground connection
	Manufacturer
	Date of Manufacture
	Waste electrical and electronic equipment

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2. SYSTEM DESCRIPTION

The Miramar Labs DTS G2 Generator is designed to deliver precise amounts of microwave energy to soft tissue while providing the ability to protect the tissue surface with an active contact cooling system. Microwave energy up to 100 Watts at 5.8 GHz can be generated and a portion of that delivered to the target tissue via specially designed Applicators.

The DTS G2 System consists of the following major components:

1. DTS Applicator
2. DTS G2 Generator
3. NanoTherm Chiller/Circulator (from ThermoTek)
4. Isolation Transformer
5. Mobile Cart (not shown in Figure 1)
6. Foot Switch (not shown in Figure 1)

See Figure 1 for basic block diagram of how the components of the system are connected. A brief description of each component is given below.

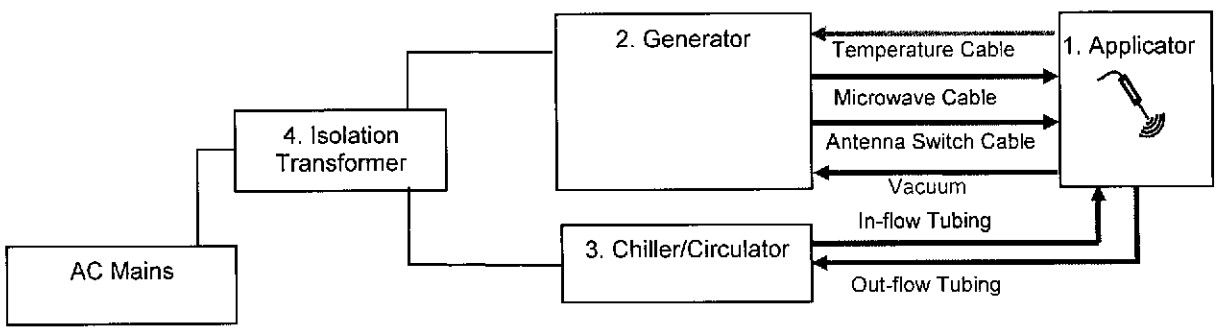

Figure 1. Block diagram of DTS G2 system components.

The Applicator has microwave antennas, a tissue acquisition vacuum chamber, and a surface cooling plate with a flow channel. The Applicator is connected as shown in Figure 1 to the two components of the DTS G2 System that provide the required functions - the Generator and the Chiller/Circulator.

The Generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, a power supply, microwave module and the front panel/control board assembly. There is also an integrated vacuum pump that provides suction (up to -28 in Hg) to the Applicator to facilitate tissue acquisition. See the next section for a detailed description of the control/display functions of the Generator.

The Chiller/Circulator provides the circulating cooling fluid that is flowing through the Applicator to prevent or minimize the thermal damage to the surface of the target tissue, if desired by the user. The Chiller/Circulator is manufactured by ThermoTek, Inc. See the NanoTherm User Manual for instructions on how to set Chiller temperature and flow.

The Isolation Transformer is an off-the-shelf component that provides protection for the patient by eliminating hazardous potential voltage differences as well as preventing hazardous levels of leakage currents between patient contact elements of the system and the AC mains.

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2.1. FRONT PANEL DISPLAY AND CONTROL FEATURES

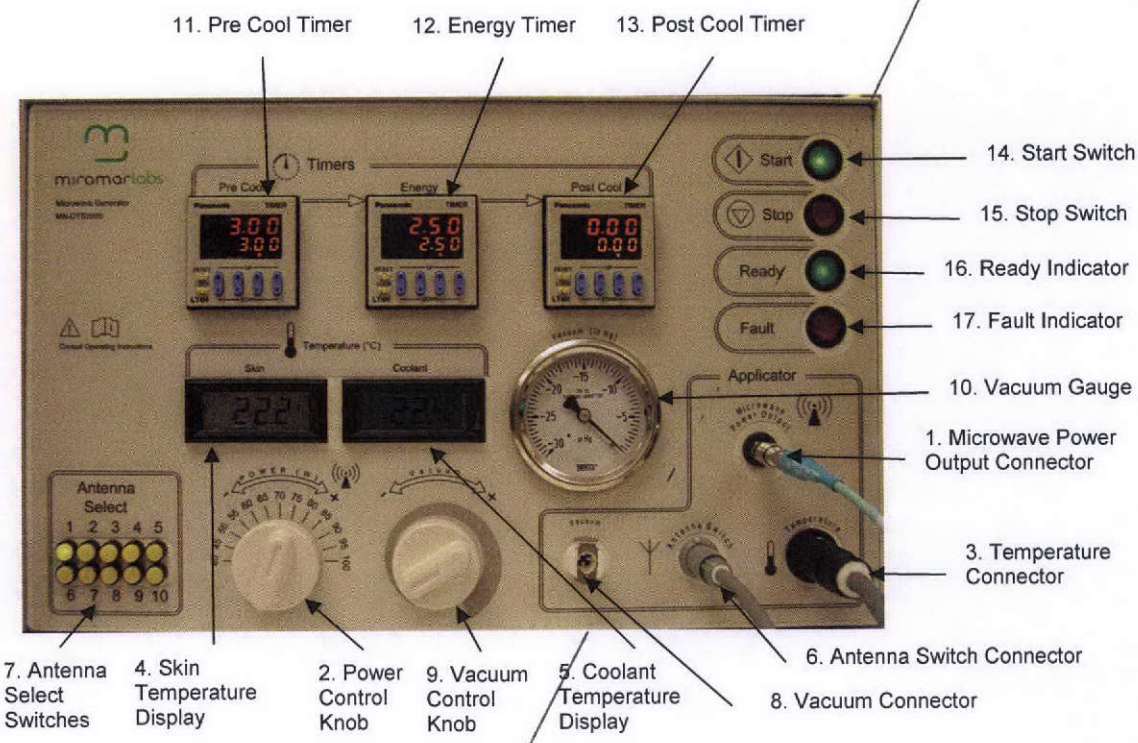

Figure 2. Generator Front Panel

1. Microwave Power Output Connector
   The Generator provides microwave power to the antennas via a coaxial QMA-type connector. The coaxial microwave cable of the Applicator is connected to this connector.

2. Power Control Knob
   A control knob on the front panel of the Generator provides the user with the ability to adjust the amount of power delivered to the Applicator.

3. Temperature Connector
   A temperature monitoring system inside the Generator provides continuous temperature monitoring of the cooling fluid line at a location inside the applicator. A second temperature monitoring system inside the Generator provides temperature monitoring of the thermocouples on the cooling plate of the Applicator between each antenna and the surface of the target tissue. This temperature monitoring is automatically switched between each of the thermocouples on the cooling plate of the applicator in coordination with automated antenna switching to provide the skin/cooling plate interface temperature associated with the active antenna.

4. Skin Temperature Display
   The skin/cooling plate interface temperature associated with the active antenna is displayed on the front panel of the Generator (°C).

5. Coolant Temperature Display
   The coolant temperature measured within the Applicator is displayed on the front panel of the Generator (°C).

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6. Antenna Switch Connector
   The antenna switch connector of the Applicator is connected on the front panel of the Generator to allow switching between antennas in Applicators that have more than one antenna.

7. Antenna Select Switches
   The user can activate one or more of the antennas (if more than one is available on a given Applicator) by pressing the appropriate antenna select switches on the front panel of the Generator. If more than one antenna is selected, the Generator will automatically deliver the energy for the set energy duration time to each of the antennas in a sequential fashion. The activation of multiple antennas enables the creation of a larger zone of heating.

8. Vacuum Connector
   A vacuum pump inside the Generator provides vacuum for tissue acquisition into the Applicator.

9. Vacuum Control Knob
   The vacuum level can be controlled by a knob on the front panel of the Generator.

10. Vacuum Gauge
    The vacuum gauge on the front panel of the Generator displays the vacuum level to the user.

11. Pre Cool Timer
    The Generator pre cool timer allows the user to set the pre-cool duration (sec).

12. Energy Timer
    The Generator energy timer allows the user to set the energy delivery duration (sec).

13. Post Cool Timer
    The Generator post cool timer allows the user to set the post-cool duration (sec).

14. Start Switch
    The pre-cool, energy delivery, and post-cool sequence shall commence upon pressing the start button. The start button is enabled when the generator Ready Indicator is illuminated.

15. Stop Switch
    The stop button can be used to abort the sequence at any time.

16. Ready Indicator
    The Ready Indicator will be illuminated when the AC mains power is turned on and no fault conditions exist.

17. Fault Indicator
    The Fault Indicator will be illuminated when a fault condition exists. Refer to Section 10 Troubleshooting Guide for details on potential fault modes and potential resolutions.

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2.2. REAR PANEL FEATURES

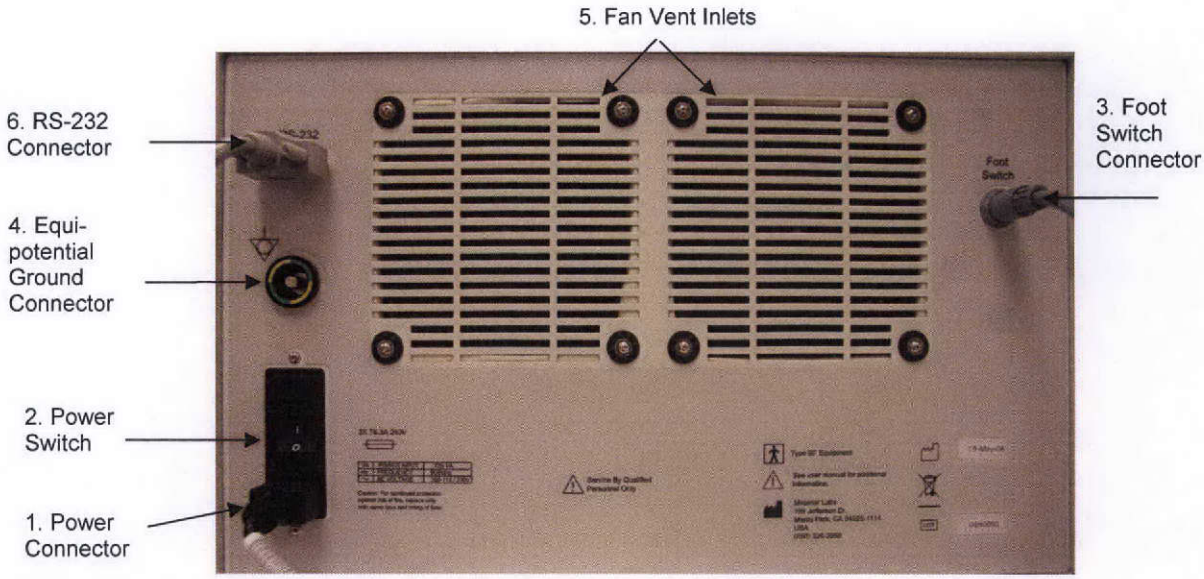

Figure 3. Generator Rear Panel

1. Power Connector
   AC mains power cord connection. This receptacle contains the Generator fuses just above the Power Switch (See instructions on How to Change the Fuses, section 2.3).

2. Power Switch
   AC mains power switch

3. Foot Switch Connector
   The Start/Stop function (as described on the Generator front-panel control) can be controlled by a foot switch (provided) that is connected to the rear panel.

4. Equipotential Ground Connector
   Use the equipotential ground connector for grounding to ensure that the generator is at the same ground potential as other equipment in the vicinity.

5. Fan Vent Inlets
   Vents allow the fans to draw ambient cooling air into the Generator. Do not block these vents to ensure proper cooling of the Generator.

6. RS-232 Connector
   The Generator provides the following data output through an RS-232 connection: antenna(s) selected, set power, actual forward power, reverse power, skin/cooling plate interface temperature (associated with the active antenna) and coolant temperature during energy delivery. This data can be collected through data acquisition devices (i.e. data-logger).

2.3. HOW TO CHANGE THE FUSES

CAUTION: Do not use repaired fuses or short-circuited fuse holders.

There are fuses in the power entry modules of the Generator, Chiller/Circulator and Isolation Transformer.

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Only use standard fuses, 2 each, current rated T6.3A/250 V @ 100-115 V ~ in the Generator.

Only use standard fuses, current rated T7A/250 V @ 100-115 V ~ in the Chiller/Circulator.

Only use standard fuses, current rated T10A/250 V @ 100-115 V ~ in the Isolation Transformer.

1. Ensure the generator, chiller and isolation transformer power switches are in the OFF (0) position.
2. Unplug the system power cord at the isolation transformer from the AC mains at the power outlet.
3. Snap the A/C RECEPTACLE-ON/OFF switch cap open by placing a flat screwdriver in the pre-marked slot located on top of the switch.
4. Remove fuses from either side of the holder and replace with standard time delay fuses, current rated T6.3A/250 V @ 100-120 V ~ for the generator, T7A/250 V @ 100-120 V ~ for the chiller/circulator, T10A/250 V @ 100-120 V ~ for the isolation transformer.
5. Replace holder and snap the cap closed.

3. CAUTIONS

Federal US law restricts this device to sale by or on the order of a licensed physician.

CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.

4. INDICATIONS FOR USE

The DTSG2 System is indicated for use for coagulation of soft tissue.

5. CONTRAINDICATIONS

The DTS G2 System is contraindicated for patients with heart pacemakers and other electronic device implants.

6. WARNINGS AND PRECAUTIONS

- ❑ Carefully read the User Manuals for the Miramar Labs DTS G2 Generator and the Nanotherm Chiller/Circulator, and the Applicator IFU prior to use. Observe all warnings and precautions. Failure to do so may result in complications.
- ❑ The DTS G2 is for use by qualified clinical personnel who have been instructed and trained in the correct use of the equipment by designated Company representatives.
- ❑ Safety of the DTS G2 has not been evaluated on patients with cardiac pacemakers or other electronic implants. The DTS G2 system should not be used on such patients.

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- Operate the DTS G2 in environmental temperatures between 16°C and 26°C (60°F and 80°F); and between 30% and 60% relative humidity (non-condensing).
- Use only the components and parts supplied by Miramar Labs.
- DO NOT attempt to repair or alter any of the System components.
- DO NOT allow fluid to contact generator, cables or connectors unless the generator is being cleaned. Do not hang fluids above the generator. The generator may not function correctly if the electronic circuitry or the connectors are wet. Do not soak cables.
- DO NOT operate if wet. Electrical shock may occur.
- DO NOT operate if there is no Applicator connected or if the Applicator is not positioned at the intended target site. See Applicator IFU for proper positioning of the applicator.
- Clean, disinfect, and maintain the electrical units in accordance with the operating instructions.
- Turn the electrical units Off using the main power On/Off switch and disconnect the power cord from the AC supply before cleaning.
- DO NOT remove the cover of any of the system components. There are no user-serviceable parts inside the components of the DTS G2. Opening the cover of any of the DTS G2 components may result in electrical shock or thermal burns.
- For warnings and precautions associated with the chiller portion of the DTS G2, see the NanoTherm Industrial User Manual. Also read the Applicator IFU.
- This equipment/system is intended for use by healthcare professionals only. The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Provide as much distance as possible between the DTS G2 and other electronic equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interteference. It may be necessary to take mitigation measures, such as reorientating or relocating the Generator or shielding the location.
- The DTS G2 should not be used or pause/terminate therapy cycle when the temperature shows abnormal fluctuations.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- Electrosurgical components, such as the Applicator, may remain hot after activation. Keep all electrosurgical equipment away from flammable materials to avoid combustion.

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- Prolonged or unneccessary activation of the DTS G2 may lead to unintentional damage to surrounding tissue.
- The output power selected should be as low as possible for the intended purpose.
- Do not obstruct the activation light or tone. The activation tone and light are important safety features.
- Use only Miramar Labs Applicators designed to be used with the DTS G2 Generator.
- Do not bend cables at acute angles or coil them tightly; the cable might break.
- The main power cord of the Isolation Transformer must be connected to a properly grounded receptacle. Extension cords and/or adaptor plugs must not be used. Plug equipment into 100-115V AC 60 Hz power receptacles.

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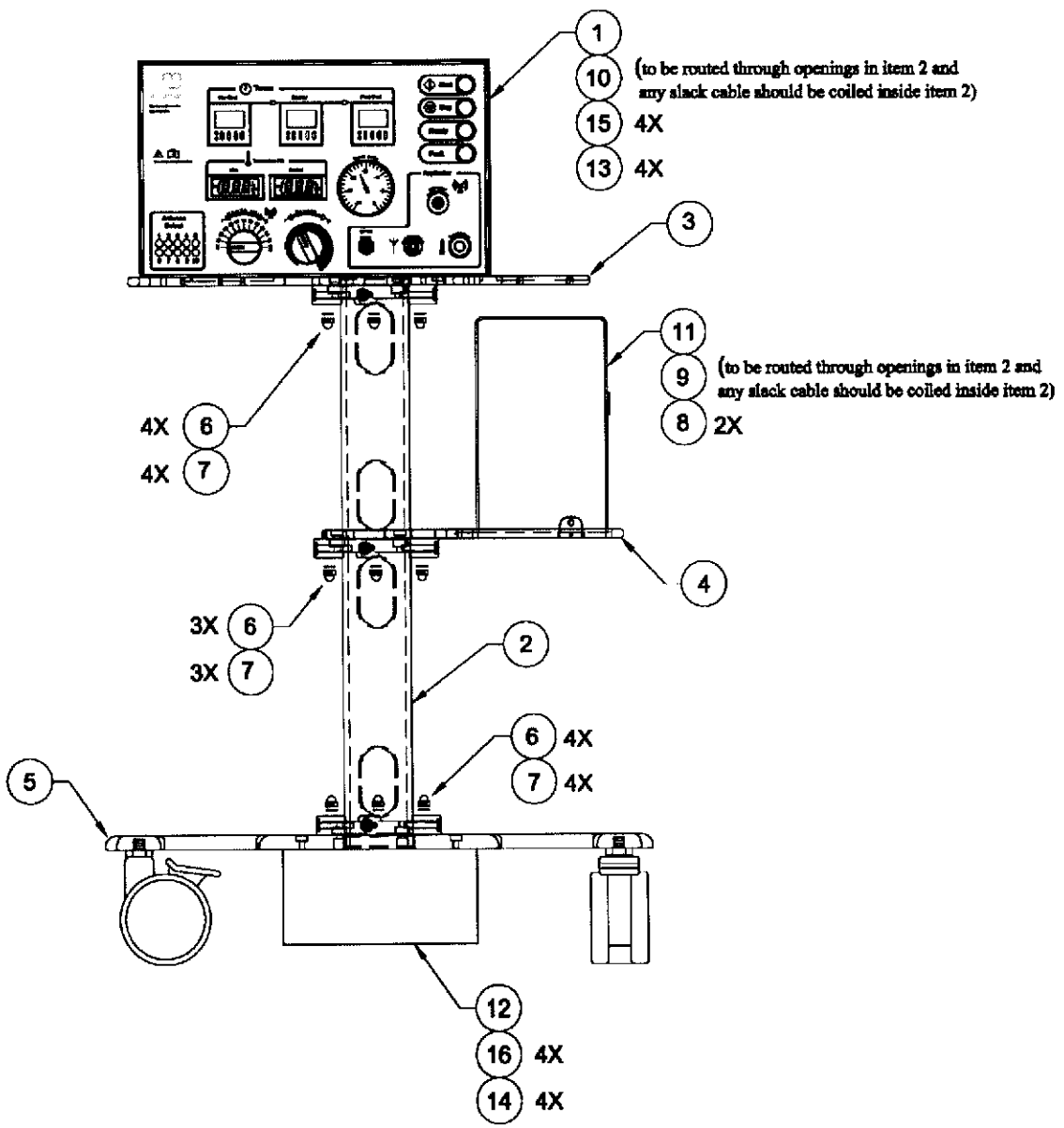
7. OPERATING INSTRUCTIONS

7.1. UNPACKING AND EQUIPMENT SET-UP

- ❑ Open each of the four cases containing the cart, generator, chiller, isolation transformer and miscellaneous cables, hardware, tools and manuals and remove the contents. Inspect all components for shipping damage. If damage has occurred, contact Miramar Labs. Verify all components are present (see section 9).

1. Refer to figure 3 below for remainder of set-up.

Figure 3. Equipment Set-up



2. Attach the isolation transformer (12) to the bottom of the cart base (5) using the four 10-32 x 5/8" long screws (14) with four #10 internal tooth lock washers (16)

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being sure to orient the connectors to the rear of the cart (the front of the cart has locking casters).

3. Attach the vertical support pole (2) to the cart base (5) using four acorn nuts (6) with four flat washers (7).
4. Attach the chiller shelf (4) to the support pole (2) using three acorn nuts (6) with three flat washers (7).
5. Attach the generator shelf (3) to the support pole (2) using four acorn nuts (6) with four flat washers (7).
6. Attach the generator (1) to the generator shelf (3) using the four 8-32 x 5/8" long screws (13) with four #8 internal tooth lock washers (15) being sure to orient the rear of the generator to the rear of the cart (the front of the cart has locking casters).
7. Attach the chiller (11) to the chiller shelf (4) using the thumb screw on the rear of the chiller (part of 11) and the two black nylon cinching straps (8).
8. Ensure the AC receptacle on/off switch, located on rear panel of the generator is off (O). Connect the longer of the two power jumper cords (10, 2 meter length) to the generator (1) and route the cable inside of the support pole (2) through the oval opening closest to the top and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
9. Connect the shorter of the two power jumper cords (9, 1.5 meter length) to the chiller (11) and route the cable inside of the support pole (2) through the oval opening just under the chiller shelf (4) and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
10. Connect the AC mains power cable (part of 12) to the isolation transformer (12).
11. Retain all packing materials, tools and manuals.

7.2. SYSTEM SETUP AND WARM-UP

1. Connect the AC mains power cable from the isolation transformer to a properly grounded AC outlet and switch the isolation transformer AC receptacle on/off switch, located on the rear panel, to the on (I) position.
2. Connect the foot switch to the connector labeled "Foot Switch" on the rear panel, if desired.
3. Set the desired power output power by rotating the rotary power knob on the front panel. Power is adjustable over the range from 40 Watts to 100 Watts in 5 Watt increments.
4. Place the Applicator in the holster provided on the front right side of the cart. Connect the microwave cable of the Applicator to the "Microwave Power Output" quick-connect QMA style connector on the front panel of the Generator.
5. Connect the vacuum tubing of the Applicator to the "Vacuum" connector on the front panel of the Generator.
6. Connect the temperature cable of the Applicator to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator.
7. Connect the antenna control cable of the Applicator to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator.
8. Select the desired Applicator antennas by pushing the "Antenna Select" push button switches located at the bottom left corner of the front panel of the Generator.

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9. Connect the cooling flow tubing of the Applicator into the Chiller/Circulator
   a. Connect the "into chiller" tubing into the "flow-in" receptacle of the Chiller/Circulator.
   b. Connect the "out from chiller" tubing into the "flow-out" receptacle of the Chiller/Circulator.
   c. Ensure the applicator fluid tubing is not placed over or on the equipment in order to prevent fluid ingress into the generator, chiller/circulator or isolation transformer, especially when disconnecting the applicator fluid tubing connectors from the chiller/circulator.
   d. Turn on the power to Chiller/Circulator, set the cooling temperature, and run until temperature is stabilized on the applicator cooling fluid temperature readout (depending on the set temperature, this can take up to 30 minutes).
   e. Only use de-ionized water in the Chiller/Circulator. Check the fluid level in the Chiller/Circulator before starting each therapy session. Coolant should be added until the fluid level is visible at the base of the reservoir neck. If the coolant level can be seen lower than halfway down the illuminated fluid level window, more coolant should be added.
10. Turn on the power to the Generator using the switch located on the AC inlet module located on the rear panel of the Generator by switching the on/off switch to the on (I) position.
11. Ensure that the "Start" and "Ready" lights are illuminated, that the two temperature displays show temperatures, that the three timers illuminate, that any selected Applicator "Antenna Switches" are illuminated and that the "Vacuum" gauge shows a vacuum level.
12. Set the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration by pressing the rocker buttons immediately below each digit display on the appropriate timer module and then pressing the reset button on that timer module. Each timer can be set to a time range of 0.00 to 99.99 seconds.
13. **WARNING:** The FAULT LED is illuminated if the system detects a malfunction (see Troubleshooting, section 0).
14. Position the system close to the patient.
15. Ensure all air vents on the equipment are not obstructed.

7.3. OPERATION

1. Confirm that the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration settings on the Timer Controller are correct. If adjustments need to be made for any of the three durations, press the rocker buttons to the desired time on the appropriate timer panel and press the Reset button. ⚠ Important note regarding the Pre-Cool cycle: In order to assess proper tissue acquisition into the Applicator vacuum chamber prior to energy delivery, do not set the Pre-Cool timer to less than 3 seconds.

2. Adjust vacuum control knob to the desired setting. Use the lowest setting necessary to get adequate tissue acquisition into the Applicator vacuum chamber. Note that vacuum will not be applied to the Applicator until the "Start" button is pressed. A vacuum level tissue acquisition test can be performed by setting the "Energy" timer to 0 seconds to confirm that the vacuum level is adequate to engage the tissue in the Applicator.

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3. Place the DTS applicator on the target tissue. **CAUTION**: DO NOT operate if the applicator is not connected or if the applicator is not correctly positioned on the patient. See Applicator Instructions for Use for correct positioning of the applicator on the patient.

4. Push the "START" button on the Generator (or depress the foot switch). An audible buzzer will indicate when microwave energy is being delivered. Another sound (1 second duration) will indicate when the entire therapy cycle has been completed, at which time the vacuum will also be turned off to the Applicator. During the pre cool, energy and post cool cycles, each of the associated timers will count down from the user selected values to zero. If more than one antenna has been selected, the energy timer will count down the number of times that corresponds to the number of antennas selected before transitioning into the post cool cycle.

5. Press the "Stop" switch (or depress the foot switch) to abort the procedure.

6. Repeat steps 1-4 for additional treatments.

7.4. SYSTEM SHUTDOWN PROCEDURE

1. Turn off the power to all of the components of the system.
2. Disconnect the cable plugged into the isolation transformer from the AC mains source and coil cable on back of the Generator shelf.
3. Place foot switch in location provided on back of Generator shelf and coil excess cable on back of Generator shelf.
4. Disconnect DTS Applicator from the Generator and Chiller/Circulator and remove/dry up any fluids that may have dripped out of the tubing or chiller.

8. CLEANING AND MAINTENANCE

8.1. CLEANING

- Components of the DTS G2 cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter connectors on Generator.
- Make sure power to the DTS G2 components are turned OFF and the power cord unplugged before cleaning.
- Do not spray or pour cleaning agents or any other liquids on the DTS G2 components.
- Dampen a clean dry cloth with a multi-purpose hospital grade detergent.
- Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into the housing or electrical components.
- Gently dry the entire Generator, including cords.
- Do not soak any of the cords or cables, especially the connectors, since this can affect electrical performance.

8.2. STORAGE

The DTS G2 system components should be stored in a cool, dry place out of direct sunlight.

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8.3. SERVICE INFORMATION

The DTS G2 has been Manufacturer tested. There are no serviceable parts inside the DTS G2 components. Contact Miramar Labs for service.

9. HOW SUPPLIED

The Miramar Labs DTS G2 is supplied with the following components:

9.1. DESCRIPTION OF DTS G2 COMPONENTS

Item	Description	Qty
1	DTS G2 Generator User Manual (this document)	1
2	DTS G2 Generator	1
3	Nanotherm Chiller/Circulator and User Manual	1
4	Isolation Transformer	1
5	Cart (assembly required, see section 8.1)	1
6	Various cables and adapters, foot switch	As Required

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10. TROUBLESHOOTING GUIDE

Problem	Troubleshooting Tips
No, or irregular system operation or no power.	1. Ensure that power switches of the isolation transformer, Generator and Chiller are all turned on (I). 2. Ensure that power cords from Generator and Chiller are plugged into the isolation transformer. 3. Ensure that the isolation transformer is plugged into a proper electrical outlet matching its electrical specification. 4. Ensure that fuses in isolation transformer, Generator and Chiller are intact and have Miramar Labs personnel replace fuses if needed (see How to Change Fuses, section 2.3). 5. If problem persists, contact Miramar Labs representative.
Red "Fault" light on right side of Generator front panel is illuminated; preventing initiation of therapy cycle with the "Start" button.	1. Ensure that the antenna control cable of the applicator is properly connected to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Ensure that the temperature cable of the applicator is properly connected to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator.. 7. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates immediately after initiation of therapy cycle with the "Start" button.	1. Ensure that the chiller temperature is set properly. 2. Ensure that the chiller is not in standby mode. 3. Ensure that the coolant level in the chiller is adequate. 4. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 5. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 6. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates during the energy delivery cycle and the energy delivery cycle terminates prematurely	1. Ensure that the microwave cable of the Applicator is properly connected to the QMA quick-connect "Microwave Power Output" connector on the front panel of the Generator. Turn the generator power off and back on. After the connector has been properly connected and after the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Check the Applicator for any visible indication of a damaged or kinked microwave cable and replace Applicator if damage is suspected. Turn the generator power off and back on. After the applicator microwave cable has been checked or the applicator has been replaced (if needed) and the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 7. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. If problem persists, contact a Miramar Labs representative.

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11. SPECIFICATIONS

Dimensions	40" H x 25" W x 25" D
Weight	125 lbs
AC input voltage	100-115V AC, 60 Hz
Protection	Protectively earthed, Class I
Microwave Output Frequency	5800MHz ± 50 MHz
Microwave Output Power	Adjustable from 40 to 100 Watts in 5 Watt increments
Integrated Vacuum setting range	0 to -28 inHg
Timer setting range	Pre-Cool 0 – 99.99 sec Energy 0 – 9.999 sec Post-Cool 0 – 99.99 sec
Patient Isolation	Class BF (body floating) for applied parts
Duty Cycle	Continuous
Environmental Operating Temperature/Humidity	Ambient Temperature: +60˚F to +80˚F (+16˚C to+26˚C) Relative Humidity (Non-condensing): 30% - 60%
Environmental Storage/Shipping Temperature/Humidity	Ambient Temperature: 0˚C to +50˚C Relative Humidity (Non-condensing): 20% to 85%
CONFORMS TO	Safety: UL 60601-1 Issued:2006/04/26 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety CSA C22.2#601.1 Issue:1990/01/11 (R2005) Medical Electrical Equipment - Part 1: General Requirements for Safety-General Instruction No 1; Update No 2 IEC 60601-1 Issue: 1998 + A1:1991 + A2: 1995. Medical Electrical Equipment Part 1: General Requirements for Safety EMC: IEC 60601-1-2 Issued:2004/11/01 Ed:2.1 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests-Edition 2.1; Consolidated Reprint –

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Manufactured by:

Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park
CA 94025
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

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miramarlabs

DTS G2 Generator

User Manual

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1. CONTACT INFORMATION

Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park
CA 94025
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

1.1. EXPLANATION OF SYMBOLS

	Attention: See user manual for additional information Service By Qualified Personnel Only
	Fuse
	Type BF (Body Floating) Applied Part
LOT	Serial Number
	On (Main Power)
	Off (Main Power)
	Start
	Stop
	Non-Ionizing Radiation
	Timer
	Temperature
	Equipotential ground connection
	Manufacturer
	Date of Manufacture
	Waste electrical and electronic equipment

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2. SYSTEM DESCRIPTION

The Miramar Labs DTS G2 Generator is designed to deliver precise amounts of microwave energy to soft tissue while providing the ability to protect the tissue surface with an active contact cooling system. Microwave energy up to 100 Watts at 5.8 GHz can be generated and a portion of that delivered to the target tissue via specially designed Applicators.

The DTS G2 System consists of the following major components:

1. DTS Applicator
2. DTS G2 Generator
3. NanoTherm Chiller/Circulator (from ThermoTek)
4. Isolation Transformer
5. Mobile Cart (not shown in Figure 1)
6. Foot Switch (not shown in Figure 1)

See Figure 1 for basic block diagram of how the components of the system are connected. A brief description of each component is given below.

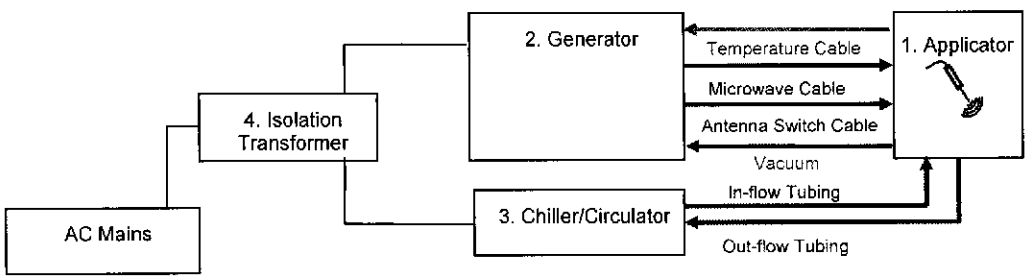

Figure 1. Block diagram of DTS G2 system components.

The Applicator has microwave antennas, a tissue acquisition vacuum chamber, and a surface cooling plate with a flow channel. The Applicator is connected as shown in Figure 1 to the two components of the DTS G2 System that provide the required functions - the Generator and the Chiller/Circulator.

The Generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, a power supply, microwave module and the front panel/control board assembly. There is also an integrated vacuum pump that provides suction (up to -28 in Hg) to the Applicator to facilitate tissue acquisition. See the next section for a detailed description of the control/display functions of the Generator.

The Chiller/Circulator provides the circulating cooling fluid that is flowing through the Applicator to prevent or minimize the thermal damage to the surface of the target tissue, if desired by the user. The Chiller/Circulator is manufactured by ThermoTek, Inc. See the NanoTherm User Manual for instructions on how to set Chiller temperature and flow.

The Isolation Transformer is an off-the-shelf component that provides protection for the patient by eliminating hazardous potential voltage differences as well as preventing hazardous levels of leakage currents between patient contact elements of the system and the AC mains.

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2.1. FRONT PANEL DISPLAY AND CONTROL FEATURES

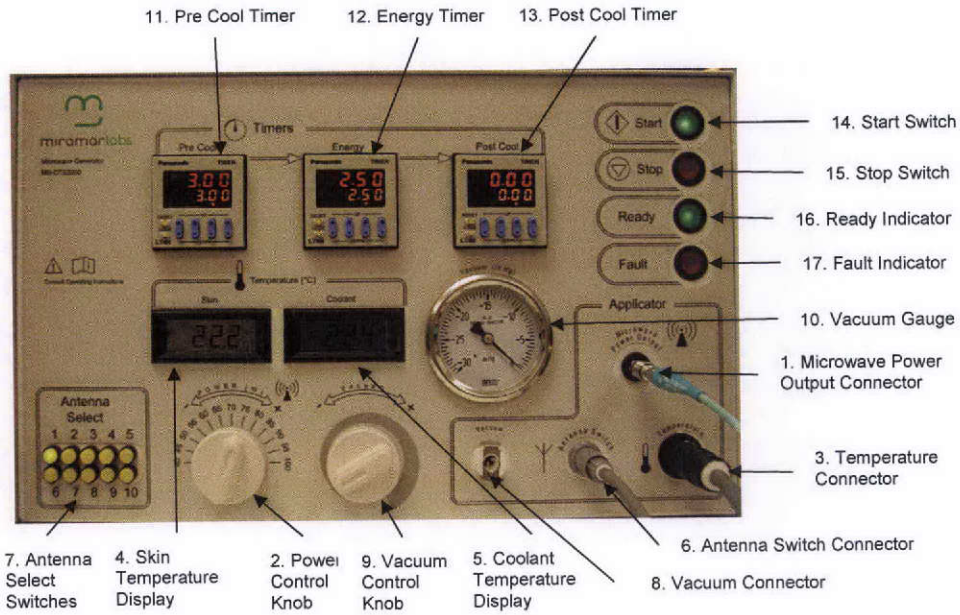

Figure 2. Generator Front Panel

1. Microwave Power Output Connector
   The Generator provides microwave power to the antennas via a coaxial QMA-type connector. The coaxial microwave cable of the Applicator is connected to this connector.

2. Power Control Knob
   A control knob on the front panel of the Generator provides the user with the ability to adjust the amount of power delivered to the Applicator.

3. Temperature Connector
   A temperature monitoring system inside the Generator provides continuous temperature monitoring of the cooling fluid line at a location inside the applicator. A second temperature monitoring system inside the Generator provides temperature monitoring of the thermocouples on the cooling plate of the Applicator between each antenna and the surface of the target tissue. This temperature monitoring is automatically switched between each of the thermocouples on the cooling plate of the applicator in coordination with automated antenna switching to provide the skin/cooling plate interface temperature associated with the active antenna.

4. Skin Temperature Display
   The skin/cooling plate interface temperature associated with the active antenna is displayed on the front panel of the Generator (°C).

5. Coolant Temperature Display
   The coolant temperature measured within the Applicator is displayed on the front panel of the Generator (°C).

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6. Antenna Switch Connector
   The antenna switch connector of the Applicator is connected on the front panel of the Generator to allow switching between antennas in Applicators that have more than one antenna.

7. Antenna Select Switches
   The user can activate one or more of the antennas (if more than one is available on a given Applicator) by pressing the appropriate antenna select switches on the front panel of the Generator. If more than one antenna is selected, the Generator will automatically deliver the energy for the set energy duration time to each of the antennas in a sequential fashion. The activation of multiple antennas enables the creation of a larger zone of heating.

8. Vacuum Connector
   A vacuum pump inside the Generator provides vacuum for tissue acquisition into the Applicator.

9. Vacuum Control Knob
   The vacuum level can be controlled by a knob on the front panel of the Generator.

10. Vacuum Gauge
    The vacuum gauge on the front panel of the Generator displays the vacuum level to the user.

11. Pre Cool Timer
    The Generator pre cool timer allows the user to set the pre-cool duration (sec).

12. Energy Timer
    The Generator energy timer allows the user to set the energy delivery duration (sec).

13. Post Cool Timer
    The Generator post cool timer allows the user to set the post-cool duration (sec).

14. Start Switch
    The pre-cool, energy delivery, and post-cool sequence shall commence upon pressing the start button. The start button is enabled when the generator Ready Indicator is illuminated.

15. Stop Switch
    The stop button can be used to abort the sequence at any time.

16. Ready Indicator
    The Ready Indicator will be illuminated when the AC mains power is turned on and no fault conditions exist.

17. Fault Indicator
    The Fault Indicator will be illuminated when a fault condition exists. Refer to Section 10 Troubleshooting Guide for details on potential fault modes and potential resolutions.

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2.2. REAR PANEL FEATURES

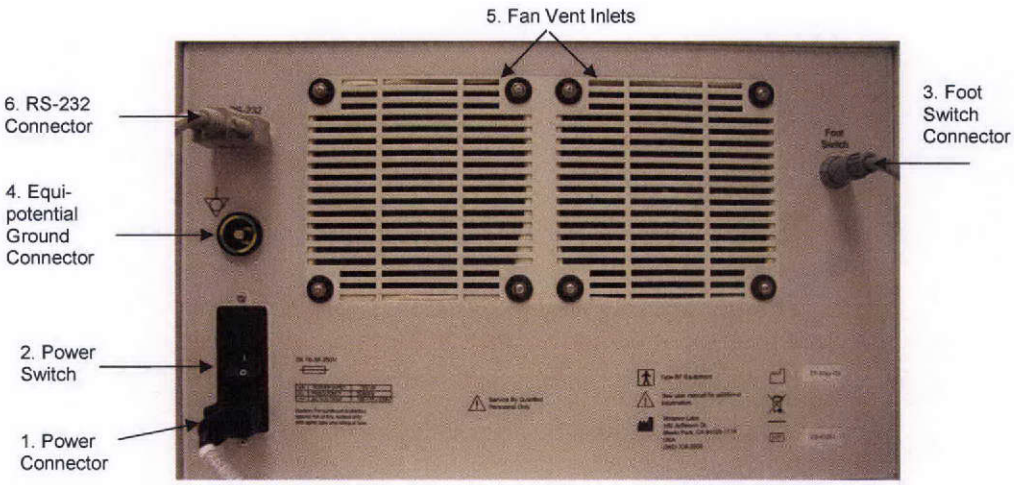

Figure 3. Generator Rear Panel

1. Power Connector
   AC mains power cord connection. This receptacle contains the Generator fuses just above the Power Switch (See instructions on How to Change the Fuses, section 2.3).

2. Power Switch
   AC mains power switch

3. Foot Switch Connector
   The Start/Stop function (as described on the Generator front-panel control) can be controlled by a foot switch (provided) that is connected to the rear panel.

4. Equipotential Ground Connector
   Use the equipotential ground connector for grounding to ensure that the generator is at the same ground potential as other equipment in the vicinity.

5. Fan Vent Inlets
   Vents allow the fans to draw ambient cooling air into the Generator. Do not block these vents to ensure proper cooling of the Generator.

6. RS-232 Connector
   The Generator provides the following data output through an RS-232 connection: antenna(s) selected, set power, actual forward power, reverse power, skin/cooling plate interface temperature (associated with the active antenna) and coolant temperature during energy delivery. This data can be collected through data acquisition devices (i.e. data-logger).

2.3. HOW TO CHANGE THE FUSES

CAUTION: Do not use repaired fuses or short-circuited fuse holders.

There are fuses in the power entry modules of the Generator, Chiller/Circulator and Isolation Transformer.

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Only use standard fuses, 2 each, current rated T6.3A/250 V @ 100-115 V ~ in the Generator.

Only use standard fuses, current rated T7A/250 V @ 100-115 V ~ in the Chiller/Circulator.

Only use standard fuses, current rated T10A/250 V @ 100-115 V ~ in the Isolation Transformer.

1. Ensure the generator, chiller and isolation transformer power switches are in the OFF (0) position.
2. Unplug the system power cord at the isolation transformer from the AC mains at the power outlet.
3. Snap the A/C RECEPTACLE-ON/OFF switch cap open by placing a flat screwdriver in the pre-marked slot located on top of the switch.
4. Remove fuses from either side of the holder and replace with standard time delay fuses, current rated T6.3A/250 V @ 100-120 V ~ for the generator, T7A/250 V @ 100-120 V ~ for the chiller/circulator, T10A/250 V @ 100-120 V ~ for the isolation transformer.
5. Replace holder and snap the cap closed.

3. CAUTIONS

Federal US law restricts this device to sale by or on the order of a licensed physician.

CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.

4. INDICATIONS FOR USE

The DTSG2 System is indicated for use for coagulation of soft tissue.

5. CONTRAINDICATIONS

The DTS G2 System is contraindicated for patients with heart pacemakers and other electronic device implants.

6. WARNINGS AND PRECAUTIONS

- Carefully read the User Manuals for the Miramar Labs DTS G2 Generator and the Nanotherm Chiller/Circulator, and the Applicator IFU prior to use. Observe all warnings and precautions. Failure to do so may result in complications.
- The DTS G2 is for use by qualified clinical personnel who have been instructed and trained in the correct use of the equipment by designated Company representatives.
- Safety of the DTS G2 has not been evaluated on patients with cardiac pacemakers or other electronic implants. The DTS G2 system should not be used on such patients.

Deleted: The Dermatologic Treatment System (DTS) G2 is indicated for use in the reduction of sweat production associated with axillary hyperhidrosis and the reduction of axillary hair. This device is under investigation, and clinical data to support this indication has not been collected.¶

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Deleted: <#>POTENTIAL ADVERSE EVENTS¶ Potential adverse events could include, but are not limited to: abcess formation, skin ulcer formation, motion limitation, hyper/hypo-pigmentation, skin burns/scars, skin dryness, and numbness/tingling.¶

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- Operate the DTS G2 in environmental temperatures between 16°C and 26°C (60°F and 80°F); and between 30% and 60% relative humidity (non-condensing).
- Use only the components and parts supplied by Miramar Labs.
- DO NOT attempt to repair or alter any of the System components.
- DO NOT allow fluid to contact generator, cables or connectors unless the generator is being cleaned. Do not hang fluids above the generator. The generator may not function correctly if the electronic circuitry or the connectors are wet. Do not soak cables.
- DO NOT operate if wet. Electrical shock may occur.
- DO NOT operate if there is no Applicator connected or if the Applicator is not positioned at the intended target site. See Applicator IFU for proper positioning of the applicator.
- Clean, disinfect, and maintain the electrical units in accordance with the operating instructions.
- Turn the electrical units Off using the main power On/Off switch and disconnect the power cord from the AC supply before cleaning.
- DO NOT remove the cover of any of the system components. There are no user-serviceable parts inside the components of the DTS G2. Opening the cover of any of the DTS G2 components may result in electrical shock or thermal burns.
- For warnings and precautions associated with the chiller portion of the DTS G2, see the NanoTherm Industrial User Manual. Also read the Applicator IFU.
- This equipment/system is intended for use by healthcare professionals only. The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Provide as much distance as possible between the DTS G2 and other electronic equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interteference. It may be necessary to take mitigation measures, such as reorientating or relocating the Generator or shielding the location.
- The DTS G2 should not be used or pause/terminate therapy cycle when the temperature shows abnormal fluctuations.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- Electrosurgical components, such as the Applicator, may remain hot after activation. Keep all electrosurgical equipment away from flammable materials to avoid combustion.

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- Prolonged or unneccessary activation of the DTS G2 may lead to unintentional damage to surrounding tissue.
- The output power selected should be as low as possible for the intended purpose.
- Do not obstruct the activation light or tone. The activation tone and light are important safety features.
- Use only Miramar Labs Applicators designed to be used with the DTS G2 Generator.
- Do not bend cables at acute angles or coil them tightly; the cable might break.
- The main power cord of the Isolation Transformer must be connected to a properly grounded receptacle. Extension cords and/or adaptor plugs must not be used. Plug equipment into 100-115V AC 60 Hz power receptacles.

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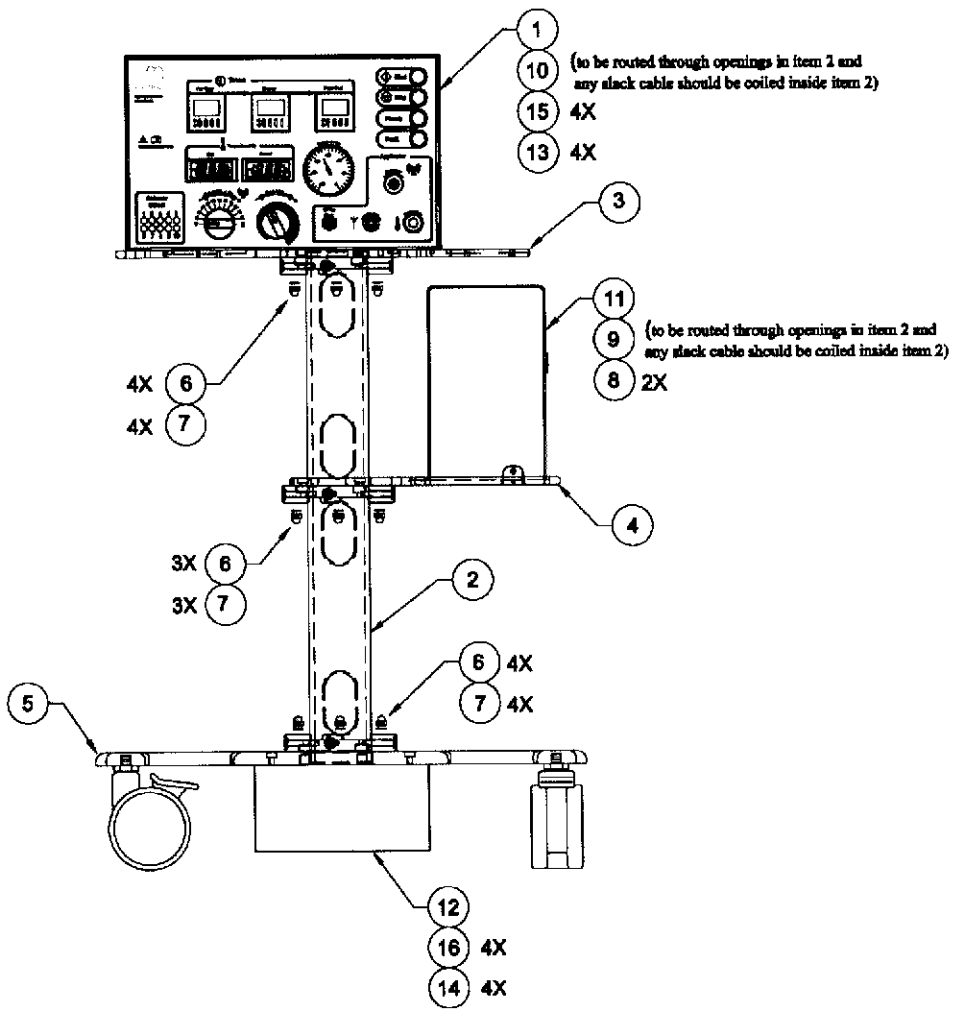
7. OPERATING INSTRUCTIONS

7.1. UNPACKING AND EQUIPMENT SET-UP

- Open each of the four cases containing the cart, generator, chiller, isolation transformer and miscellaneous cables, hardware, tools and manuals and remove the contents. Inspect all components for shipping damage. If damage has occurred, contact Miramar Labs. Verify all components are present (see section 9).

1. Refer to figure 3 below for remainder of set-up.

Figure 3. Equipment Set-up



2. Attach the isolation transformer (12) to the bottom of the cart base (5) using the four 10-32 x 5/8" long screws (14) with four #10 internal tooth lock washers (16)

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being sure to orient the connectors to the rear of the cart (the front of the cart has locking casters).

3. Attach the vertical support pole (2) to the cart base (5) using four acorn nuts (6) with four flat washers (7).
4. Attach the chiller shelf (4) to the support pole (2) using three acorn nuts (6) with three flat washers (7).
5. Attach the generator shelf (3) to the support pole (2) using four acorn nuts (6) with four flat washers (7).
6. Attach the generator (1) to the generator shelf (3) using the four 8-32 x 5/8" long screws (13) with four #8 internal tooth lock washers (15) being sure to orient the rear of the generator to the rear of the cart (the front of the cart has locking casters).
7. Attach the chiller (11) to the chiller shelf (4) using the thumb screw on the rear of the chiller (part of 11) and the two black nylon cinching straps (8).
8. Ensure the AC receptacle on/off switch, located on rear panel of the generator is off (O). Connect the longer of the two power jumper cords (10, 2 meter length) to the generator (1) and route the cable inside of the support pole (2) through the oval opening closest to the top and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
9. Connect the shorter of the two power jumper cords (9, 1.5 meter length) to the chiller (11) and route the cable inside of the support pole (2) through the oval opening just under the chiller shelf (4) and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
10. Connect the AC mains power cable (part of 12) to the isolation transformer (12).
11. Retain all packing materials, tools and manuals.

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7.2. SYSTEM SETUP AND WARM-UP

1. Connect the AC mains power cable from the isolation transformer to a properly grounded AC outlet and switch the isolation transformer AC receptacle on/off switch, located on the rear panel, to the on (I) position.
2. Connect the foot switch to the connector labeled "Foot Switch" on the rear panel, if desired.
3. Set the desired power output power by rotating the rotary power knob on the front panel. Power is adjustable over the range from 40 Watts to 100 Watts in 5 Watt increments.
4. Place the Applicator in the holster provided on the front right side of the cart. Connect the microwave cable of the Applicator to the "Microwave Power Output" quick-connect QMA style connector on the front panel of the Generator.
5. Connect the vacuum tubing of the Applicator to the "Vacuum" connector on the front panel of the Generator.
6. Connect the temperature cable of the Applicator to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator.
7. Connect the antenna control cable of the Applicator to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator.
8. Select the desired Applicator antennas by pushing the "Antenna Select" push button switches located at the bottom left corner of the front panel of the Generator.

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9. Connect the cooling flow tubing of the Applicator into the Chiller/Circulator
   a. Connect the "into chiller" tubing into the "flow-in" receptacle of the Chiller/Circulator.
   b. Connect the "out from chiller" tubing into the "flow-out" receptacle of the Chiller/Circulator.
   c. Ensure the applicator fluid tubing is not placed over or on the equipment in order to prevent fluid ingress into the generator, chiller/circulator or isolation transformer, especially when disconnecting the applicator fluid tubing connectors from the chiller/circulator.
   d. Turn on the power to Chiller/Circulator, set the cooling temperature, and run until temperature is stabilized on the applicator cooling fluid temperature readout (depending on the set temperature, this can take up to 30 minutes).
   e. Only use de-ionized water in the Chiller/Circulator. Check the fluid level in the Chiller/Circulator before starting each therapy session. Coolant should be added until the fluid level is visible at the base of the reservoir neck. If the coolant level can be seen lower than halfway down the illuminated fluid level window, more coolant should be added.
10. Turn on the power to the Generator using the switch located on the AC inlet module located on the rear panel of the Generator by switching the on/off switch to the on (I) position.
11. Ensure that the "Start" and "Ready" lights are illuminated, that the two temperature displays show temperatures, that the three timers illuminate, that any selected Applicator "Antenna Switches" are illuminated and that the "Vacuum" gauge shows a vacuum level.
12. Set the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration by pressing the rocker buttons immediately below each digit display on the appropriate timer module and then pressing the reset button on that timer module. Each timer can be set to a time range of 0.00 to 99.99 seconds.
13. **WARNING:** The FAULT LED is illuminated if the system detects a malfunction (see Troubleshooting, section 0).
14. Position the system close to the patient.
15. Ensure all air vents on the equipment are not obstructed.

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7.3. OPERATION

1. Confirm that the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration settings on the Timer Controller are correct. If adjustments need to be made for any of the three durations, press the rocker buttons to the desired time on the appropriate timer panel and press the Reset button. ⚠ Important note regarding the Pre-Cool cycle: In order to assess proper tissue acquisition into the Applicator vacuum chamber prior to energy delivery, do not set the Pre-Cool timer to less than 3 seconds.

2. Adjust vacuum control knob to the desired setting. Use the lowest setting necessary to get adequate tissue acquisition into the Applicator vacuum chamber. Note that vacuum will not be applied to the Applicator until the "Start" button is pressed. A vacuum level tissue acquisition test can be performed by setting the "Energy" timer to 0 seconds to confirm that the vacuum level is adequate to engage the tissue in the Applicator.

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3. Place the DTS applicator on the target tissue. **CAUTION**: DO NOT operate if the applicator is not connected or if the applicator is not correctly positioned on the patient. See Applicator Instructions for Use for correct positioning of the applicator on the patient.

4. Push the "START" button on the Generator (or depress the foot switch). An audible buzzer will indicate when microwave energy is being delivered. Another sound (1 second duration) will indicate when the entire therapy cycle has been completed, at which time the vacuum will also be turned off to the Applicator. During the pre cool, energy and post cool cycles, each of the associated timers will count down from the user selected values to zero. If more than one antenna has been selected, the energy timer will count down the number of times that corresponds to the number of antennas selected before transitioning into the post cool cycle.

5. Press the "Stop" switch (or depress the foot switch) to abort the procedure.

6. Repeat steps 1-4 for additional treatments.

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7.4. SYSTEM SHUTDOWN PROCEDURE

1. Turn off the power to all of the components of the system.
2. Disconnect the cable plugged into the isolation transformer from the AC mains source and coil cable on back of the Generator shelf.
3. Place foot switch in location provided on back of Generator shelf and coil excess cable on back of Generator shelf.
4. Disconnect DTS Applicator from the Generator and Chiller/Circulator and remove/dry up any fluids that may have dripped out of the tubing or chiller.

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8. CLEANING AND MAINTENANCE

8.1. CLEANING

- Components of the DTS G2 cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter connectors on Generator.
- Make sure power to the DTS G2 components are turned OFF and the power cord unplugged before cleaning.
- Do not spray or pour cleaning agents or any other liquids on the DTS G2 components.
- Dampen a clean dry cloth with a multi-purpose hospital grade detergent.
- Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into the housing or electrical components.
- Gently dry the entire Generator, including cords.
- Do not soak any of the cords or cables, especially the connectors, since this can affect electrical performance.

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8.2. STORAGE

The DTS G2 system components should be stored in a cool, dry place out of direct sunlight.

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8.3. SERVICE INFORMATION

The DTS G2 has been Manufacturer tested. There are no serviceable parts inside the DTS G2 components. Contact Miramar Labs for service.

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9. HOW SUPPLIED

The Miramar Labs DTS G2 is supplied with the following components:

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9.1. DESCRIPTION OF DTS G2 COMPONENTS

Item	Description	Qty
1	DTS G2 Generator User Manual (this document)	1
2	DTS G2 Generator	1
3	Nanotherm Chiller/Circulator and User Manual	1
4	Isolation Transformer	1
5	Cart (assembly required, see section 8.1)	1
6	Various cables and adapters, foot switch	As Required

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10. TROUBLESHOOTING GUIDE

Problem	Troubleshooting Tips
No, or irregular system operation or no power.	1. Ensure that power switches of the isolation transformer, Generator and Chiller are all turned on (I). 2. Ensure that power cords from Generator and Chiller are plugged into the isolation transformer. 3. Ensure that the isolation transformer is plugged into a proper electrical outlet matching its electrical specification. 4. Ensure that fuses in isolation transformer, Generator and Chiller are intact and have Miramar Labs personnel replace fuses if needed (see How to Change Fuses, section 2.3). 5. If problem persists, contact Miramar Labs representative.
Red "Fault" light on right side of Generator front panel is illuminated; preventing initiation of therapy cycle with the "Start" button.	1. Ensure that the antenna control cable of the applicator is properly connected to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Ensure that the temperature cable of the applicator is properly connected to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 7. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates immediately after initiation of therapy cycle with the "Start" button.	1. Ensure that the chiller temperature is set properly. 2. Ensure that the chiller is not in standby mode. 3. Ensure that the coolant level in the chiller is adequate. 4. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 5. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 6. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates during the energy delivery cycle and the energy delivery cycle terminates prematurely	1. Ensure that the microwave cable of the Applicator is properly connected to the QMA quick-connect "Microwave Power Output" connector on the front panel of the Generator. Turn the generator power off and back on. After the connector has been properly connected and after the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Check the Applicator for any visible indication of a damaged or kinked microwave cable and replace Applicator if damage is suspected. Turn the generator power off and back on. After the applicator microwave cable has been checked or the applicator has been replaced (if needed) and the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 7. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. If problem persists, contact a Miramar Labs representative.

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11. SPECIFICATIONS

Dimensions	40" H x 25" W x 25" D
Weight	125 lbs
AC input voltage	100-115V AC, 60 Hz
Protection	Protectively earthed, Class I
Microwave Output Frequency	5800MHz ± 50 MHz
Microwave Output Power	Adjustable from 40 to 100 Watts in 5 Watt increments
Integrated Vacuum setting range	0 to -28 inHg
Timer setting range	Pre-Cool 0 – 99.99 sec Energy 0 – 9.999 sec Post-Cool 0 – 99.99 sec
Patient Isolation	Class BF (body floating) for applied parts
Duty Cycle	Continuous
Environmental Operating Temperature/Humidity	Ambient Temperature: +60˚F to +80˚F (+16˚C to+26˚C) Relative Humidity (Non-condensing): 30% - 60%
Environmental Storage/Shipping Temperature/Humidity	Ambient Temperature: 0˚C to +50˚C Relative Humidity (Non-condensing): 20% to 85%
CONFORMS TO	Safety: UL 60601-1 Issued:2006/04/26 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety CSA C22.2#601.1 Issue:1990/01/11 (R2005) Medical Electrical Equipment - Part 1: General Requirements for Safety-General Instruction No 1; Update No 2 IEC 60601-1 Issue: 1998 + A1:1991 + A2: 1995. Medical Electrical Equipment Part 1: General Requirements for Safety EMC: IEC 60601-1-2 Issued:2004/11/01 Ed:2.1 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests-Edition 2.1; Consolidated Reprint –

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Product under Evaluation: DTS G2 System for soft tissue coagulation

Item #	HAZARD Failure Mode (what can go wrong during usage?)	Root CAUSE of Failure Mode (what is likely root cause of the hazard?)	EFFECT of Failure Mode (what will the hazard do to user, patient, or environment?)	Severity (S)	Control(s) Implemented	Probability (P)	Risk Rating	ALARP limit	Intol. Limit	Planned Control(s) or Recommended Improvements	Method for Verifying Effectiveness of Implemented Control(s)	ALARP Justification
SYSTEM OPERATION and POWER DELIVERY												
1	Insufficient or no target tissue coagulation	Fault in timer state machine circuitry that causes insufficient delivery time	physician annoyance	2	Robust circuit design with robust fault detection and control logic	1	2	4	10	N/A	design verification testing	N/A
2	Insufficient or no target tissue coagulation	Fault in fault logic that causes insufficient delivery time	physician annoyance	2	Robust circuit design with robust fault detection and control logic	1	2	4	10	N/A	design verification testing	N/A
3	Insufficient or no target tissue coagulation	Fault in PWM state machine that causes insufficient power level	physician annoyance	2	Robust circuit design with robust fault detection and control logic	1	2	4	10	N/A	design verification testing	N/A
4	Insufficient or no target tissue coagulation	Fault in control logic that causes insufficient delivery time	physician annoyance	2	Robust circuit design with robust fault detection and control logic	1	2	4	10	N/A	design verification testing	N/A
5	tissue coagulation beyond the intended zone	Fault in timer state machine circuitry that causes excess delivery time	Thermal injury to non target tissue due to conduction of heat to areas outside the intended zone	4	Robust circuit design with robust fault detection and control logic	1	4	4	12	N/A	design verification testing	N/A
6	tissue coagulation beyond the intended zone	Fault in fault logic that causes excess delivery time	Thermal injury to non target tissue due to conduction of heat to areas outside the intended zone	4	Robust circuit design with robust fault detection and control logic	1	4	4	12	N/A	design verification testing	N/A
7	tissue coagulation beyond the intended zone	Fault in PWM state machine that causes excess power level	Thermal injury to non target tissue due to conduction of heat to areas outside the intended zone	4	Robust circuit design with robust fault detection and control logic	1	4	4	12	N/A	design verification testing	N/A
8	tissue coagulation beyond the intended zone	Fault in control logic that causes excess delivery time	Thermal injury to non target tissue due to conduction of heat to areas outside the intended zone	4	Robust circuit design with robust fault detection and control logic	1	4	4	12	N/A	design verification testing	N/A
9	Insufficient or no target tissue coagulation	Power measurement circuitry fault that causes insufficient energy delivery	physician annoyance	2	Robust circuit design with robust fault detection and control logic, calibration accuracy, Forward power threshold fault detection and control circuit halts energy if the forward power is too low and energy is stopped when timer countdown is complete	1	2	4	10	N/A	design verification testing, system calibrated during manufacture to test operation of forward power detector reading and error flag, Output power verified during calibration.	N/A

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Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Product under Evaluation: DTS G2 System for soft tissue coagulation

Item #	**HAZARD** Failure Mode (what can go wrong during usage?)	Root **CAUSE** of Failure Mode (what is likely root cause of the hazard?)	**EFFECT** of Failure Mode (what will the hazard do to user, patient, or environment?)	Severity (S)	Control(s) Implemented	Probability (P)	Risk Rating	ALARP limit	Intol. Limit	Planned Control(s) or Recommended Improvements	Method for Verifying Effectiveness of Implemented Control(s)	ALARP Justification
10	Insufficient or no target tissue coagulation	Power control circuitry fault that causes insufficient energy delivery	physician annoyance	2	Robust circuit design with robust fault detection and control logic, calibration accuracy, Forward power threshold fault detection and control circuit halts energy if the forward power is too low and energy is stopped when timer countdown is complete	1	2	4	10	N/A	design verification testing, system calibrated during manufacture to test operation of forward power detector reading and error flag, Output power verified during calibration.	N/A
11	tissue coagulation beyond the intended zone	Power measurement circuitry fault that causes excess energy delivery	Thermal injury to non target tissue due to penetration of heat to areas outside the intended zone	4	Robust circuit design with robust fault detection and control logic, calibration accuracy, Forward power threshold fault detection and control circuit halts energy if the forward power is too high and energy is stopped when timer countdown is complete	1	4	4	12	N/A	design verification testing, system calibrated during manufacture to test operation of forward power detector reading and error flag, Output power verified during calibration.	N/A
12	tissue coagulation beyond the intended zone	Power control circuitry fault that causes excess energy delivery	Thermal injury to non target tissue due to penetration of heat to areas outside the intended zone	4	Robust circuit design with robust fault detection and control logic, calibration accuracy, Forward power threshold fault detection and control circuit halts energy if the forward power is too high and energy is stopped when timer countdown is complete	1	4	4	12	N/A	design verification testing, system calibrated during manufacture to test operation of forward power detector reading and error flag, Output power verified during calibration.	N/A
13	Insufficient or no target tissue coagulation	Reverse power measurement circuitry fault that results in artificially low reading due to phase cancellation at the detector that causes insufficient energy delivery, causes failure of safety reverse shut off	physician annoyance	2	Robust circuit design with robust fault detection and control logic, calibration accuracy, provide sensing circuit on the tuning voltage line	1	2	4	10	N/A	design verification testing, system calibrated with a spectrum analyzer during manufacture to demonstrate specified output frequency response	N/A
14	Insufficient or no target tissue coagulation	Frequency generation circuitry creates an incorrect frequency that the antenna cannot couple	physician annoyance	2	Robust circuit design with robust fault detection and control logic, calibration accuracy. The band-pass filter does not pass out of band frequencies to the amplifier. Forward power detector will shut down the system if the forward power is too low	1	2	4	10	N/A	design verification testing, system calibrated during manufacture to test operation of forward power detector reading and error flag, System calibrated with a spectrum analyzer during manufacture to demonstrate specified output frequency response	N/A

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Product under Evaluation: DTS G2 System for soft tissue coagulation

Item #	HAZARD Failure Mode (what can go wrong during usage?)	Root CAUSE of Failure Mode (what is likely root cause of the hazard?)	EFFECT of Failure Mode (what will the hazard do to user, patient, or environment?)	Severity (S)	Control(s) Implemented	Probability (P)	Risk Rating	ALARP limit	Intol. Limit	Planned Control(s) or Recommended Improvements	Method for Verifying Effectiveness of Implemented Control(s)	ALARP Justification
15	Interference with other equipment in lab	Excessive electromagnetic emissions causing interference with other equipment	Electromagnetic interference could cause other equipment to function improperly	2	Electromagnetically sealed enclosure design and filter circuitry	1	2	4	10	N/A	design verification testing, electromagnetic compatibility testing to established standards	N/A
16	Electrical shock - patient	Failure of electrical insulation barriers in components electrically connected to the applicator	electrical shock	3	Component selection and use of double insulation barriers on all high voltage components and wiring, isolation circuitry to provide low leakage current	1	3	3	12	N/A	design verification testing, leakage current and hipot testing in production	N/A
17	Electrical shock - user	Failure of electrical insulation barriers in components electrically connected to the applicator	electrical shock	3	Component selection and use of double insulation barriers on all high voltage components and wiring, isolation circuitry to provide low leakage current	1	3	3	12	N/A	design verification testing, leakage current and hipot testing in production	N/A
NEW - 18	treatment to unintended area	user places applicator in wrong location	thermal injury to non target tissue	4	User training and IFU	2	8	4	12	N/A	validation testing*	Training is only control for inaccurate targeting by the user for general coagulation device
NEW - 19	uneven tissue coagulation	Faults in control logic causes too few antennae to fire	physician annoyance, requires additional treatment to complete treatment area	2	Robust circuit design with robust fault detection and control logic	1	2	4	10	N/A	design verification testing	N/A
NEW - 20	tissue coagulation beyond the intended zone	Faults in control logic causes too many antennae to fire	thermal injury to non target tissue	4	Robust circuit design with robust fault detection and control logic	1	4	4	12	N/A	design verification testing	N/A
NEW - 21	uneven tissue coagulation	Antenna output difference causes uneven heating between different antennae; undertreat	physician annoyance, requires additional treatment to complete treatment area	2	Robust circuit design with robust fault detection and control logic; in-process testing during manufacture	1	2	4	10	N/A	design verification testing	N/A
NEW - 22	uneven tissue coagulation	Antenna output difference causes uneven heating between different antennae; overtreat	thermal injury to non target tissue	4	Robust circuit design with robust fault detection and control logic; in-process testing during manufacture	1	4	4	12	N/A	design verification testing	N/A
NEW - 23	uneven tissue coagulation	Faults in control logic cause a single antenna to fire repetitively	thermal injury to target tissue	4	Robust circuit design with robust fault detection and control logic; in-process testing during manufacture	1	4	4	12	N/A	design verification testing	N/A
NEW - 24	tissue coagulation beyond the intended zone	Faults in control logic causes incorrect antenna to fire	thermal injury to non target tissue	4	Robust circuit design with robust fault detection and control logic; in-process testing during manufacture	1	4	4	12	N/A	design verification testing	N/A
NEW - 25	gaps in intended tissue coagulation zone	Incorrect selection of antennae number by the user - too few antennae	physician annoyance, requires additional treatment to complete treatment area	2	User training and IFU. Visible display on control unit to indicate which antennae are active	2	4	4	10	N/A	design verification testing	N/A

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

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Product under Evaluation: DTS G2 System for soft tissue coagulation

Item #	HAZARD Failure Mode (what can go wrong during usage?)	Root CAUSE of Failure Mode (what is likely root cause of the hazard?)	EFFECT of Failure Mode (what will the hazard do to user, patient, or environment?)	Severity (S)	Control(s) Implemented	Probability (P)	Risk Rating	ALARP limit	Intol. Limit	Planned Control(s) or Recommended Improvements	Method for Verifying Effectiveness of Implemented Control(s)	ALARP Justification
NEW - 26	tissue coagulation beyond the intended zone	Incorrect selection of antennae number by the user - too many antennae	thermal injury to non target tissue	4	User training and IFU. Visible display on control unit to indicate which antennae are active	2	8	4	12	N/A	design verification testing	Training is only control for inaccurate targeting by the user for general coagulation device
NEW - 27	Insufficient treatment	Disposable not fully inserted resulting in ineffective vacuum acquisition	Ineffective or no treatment	2	Visible display on control unit to indicate vacuum - would show problem; training	2	4	4	10	N/A	design verification testing; validation testing*	N/A
NEW - 28	Inconsistent Treatment	No Disposable attached	Inconsistent (lower) delivery of energy because of lack of vacuum acquisition of tissue	2	User training and IFU	1	2	4	10	N/A	validation testing*	N/A
NEW - 29	Inconsistent Treatment	No Disposable attached	infection	3	User training and IFU	1	3	3	12	N/A	validation testing*	N/A
NEW - 30	Integrity of Disposable Head barrier film compromised	Mishandling of disposable leads to film break	infection	3	User training and IFU	1	3	3	12	N/A	validation testing*	N/A

*** All testing to be completed and passed prior to product distribution**

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

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K082819/S2

February 27, 2008

Copy 2 of 2 (electronic)

FDA CDRH DMC
Received
MAR - 2 2009

Long Chen, PhD
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850
Email: long.chen@fda.hhs.gov

Re: 510(k) Supplement - DTS G2 (K082819/S2) Additional Information

Dear Dr. Chen,

Please see below the Additional Information requested in your email of Dec 2, 2008 and in subsequent email correspondence. Your request is listed below in italics, with our response in normal font.

As permitted by FDA's guidance on the website http://www.fda.gov/cdrh/elecsub.html, one of the copies is supplied as an electronic copy. This letter certifies that the included electronic copy is an exact copy of this submission.

Please let me know if you have any further questions or issues about this information.

Best regards,

Kathy O'Shaughnessy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
Miramar Labs, Inc.

K37

miramar labs
199 Jefferson Drive
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
02/27/2009		K082819

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Miramar Labs, Inc	Establishment Registration Number *(if known)*:		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (650) 326-2656		
Street Address: 199 Jefferson Drive	FAX Number *(including area code)*: (650) 326-3108		
City: Menlo Park	State / Province: California	ZIP/Postal Code: 94025	Country: USA
Contact Name: Kathy O'Shaughnessy			
Contact Title: VP, Clinical and Regulatory	Contact E-mail Address: kathyo@miramarlabs.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics: (301) 443-1090 EF

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

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

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☑ Other Reason *(specify)*:

Additional information submitted for device

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NEY	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072870	1	Microwave Tissue Coagulation System	1	Miramar Labs, Inc. (formerly Foundry Newco X, Inc)
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	DTS G2 System	1	
2		2	
3		3	
4		4	
5		5	

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

1 K072870	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 - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NEY	878.4400	☐ Class I ☑ Class II
Classification Panel: General and Plastic Surgery		☐ Class III ☐ Unclassified

Indications *(from labeling)*

The DTS G2 System is indicated for use for coagulation of soft tissue.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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

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

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number: Pending	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: Miramar Labs, Inc.		Establishment Registration Number: pending		
Division Name *(if applicable)*:		Phone Number *(including area code)*: (650) 326-2656		
Street Address: 199 Jefferson Drive		FAX Number *(including area code)*: (650) 326-3108		
City: Menlo Park		State / Province: California	ZIP/Postal Code: 94025	Country: USA
Contact Name: Kathy O'Shaughnessy	Contact Title: VP, Clinical and Regulatory Affairs		Contact E-mail Address: kathyo@miramarlabs.com	

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number:	☐ Manufacturer ☑ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: Centurion Sterilization Services		Establishment Registration Number: 2032758		
Division Name *(if applicable)*: Tri-State Hospital Supply Corp		Phone Number *(including area code)*: (517) 545-1150		
Street Address: 3173 East 43rd Street		FAX Number *(including area code)*: ( )		
City: Yuma		State / Province: Arizona	ZIP/Postal Code: 85365	Country: USA
Contact Name: Brenda Sparks	Contact Title: Director of Corporate Accounts		Contact E-mail Address: bsparks@tshsc.com	

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

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-2-2	IEC	Medical Electrical Equipment: Part 2-2: Particular Requirements for the safety of high frequency surgical equipment	4th Edition	07/01/2006
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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

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February 27, 2008

Copy 2 of 2 (electronic)

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General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/CDRH
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Rockville, MD 20850
Email: long.chen@fda.hhs.gov

Re: 510(k) Supplement - DTS G2 (K082819/S2) Additional Information

Dear Dr. Chen,

Please see below the Additional Information requested in your email of Dec 2, 2008 and in subsequent email correspondence. Your request is listed below in italics, with our response in normal font.

As permitted by FDA's guidance on the website http://www.fda.gov/cdrh/elecsub.html, one of the copies is supplied as an electronic copy. This letter certifies that the included electronic copy is an exact copy of this submission.

Please let me know if you have any further questions or issues about this information.

Best regards,

Kathy O'Shaughnessy

Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
Miramar Labs, Inc.

miramar labs
199 Jefferson Drive
Menlo Park, CA 94025
P 650 326 2656
F 650 326 3108

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

1) Name of the Device
You have changed the device name from "Dermatologic Treatment System (DTS) G2" to "DTS G2" in this supplement. Please submit a letter to inform FDA such change together with your revised CDRH Premarket Review Submission Cover Sheet.

In our last response (dated Nov 17, 2008) we agreed that we would remove language from our Indications for Use statement regarding "dermatologic treatment". In order to avoid confusion, we therefore changed the name of the device from the "Dermatologic Treatment System (DTS) G2" to simply the "DTS G2 System".

A revised CDRH Premarket Review Submission Cover Sheet is submitted along with this response that contains the following changes (that were described in the previous response):

- revised description of predicate devices (section E on page 3 of Form 3514);
- revised product name (section F on page 3 of Form 3514);
- the revised Indications for Use (section G on page 3 of Form 3514);
- the IEC 60601-2-2 standard that is discussed in this submission is added (section I on page 5 of Form 3514)

All other information provided in the cover sheet remains the same.

2) Maximum Time Setting - Implementation and Verification
In your response to deficiency #4, you stated that you have implemented the change to the system that will limit the maximum time setting to 9.999 seconds instead of the 99.99 seconds proposed in your original submission. However, how the maximum time setting of 9.999 seconds was implemented to mitigate the potential risk of taking a time setting input that is higher than the maximum time setting has not been described. Please describe the details of the implementation of the maximum time setting and provide verification that your implementation has been done correctly.

Miramar Labs follows its Design Control operating procedures to implement such changes to devices.

The following table describes all the changes to implement the new maximum energy timer setting. The change is implemented by using different dip switch settings in the timer module to change the decimal point location. This changes the settings that the user is allowed to set, therefore it is no longer possible to set energy delivery times longer than 9.999 seconds. Note that no changes were needed in other parts of the DTS G2 Generator, e.g. the logic part of the generator.

Figure 1 helps illustrate the change, by showing the energy timer switch in the old configuration with a maximum possible time of 99.99 sec compared to the switch with the change implemented, with the maximum time of 9.999 sec.

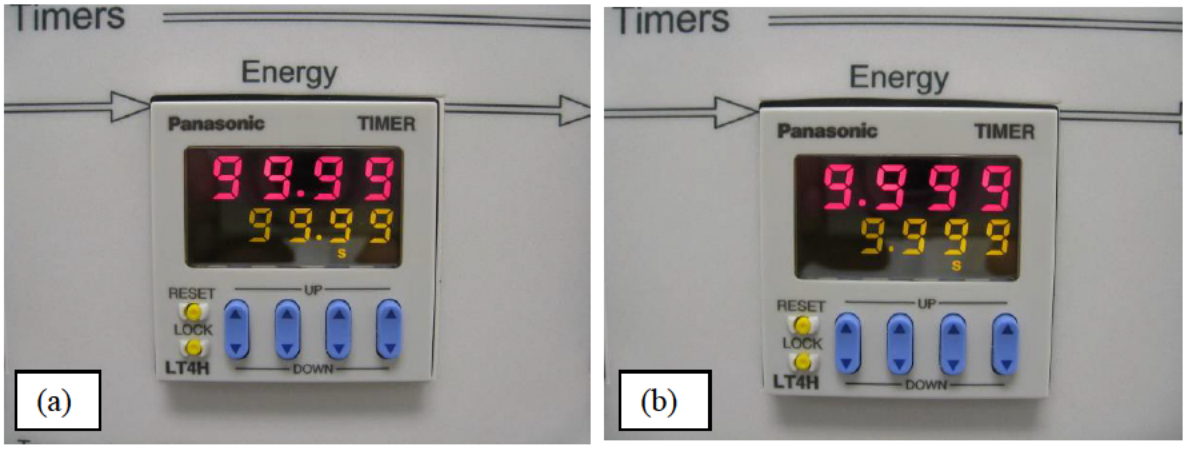

Figure 1. (a) face of timer switch in older configuration allowing maximum of 99.99 seconds (yellow numbers) showing time that has run to 99.99 seconds (red numbers); (b) face of timer switch with new configuration. Maximum time that can be set is 9.999 seconds

Document name and number	Change description
Revise DTS2000* System Instrumentation Product Specification PS0003	Section 1.2.3.2 Energy Timer **Was:** 0.01 to 99.99 seconds in .01 second increments **Is:** 0.001 to 9.999 seconds in .001 second increments (also concurrent changes to Section 1.2.3 Specification Source)
Revise Assembly, Microwave Generator PN0247 (assembly drawing and parts list)	Add a depiction (diagram and notes) that shows the timer module DIP switches and requires that the DIP switch settings for only the energy delivery timer (PN0433 Assembly, Timer with Cable/PN0063 Timer Relay Dig 24VDC Screw Term) be re-set at the final assembly so that switches 6, 7 and 8 are "on" (up) instead of "off" (down) in order to change the decimal point location for that timer. Additional instruction note requires that this DIP switch setting change be performed only after all temperature and power calibration has been performed.
DTS G2 Generator User Manual **revise** draft labeling	Update references to maximum energy timer setting (changes already submitted in additional information sent in prior supplement)
New Test Verification Protocol TP0027 Rev A – DTS G2 Generator Energy Time Limit Verification Protocol	Relevant sections of test protocol and report can be found in Attachment A.

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

New Test Verification Report TR0027-01A DTS G2 Generator Energy Time Limit Verification Report	
Revise TP0026 DTS2000* Final Acceptance Test Protocol	Section 7.5.2.1 - was 10 s, is 9.999 s Section 7.5.2.2 - was 10 s, is 9.999 s Section 7.5.2.5 - was 10 s, is 9.999 s Section 7.5.2.9 - was 10 s, is 9.999 s Section 7.5.2.13 - was 10 s, is 9.999 s Section 7.6.1.7 - was 10 sec, is 9.999 sec Section 7.6.2.4 - was 10 second, is 9.999 second Section 7.6.2.23 - was 30 seconds, is 9.999 seconds Section 7.6.2.25 - was 30 sec, is 9.999 sec Section 7.6.2.26 - was 30 sec, is 9.999 sec Section 7.6.2.27 - was 30 sec, is 9.999 sec Section 7.6.2.28 - was 30 sec, is 9.999 sec Section 7.6.2.29 - was 30 sec, is 9.999 sec Data Sheet 6 – step/test 7.6.2.25, 7.6.2.27, 7.6.2.28, 7.6.2.29 - was 30 sec, is 9.999 sec

*The internal project name for the DTS G2 Generator was the DTS2000 System Instrumentation.

The results of the test verification demonstrate that the system performs as expected and the maximum energy delivery time is 9.999 seconds.

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3) <u>Performance Testing- Electrical Safety</u>
In your response to deficiency #6, you indicated that your DTS G2 system utilizes microwave energy which does not send any electric current through the body. The active part of the applicator, the microwave antenna, is never in contact with the body. Therefore, you stated that the IEC 60601-2-2 standard is not applicable to the subject device. However, the basic definition of high frequency device, as it applies to IEC 60601-2-2, is any equipment operating at frequencies above 20 kHz, regardless of power. Therefore, this IEC 60601-2-2 standard is an applicable standard to the subject microwave coagulation system. Furthermore, the generator cannot be evaluated for applicability to IEC 60601-2-2 by itself. The entire system, including DTS LT-Applicator, has to be evaluated as a whole. Please provide test results to demonstrate that your DTS G2 System complies with applicable clauses of the IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, 2006.

During our informal correspondence on this issue, we recognized that we did not provide a clear enough description of the device, and in particular the DTS-LT Applicator, to allow the reviewer to understand the interface between the device and the patient. Therefore in our response below we provide more information about the DTS-LT Applicator and also its connections to the DTS G2 Generator. In addition, we have consulted with Dr. Mark Mirotznik, Associate Professor of Electrical Engineering at The Catholic University of America, an expert on the interaction of microwaves with tissue. We believe that the response below is a clarified review of how the mentioned standard applies to the DTS G2 System as a whole. A majority of the clauses are not applicable to the DTS G2 System; for those that are applicable, the DTS G2 System complies with all but one. Miramar Labs does not believe this affects the safety or effectiveness of the device.

This response includes the following information:

1) More detailed explanation of the DTS G2 Applicator and a general explanation of concepts that have arisen during our discussion of how the IEC 60601-2-2 standard applies to the DTS G2 System.
2) We have completed the clause-by-clause analysis that was requested during our call on December16, 2008, with the expectation that some of the clauses wouldn't apply. In summary, the DTS G2 System complies with all but one of the applicable requirements. We do not believe this affects the safety of the device.
3) We include below the response to the additional questions submitted via email to Miramar Labs on Jan 22, 2009.
4) We include below the response to the further additional questions submitted via email to Miramar Labs on February 24, 2009.

We would like to note that some of the items that came up during informal discussions were tested under the IEC60601-1 standard or other testing previously submitted. For example, bench testing was performed to confirm that the surfaces that the user might contact (primarily the DTS-LT Applicator and cable) do not overheat (see Attachment G of our response dated Nov 17, 2008). It should be noted that all surfaces of the Applicator that may contact the patient or user (i.e. cable bundle, plastic handle, dielectric antenna

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cradle and patient contact surface) are non-conductive and well isolated from any high frequency or low frequency voltage source or ground. This makes accidental grounding of the patient non-hazardous under normal operation or single fault mode. Additionally the device is designed with coaxial cables that have a shielding effectiveness of at least 70dB per foot of cable length, indicating a maximum of 0.00001% of the input power leaks out of the cable in the form of electromagnetic fields. Also, appropriate leakage currents and dielectric withstand were tested for the IEC 60601-1. The DTS G2 System has been shown to meet all test requirements of the 60601-1 standard. The test report was submitted as Attachment H of our response dated Nov 17, 2008.

1) More detailed information about the DTS-LT Applicator design and operation.

Figure 2 below shows a depiction of the DTS-LT Applicator with a cutaway section (b)(4) [redacted].

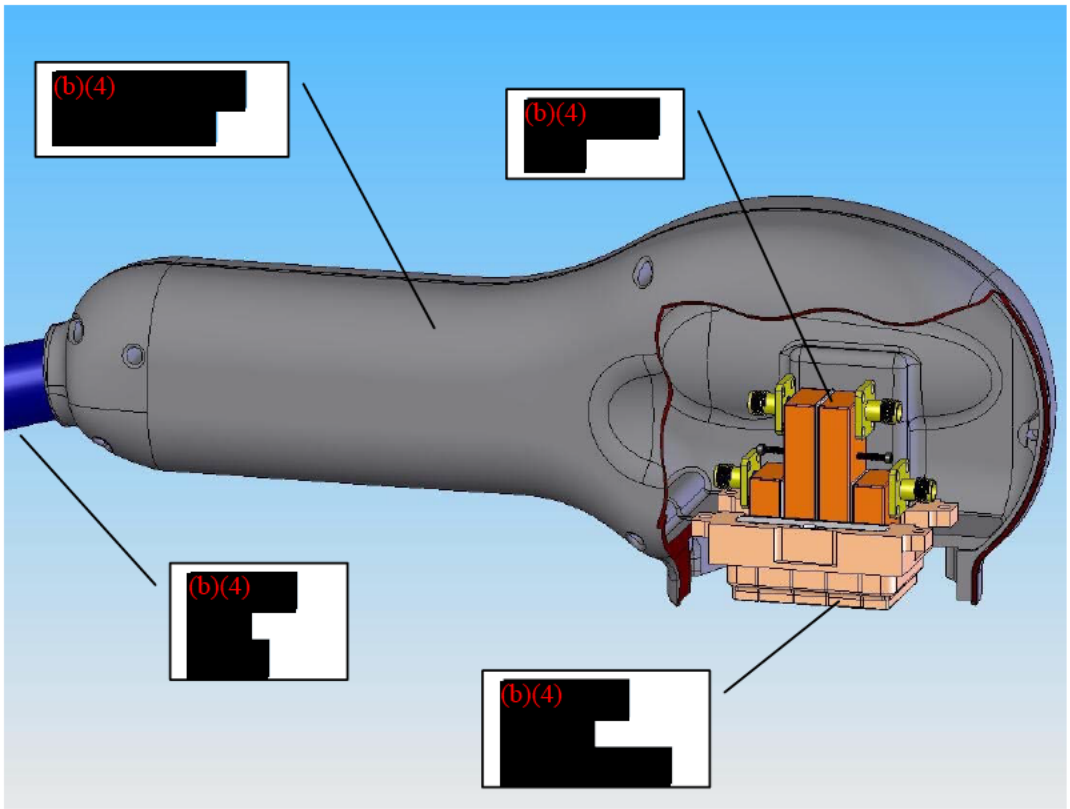

Figure 2. (b)(4) [redacted].

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(b)(4)

[redacted]

Figure 3. Cross-sectional view of the applicator waveguide array.

(b)(4)

[redacted]

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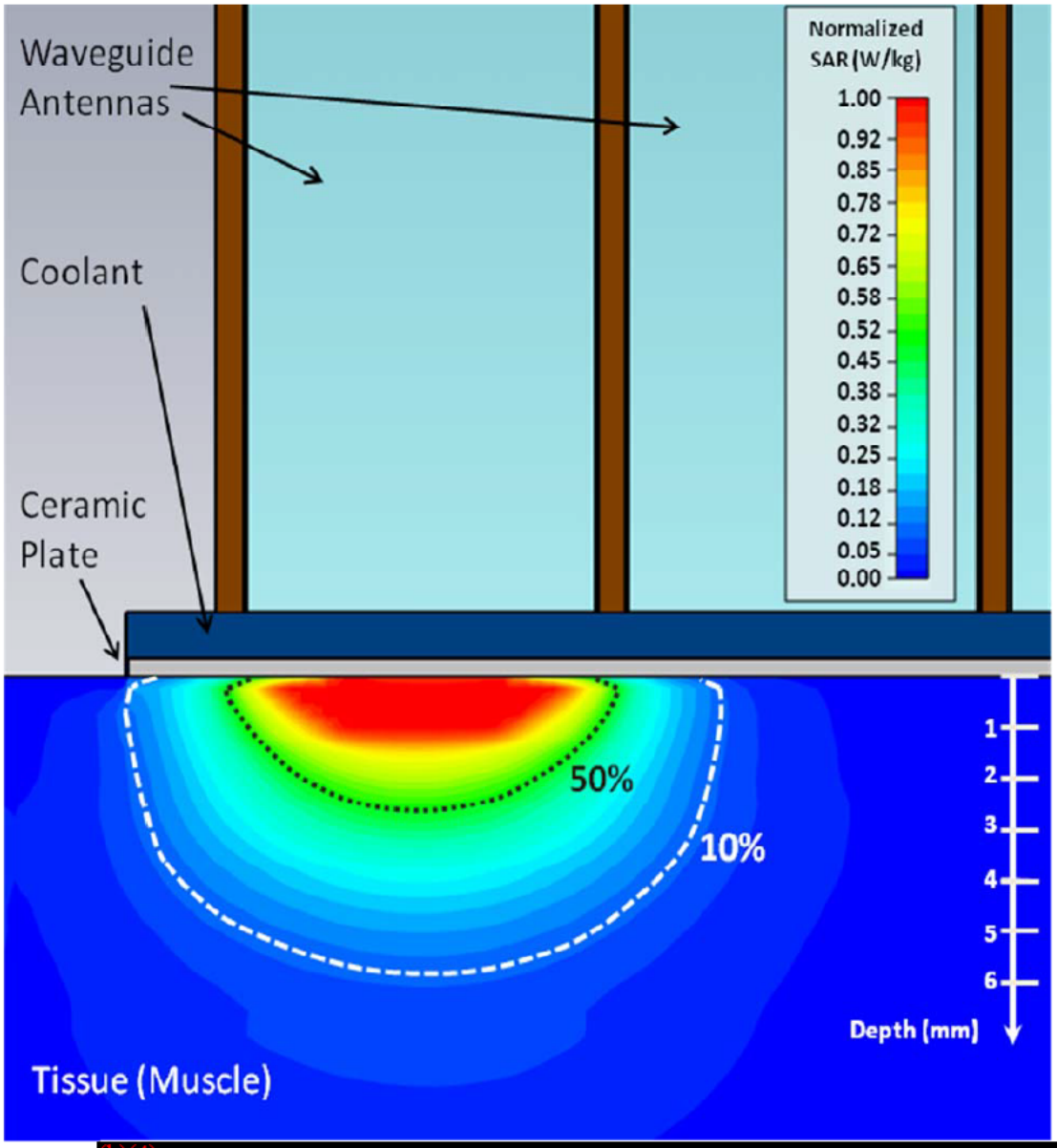

Figure 4. (b)(4) [redacted].

(b)(4) [redacted]

(b)(4) [redacted]

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(b)(4)

[redacted]

(b)(4)

[redacted]

Patient connection

(b)(4)

[redacted]

Output voltage

(b)(4)

[redacted]

(b)(4)

[redacted]

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3) Responses to questions sent by email on January 22, 2009 related to draft response regarding the clause-by-clause analysis (provided to FDA on January 5, 2009). The questions are in italics.

Jan 22 Question 1) Clause 6.8.2. section aa: You need to specify output voltage. We do not accept your assertion that there is no output voltage for the device. While we are willing to accept that energy transfer is not in the traditional monopolar or bipolar modes, an output voltage certainly exists to drive current through their antenna – this should be stated so that it is clear what the voltage potential is in case of accidental grounding.

This specific clause relates to labeling required for accessories. As stated in the table in Attachment B, the DTS G2 System is only to be used with provided accessories and the labeling states this. The clause has been reworded to remove the language regarding output voltage as this is not relevant to the clause.

With regards to output voltage, as discussed and shown in Figure 3 above, there are no patient connections in the language of the standard across which a relevant output voltage can be defined.

Jan 22 Question 2) Clause 6.8.2. section bb, paragraph 2-4; section ff, kk. You indicated that your device is incapable of causing burns since the device does not have a neutral ground electrode and does not have a patient path to ground. We do not agree as we believe that it is possible for accidental grounding to occur. (For example, if the isolation transformer is not used for any reason; or if equipment comes into contact with other pathway to ground.) Should the patient become accidentally grounded there is potential risk of significant leakage current – which may cause injury. We request that (1) please provide an analysis of how you mitigate against this hazard; (2) please describe what injury would occur should this hazard occur. (Patient auxillary leakage current)

With the extra detail in the figures above and the additional explanation, we hope that it is clearer that there no hazards introduced by accidental grounding. All surfaces of the Applicator that may contact the patient or user (i.e. cable bundle, plastic handle, dielectric antenna cradle and patient contact surface) are non-conductive and well isolated from any high frequency or low frequency voltage source or ground.

In addition, we have shown in Figure 4 above that the polarization currents induced in the tissue are very localized and thus an accidental grounding would not introduce any change to the energy deposition or introduce any additional hazards.

These device characteristics and design choices are how mitigations were put in place regarding this hazard. We have not identified any injuries for the patient or user should the patient become grounded. These clauses have been reworded to remove the ambiguous language.

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Jan 22 Question 3) Clause 19.2 – You specified that single fault testing is not necessary as no failure of circuits in the device can cause elevated leakage current since there is no conductive patient connection. However, we believe that single fault testing is still applicable since accidental grounding may cause elevated leakage current.

As clarified in the table in Attachment B, appropriate single fault testing was done as part of the testing for the IEC 60601-1 standard. No additional single fault testing is required as there is no patient connection in normal operation or single fault condition, as discussed above. See the response to Jan 22 Question 2 for the discussion on accidental grounding.

Jan 22 Question 4) Clause 20.3 – We believe that dielectric withstand testing is applicable regardless of mode of operation. This test is inter-related to our comments for Clauses 6.8.2 and 19.2 since dielectric failure will elevate patient leakage currents.

All IEC 60601-1 dielectric withstand tests were performed and passed successfully. The applied part withstood a double insulation test of 3000V per the IEC 60601-1 requirement. The purpose of this modification to the 60601-1 requirements is to standardize the calculation of U (reference voltage) for the non-sinusoidal output of traditional high frequency devices. Our power source is sinusoidal in nature and, thus, the worst case has already been considered in the calculation of U. Further, taking the rms value of the voltage associated with our microwave amplifier leaves a much smaller value than our mains voltage of 120V. Therefore, our reference voltage, U, is determined by the mains and all tests were performed appropriately.

Jan 22 Question 5) Clause 46.104, section a. It is not clear from the diagrams of the disposable head whether the connectors to the generator are unique enough as to avoid confusion when connecting to the generator.

Attachment D contains photographs of the DTS G2 Generator with larger photos of the connections between the DTS G2 Generator and DTS-LT Applicator. All of the connections are of a unique design that avoids the possibility of misconnecting the devices. This has been clarified in the wording of this clause analysis.

Jan 22 Question 6) Clause 51.5 – In your response to this clause, you indicate that the maximum output power of your device is 100 W. If the detected power is over 13 W away from the front panel set power, an error LED illuminates and the energy cycle is terminated. Please provide justification for the selection of 13 W as the maximum allowable deviation from set power.

An analysis of the allowable errors according to the standard gives two different settings, depending on the set power. Given that the rated output power is 100 W and the front panel settings range from 40 W to 100 W, the allowable error is 25W when output power is set between 40W and 80W; the allowable error is 30W when power is set to be between 80W and 100W. The fault limit of 13 W was chosen as approximately half of the 25W limit.

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4) Responses to questions sent by email on February 24, 2009. The questions are provided in italics.

Feb 24 Question a) Please describe the effect of coolant temperature on the lesion size.

The effect of coolant temperature on lesion size was characterized but not originally included in the Applicator Instructions for Use. Attachment E has the revised IFU with examples for the user to understand the potential implications that changing coolant temperatures may have on lesion size.

Feb 24 Question b) Please describe the mechanism to maintain the coolant temperature at the proposed 10°C.

The Nanotherm chiller/circulator that is used in the DTS G2 System is an off-the-shelf component manufactured by ThermoTek. The User Manual for the system was provided in Attachment B of the original 510(k) submission, and is included here in Attachment F for convenience. The description of how to set the temperature can be found on pages 7-3 and 7-4. The chiller/circulator specifies an accuracy of ± 2°F.

Feb 24 Question c) Please describe the control you have implemented to mitigate the potential hazardous events such as temperature deviation from the loss of target coolant temperature, loss of coolant, etc.

The front panel of the DTS G2 Generator has a display showing the coolant temperature as measured in the flow path. The coolant temperature thermocouple resides in the Applicator near the exit of the cooling chamber within the Applicator body. If a failure mode such as a significant loss of coolant or a loss of target coolant temperature within the Nanotherm chiller were to occur, the user would be able to see the rise in coolant temperature on the front panel. Additionally, the Nanotherm has several safety shut-offs which will occur under various conditions, including overheating. See the Nanotherm User Manual for shut-off conditions.

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ATTACHMENT A

Change to Generator Energy Time Limit

Test Protocol TP0027 (relevant sections)
Test Report TR0027 (relevant sections)

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1.0 PURPOSE

The purpose of this protocol is to specify the verification testing for the Miramar Labs DTS G2 Generator Instrumentation once the energy time limit is changed from 99.99 seconds to 9.999 seconds.

2.0 BACKGROUND

See the product specification PS0003, for a detailed description of the DTS G2 Generator and its intended function.

3.0 REFERENCES

3.1 PS0003, DTS2000 System Instrumentation Product Specification
3.2 OP0008, Equipment and Tool Controls

4.0 MATERIALS AND EQUIPMENT

4.1 Oscilloscope (EQ 0049-01) - Tektronix MSO4104 or equivalent
4.2 Power Meter (EQ 0007-02) – Agilent E4419B or equivalent
4.3 Power Sensor (EQ 0037-02, EQ 0037-03) – Agilent HP8481A or equivalent
4.4 High Power Termination Fixture (EQ 0053-01).
4.5 Microwave Coupler Fixture (EQ 0054-01)
4.6 Equipment identification numbers shall be recorded on the appropriate data sheets.
4.7 All measuring equipment shall be calibrated or verified to calibrated equipment per OP0008.

5.0 RECORDING OF DATA

5.1 All raw data sheets shall be filed with the final test report.
5.2 The serial number of the DTS G2 Generator system, the serial number of the Generator and the serial number of the Generator circuit board will be documented.
5.3 Deviations to any of the test protocols or test methods shall be noted in the test report.
5.4 The final test report will contain a summary of all the data.

6.0 ACCEPTANCE CRITERIA

6.1 The acceptance criterion for each test is clearly indicated in section 7 of this document.
6.2 The acceptance criterion for each test shall be reiterated in the final report and a statement regarding whether the criterion was met shall be made.

7.0 DESIGN VERIFICATION TEST PROCEDURE

7.1 Energy Time Limit Testing

7.1.1 <u>Test Setup</u>
7.1.1.1 Connect the High Power Termination to the Microwave Power Output port on the DTS G2 Generator.
7.1.1.2 Connect a power meter to the forward power output of the Microwave Coupler Fixture.

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7.1.1.3 Connect recorder output of power meter to channel 1 of the oscilloscope with the following settings: 100mV/div, 20MHz Bandwidth Limiting, 2 sec/div, trigger on rising edge of channel 1 set to left of the display.
7.1.1.4 Power up the DTS G2 Generator and allow the system to complete self-test.
7.1.1.5 Program the following times on the DTS G2 Generator: Pre-Cool = 2 s, Energy = 9.999 s, Post-Cool = 2 s.
7.1.1.6 Rotate the power control rotary knob to command the microwave power to maximum.
7.1.1.7 Rotate the vacuum control rotary knob to command the vacuum to maximum.
7.1.1.8 Select antenna 2.
7.1.1.9 Press the “start” switch and on the front panel of the DTS G2 Generator and allow the treatment to complete the post-cool.
7.1.2 Test Protocol
7.1.2.1 Confirm pre-cool timer starts countdown to zero and resets upon completion of 2 second countdown.
7.1.2.2 Confirm energy timer starts countdown and resets upon completion of 9.999 second countdown.
7.1.2.3 Confirm the audio alarm gives continuous audible signal only during the energy timer countdown.
7.1.2.4 Confirm post-cool timer starts countdown to zero and resets upon completion of 2 second countdown.
7.1.2.5 Confirm a 1 second audio alarm at the end of the post-cool timer countdown.
7.1.2.6 Note the energy delivery time on the oscilloscope, i.e. the time between the rising edge of channel 1 to falling edge of channel 1. Confirm 9.999 seconds ± 100ms.
7.1.2.7 Press the up arrow on all 4 digits of the energy timer. Confirm 0.000 is displayed.

8.0 LIST OF ATTACHMENTS

8.1 Datasheet for Energy Time Limit Testing.

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Data Sheet 1: Energy Time Limit Testing

Test operator: _____ Date: _____ Location: _____

Test Equipment Description/Model Number	Serial Number	Calibration Due Date

Step/Test #	Pass/Fail	Comments
7.1.2.1		
7.1.2.2		
7.1.2.3		
7.1.2.4		
7.1.2.5		
7.1.2.7		

Step/Test #	Energy Time (ms)	>9899 and <10099 Pass/Fail	Comments
7.1.2.6			

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1.0 PURPOSE

This report summarizes the testing completed, per TP0027, to satisfy design verification, as described in OP0002, with respect to verification testing for the Miramar Labs DTS G2 Generator once the energy time limit is changed from 99.99 seconds to 9.999 seconds.

2.0 REFERENCES

2.1 PS0003, DTS2000 System Instrumentation Product Specification
2.2 TP0027, DTS G2 Generator Energy Time Limit Verification Protocol
2.3 TP0026.A DTS2000 Final Acceptance Test Protocol
2.4 OP0008, Equipment and Tool Controls
2.5 OP0002, Design Controls

3.0 TEST SAMPLES AND RECORDING OF DATA

3.1 The raw data sheet is filed with this test report, see appendix.

3.2 The model number of the system is MN-DTS2000 and the name is Dermatologic Treatment System (DTS) Equipment. The name has recently been revised to DTS G2 System. The testing referenced in the appendix was performed on the DTS G2 Generator, a component of the DTS G2 system, with a serial number (lot number) of 08H0109. Lot history build documentation has been filed in Document Control for the DTS G2 Generator used for testing.

3.3 The test sample shall be one unit. The DTS G2 Generator aspect of the change, the ability in operate appropriately with the timer module, is embedded in the acceptance test, TP0026.A DTS2000 Final Acceptance Test Protocol, and is done with every unit. The ability of the timer module to move the decimal point is a feature of the timer module itself and is tested by the vendor.

4.0 DEVIATIONS

4.1 No deviations required.

5.0 TEST SUMMARY AND ACCEPTANCE CRITERIA

Test	Description	Acceptance Criteria	Pass/Fail
7.1.2.1	Confirm pre-cool timer starts and resets appropriately.	The front panel display of the pre-cool timer should countdown to zero and immediately reset to 2 seconds.	Pass
7.1.2.2	Confirm energy timer starts and resets appropriately..	The front panel display of the energy timer should countdown to zero and immediately reset to 2 seconds.	Pass

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Test	Description	Acceptance Criteria	Pass/Fail
7.1.2.3	Confirm the energy audio alarm is activated appropriately.	The audio alarm should give a continuous audible signal only during the energy timer countdown.	Pass
7.1.2.4	Confirm post-cool timer starts and resets appropriately.	The front panel display of the post-cool timer should countdown to zero and immediately reset to 2 seconds.	Pass
7.1.2.5	Confirm the "treatment done" audio alarm is activated appropriately.	A one-second audio alarm should sound at the end of the post-cool timer countdown.	Pass
7.1.2.6	Confirm that the timer accuracy is within ± 0.1 second by comparing the timer set/countdown time with the time measured using the oscilloscope.	Measure the Energy time interval (time between activation and deactivation of the energy cycle). Confirm 9.999seconds ± 100ms.	Pass
7.1.2.7	Confirm that 9.999 is the maximum allowable commanded time for the energy cycle.	Scrolling up from 9.999 seconds on the energy results in 0.000 on the display.	Pass

6.0 DISCUSSION

6.1 No discussion required.

7.0 CONCLUSION

7.1 The DTS G2 Generator system has met all of the requirements to support changing the energy time limit to 9.999 seconds.

8.0 APPENDIX

8.1 Filled out Data Sheet 1: Energy Time Limit Testing

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Data Sheet 1: Energy Time Limit Testing

Test operator: W. Segalla Date: 12-5-08 Location: Miramar Labs

Test Equipment Description/Model Number	Serial Number	Calibration Due Date
DTS G2 Generator	08H0109	N/A
Oscilloscope Tek MSO4104	C000696	6-12-09
Power Meter Agilent E4419B	MY45103414	3-23-10
Power Sensor Agilent HP8481A	SG41093563	2-26-09
High Power Termination Fixture EQ 0054-01	NA	NA
Microwave Coupler EQ 0054-01	NA	NA

Step/Test #	Pass/Fail	Comments
7.1.2.1	Pass	
7.1.2.2	Pass	
7.1.2.3	Pass	
7.1.2.4	Pass	
7.1.2.5	Pass	
7.1.2.7	Pass	

Step/Test #	Energy Time (ms)	>9899 and <10099 Pass/Fail	Comments
7.1.2.6	9920	Pass	

ORIGINAL

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ATTACHMENT B

(b)(4) [redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

(b)(4) CCI

(b)(4) CCI

[redacted]

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ATTACHMENT C

DTS G2 Generator User Manual

Revisions:
1) Remove investigational device caution on page 8
2) Add one warning on page 10 related to IEC 60601-2-2 standard, clause 6.8.2 gg.

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miramarlabs

DTS G2 Generator

User Manual

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1. CONTACT INFORMATION

Miramar Labs, Inc.
199 Jefferson Drive
Menlo Park
CA 94025
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

1.1. EXPLANATION OF SYMBOLS

	Attention: See user manual for additional information Service By Qualified Personnel Only
	Fuse
	Type BF (Body Floating) Applied Part
LOT	Serial Number
	On (Main Power)
	Off (Main Power)
	Start
	Stop
	Non-Ionizing Radiation
	Timer
	Temperature
	Equipotential ground connection
	Manufacturer
	Date of Manufacture
	Waste electrical and electronic equipment

Deleted: Nov08

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2. SYSTEM DESCRIPTION

The Miramar Labs DTS G2 Generator is designed to deliver precise amounts of microwave energy to soft tissue while providing the ability to protect the tissue surface with an active contact cooling system. Microwave energy up to 100 Watts at 5.8 GHz can be generated and a portion of that delivered to the target tissue via specially designed Applicators.

The DTS G2 System consists of the following major components:

1. DTS Applicator
2. DTS G2 Generator
3. NanoTherm Chiller/Circulator (from ThermoTek)
4. Isolation Transformer
5. Mobile Cart (not shown in Figure 1)
6. Foot Switch (not shown in Figure 1)

See Figure 1 for basic block diagram of how the components of the system are connected. A brief description of each component is given below.

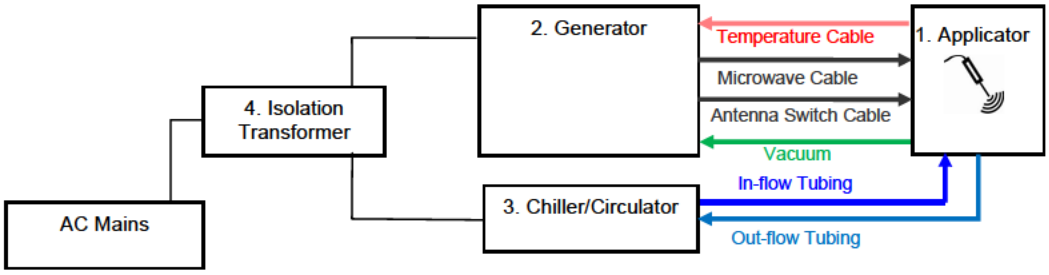

Figure 1. Block diagram of DTS G2 system components.

The Applicator has microwave antennas, a tissue acquisition vacuum chamber, and a surface cooling plate with a flow channel. The Applicator is connected as shown in Figure 1 to the two components of the DTS G2 System that provide the required functions - the Generator and the Chiller/Circulator.

The Generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, a power supply, microwave module and the front panel/control board assembly. There is also an integrated vacuum pump that provides suction (up to -28 in Hg) to the Applicator to facilitate tissue acquisition. See the next section for a detailed description of the control/display functions of the Generator.

The Chiller/Circulator provides the circulating cooling fluid that is flowing through the Applicator to prevent or minimize the thermal damage to the surface of the target tissue, if desired by the user. The Chiller/Circulator is manufactured by ThermoTek, Inc. See the NanoTherm User Manual for instructions on how to set Chiller temperature and flow.

The Isolation Transformer is an off-the-shelf component that provides protection for the patient by eliminating hazardous potential voltage differences as well as preventing hazardous levels of leakage currents between patient contact elements of the system and the AC mains.

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2.1. FRONT PANEL DISPLAY AND CONTROL FEATURES

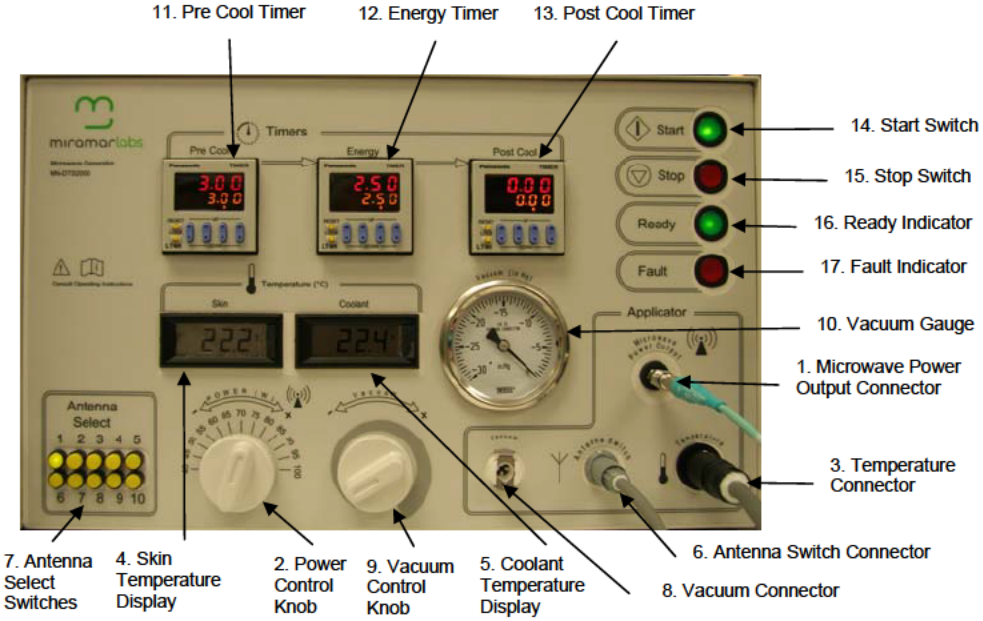

Figure 2. Generator Front Panel

1. Microwave Power Output Connector
   The Generator provides microwave power to the antennas via a coaxial QMA-type connector. The coaxial microwave cable of the Applicator is connected to this connector.

2. Power Control Knob
   A control knob on the front panel of the Generator provides the user with the ability to adjust the amount of power delivered to the Applicator.

3. Temperature Connector
   A temperature monitoring system inside the Generator provides continuous temperature monitoring of the cooling fluid line at a location inside the applicator. A second temperature monitoring system inside the Generator provides temperature monitoring of the thermocouples on the cooling plate of the Applicator between each antenna and the surface of the target tissue. This temperature monitoring is automatically switched between each of the thermocouples on the cooling plate of the applicator in coordination with automated antenna switching to provide the skin/cooling plate interface temperature associated with the active antenna.

4. Skin Temperature Display
   The skin/cooling plate interface temperature associated with the active antenna is displayed on the front panel of the Generator (°C).

5. Coolant Temperature Display
   The coolant temperature measured within the Applicator is displayed on the front panel of the Generator (°C).

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6. Antenna Switch Connector
   The antenna switch connector of the Applicator is connected on the front panel of the Generator to allow switching between antennas in Applicators that have more than one antenna.

7. Antenna Select Switches
   The user can activate one or more of the antennas (if more than one is available on a given Applicator) by pressing the appropriate antenna select switches on the front panel of the Generator. If more than one antenna is selected, the Generator will automatically deliver the energy for the set energy duration time to each of the antennas in a sequential fashion. The activation of multiple antennas enables the creation of a larger zone of heating.

8. Vacuum Connector
   A vacuum pump inside the Generator provides vacuum for tissue acquisition into the Applicator.

9. Vacuum Control Knob
   The vacuum level can be controlled by a knob on the front panel of the Generator.

10. Vacuum Gauge
    The vacuum gauge on the front panel of the Generator displays the vacuum level to the user.

11. Pre Cool Timer
    The Generator pre cool timer allows the user to set the pre-cool duration (sec).

12. Energy Timer
    The Generator energy timer allows the user to set the energy delivery duration (sec).

13. Post Cool Timer
    The Generator post cool timer allows the user to set the post-cool duration (sec).

14. Start Switch
    The pre-cool, energy delivery, and post-cool sequence shall commence upon pressing the start button. The start button is enabled when the generator Ready Indicator is illuminated.

15. Stop Switch
    The stop button can be used to abort the sequence at any time.

16. Ready Indicator
    The Ready Indicator will be illuminated when the AC mains power is turned on and no fault conditions exist.

17. Fault Indicator
    The Fault Indicator will be illuminated when a fault condition exists. Refer to Section 10 Troubleshooting Guide for details on potential fault modes and potential resolutions.

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2.2. REAR PANEL FEATURES

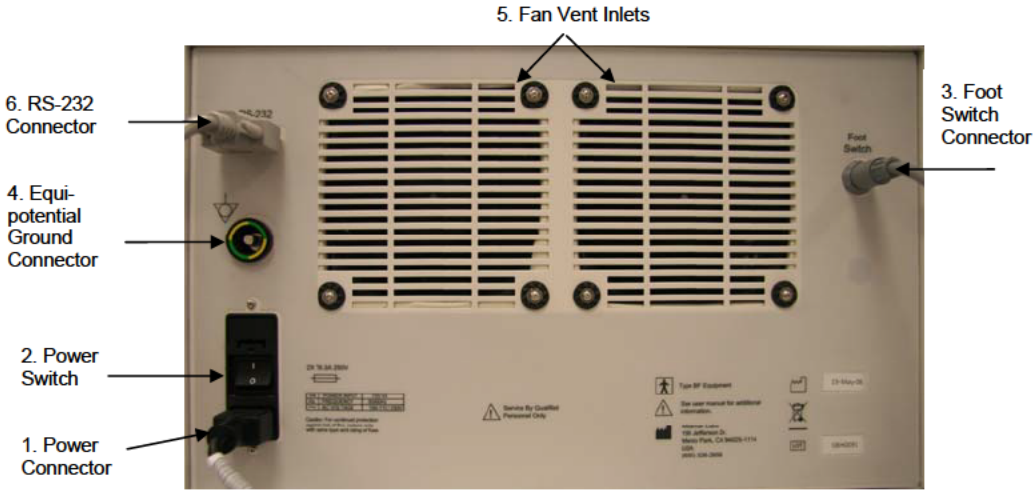

Figure 3. Generator Rear Panel

1. Power Connector
   AC mains power cord connection. This receptacle contains the Generator fuses just above the Power Switch (See instructions on How to Change the Fuses, section 2.3).

2. Power Switch
   AC mains power switch

3. Foot Switch Connector
   The Start/Stop function (as described on the Generator front-panel control) can be controlled by a foot switch (provided) that is connected to the rear panel.

4. Equipotential Ground Connector
   Use the equipotential ground connector for grounding to ensure that the generator is at the same ground potential as other equipment in the vicinity.

5. Fan Vent Inlets
   Vents allow the fans to draw ambient cooling air into the Generator. Do not block these vents to ensure proper cooling of the Generator.

6. RS-232 Connector
   The Generator provides the following data output through an RS-232 connection: antenna(s) selected, set power, actual forward power, reverse power, skin/cooling plate interface temperature (associated with the active antenna) and coolant temperature during energy delivery. This data can be collected through data acquisition devices (i.e. data-logger).

2.3. HOW TO CHANGE THE FUSES

CAUTION: Do not use repaired fuses or short-circuited fuse holders.

There are fuses in the power entry modules of the Generator, Chiller/Circulator and Isolation Transformer.

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Only use standard fuses, 2 each, current rated T6.3A/250 V @ 100-115 V ~ in the Generator.

Only use standard fuses, current rated T7A/250 V @ 100-115 V ~ in the Chiller/Circulator.

Only use standard fuses, current rated T10A/250 V @ 100-115 V ~ in the Isolation Transformer.

1. Ensure the generator, chiller and isolation transformer power switches are in the OFF (0) position.
2. Unplug the system power cord at the isolation transformer from the AC mains at the power outlet.
3. Snap the A/C RECEPTACLE-ON/OFF switch cap open by placing a flat screwdriver in the pre-marked slot located on top of the switch.
4. Remove fuses from either side of the holder and replace with standard time delay fuses, current rated T6.3A/250 V @ 100-120 V ~ for the generator, T7A/250 V @ 100-120 V ~ for the chiller/circulator, T10A/250 V @ 100-120 V ~ for the isolation transformer.
5. Replace holder and snap the cap closed.

3. CAUTIONS

Federal US law restricts this device to sale by or on the order of a licensed physician.

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4. INDICATIONS FOR USE

The DTSG2 System is indicated for use for coagulation of soft tissue.

5. CONTRAINDICATIONS

The DTS G2 System is contraindicated for patients with heart pacemakers and other electronic device implants.

6. WARNINGS AND PRECAUTIONS

- Carefully read the User Manuals for the Miramar Labs DTS G2 Generator and the Nanotherm Chiller/Circulator, and the Applicator IFU prior to use. Observe all warnings and precautions. Failure to do so may result in complications.
- The DTS G2 is for use by qualified clinical personnel who have been instructed and trained in the correct use of the equipment by designated Company representatives.
- Safety of the DTS G2 has not been evaluated on patients with cardiac pacemakers or other electronic implants. The DTS G2 system should not be used on such patients.

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- Operate the DTS G2 in environmental temperatures between 16˚C and 26°C (60˚F and 80°F); and between 30% and 60% relative humidity (non-condensing).
- Use only the components and parts supplied by Miramar Labs.
- DO NOT attempt to repair or alter any of the System components.
- DO NOT allow fluid to contact generator, cables or connectors unless the generator is being cleaned. Do not hang fluids above the generator. The generator may not function correctly if the electronic circuitry or the connectors are wet. Do not soak cables.
- DO NOT operate if wet. Electrical shock may occur.
- DO NOT operate if there is no Applicator connected or if the Applicator is not positioned at the intended target site. See Applicator IFU for proper positioning of the applicator.
- Clean, disinfect, and maintain the electrical units in accordance with the operating instructions.
- Turn the electrical units Off using the main power On/Off switch and disconnect the power cord from the AC supply before cleaning.
- DO NOT remove the cover of any of the system components. There are no user-serviceable parts inside the components of the DTS G2. Opening the cover of any of the DTS G2 components may result in electrical shock or thermal burns.
- For warnings and precautions associated with the chiller portion of the DTS G2, see the NanoTherm Industrial User Manual. Also read the Applicator IFU.
- This equipment/system is intended for use by healthcare professionals only. The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Provide as much distance as possible between the DTS G2 and other electronic equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interteference. It may be necessary to take mitigation measures, such as reorientating or relocating the Generator or shielding the location.
- The DTS G2 should not be used or pause/terminate therapy cycle when the temperature shows abnormal fluctuations.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- Electrosurgical components, such as the Applicator, may remain hot after activation. Keep all electrosurgical equipment away from flammable materials to avoid combustion.

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- Prolonged or unneccessary activation of the DTS G2 may lead to unintentional damage to surrounding tissue.
- The output power selected should be as low as possible for the intended purpose.
- Failure of the system could result in an unintended increase of output power.
- Do not obstruct the activation light or tone. The activation tone and light are important safety features.
- Use only Miramar Labs Applicators designed to be used with the DTS G2 Generator.
- Do not bend cables at acute angles or coil them tightly; the cable might break.
- The main power cord of the Isolation Transformer must be connected to a properly grounded receptacle. Extension cords and/or adaptor plugs must not be used. Plug equipment into 100-115V AC 60 Hz power receptacles.

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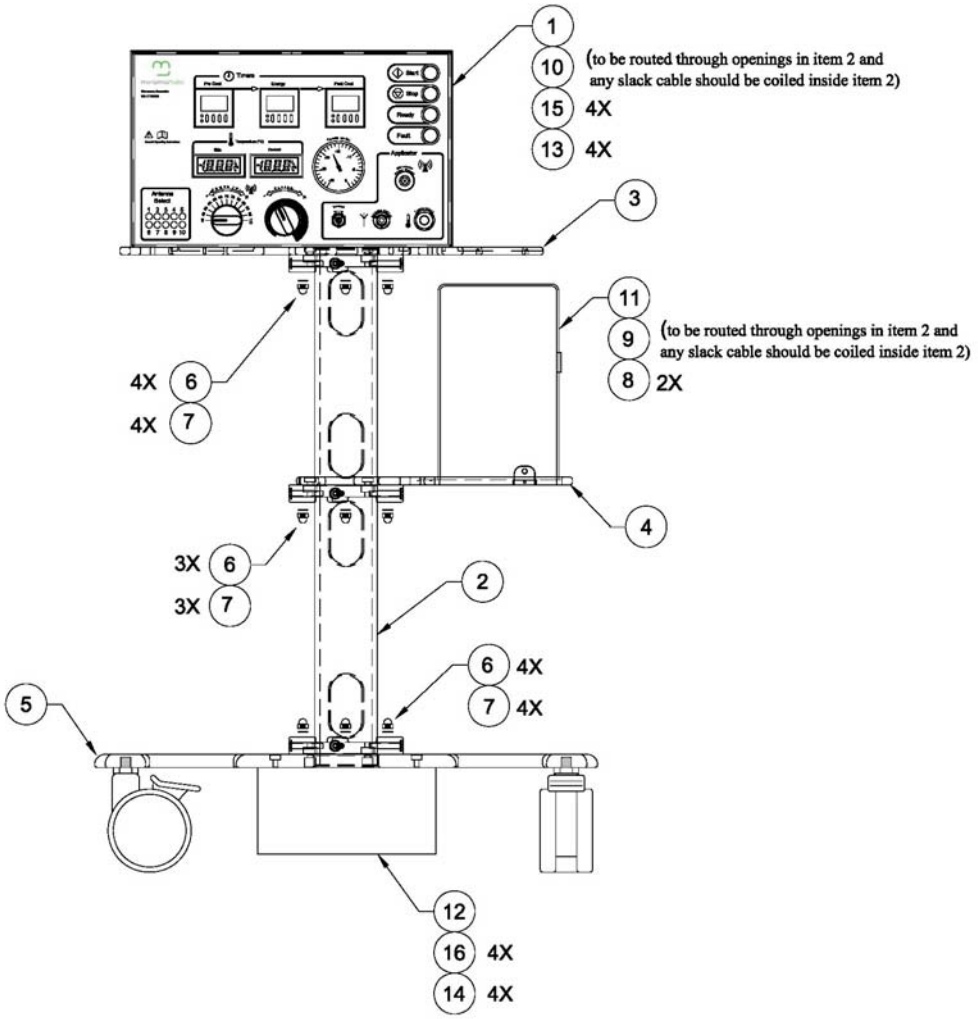
7. OPERATING INSTRUCTIONS

7.1. UNPACKING AND EQUIPMENT SET-UP

- ❑ Open each of the four cases containing the cart, generator, chiller, isolation transformer and miscellaneous cables, hardware, tools and manuals and remove the contents. Inspect all components for shipping damage. If damage has occurred, contact Miramar Labs. Verify all components are present (see section 9).

1. Refer to figure 3 below for remainder of set-up.

Figure 3. Equipment Set-up



2. Attach the isolation transformer (12) to the bottom of the cart base (5) using the four 10-32 x 5/8" long screws (14) with four #10 internal tooth lock washers (16)

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being sure to orient the connectors to the rear of the cart (the front of the cart has locking casters).

3. Attach the vertical support pole (2) to the cart base (5) using four acorn nuts (6) with four flat washers (7).
4. Attach the chiller shelf (4) to the support pole (2) using three acorn nuts (6) with three flat washers (7).
5. Attach the generator shelf (3) to the support pole (2) using four acorn nuts (6) with four flat washers (7).
6. Attach the generator (1) to the generator shelf (3) using the four 8-32 x 5/8" long screws (13) with four #8 internal tooth lock washers (15) being sure to orient the rear of the generator to the rear of the cart (the front of the cart has locking casters).
7. Attach the chiller (11) to the chiller shelf (4) using the thumb screw on the rear of the chiller (part of 11) and the two black nylon cinching straps (8).
8. Ensure the AC receptacle on/off switch, located on rear panel of the generator is off (O). Connect the longer of the two power jumper cords (10, 2 meter length) to the generator (1) and route the cable inside of the support pole (2) through the oval opening closest to the top and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
9. Connect the shorter of the two power jumper cords (9, 1.5 meter length) to the chiller (11) and route the cable inside of the support pole (2) through the oval opening just under the chiller shelf (4) and out through the oval opening closest to the bottom and connect to the isolation transformer (12). Coil up any excess power jumper cord length back inside the support pole.
10. Connect the AC mains power cable (part of 12) to the isolation transformer (12).
11. Retain all packing materials, tools and manuals.

7.2. SYSTEM SETUP AND WARM-UP

1. Connect the AC mains power cable from the isolation transformer to a properly grounded AC outlet and switch the isolation transformer AC receptacle on/off switch, located on the rear panel, to the on (I) position.
2. Connect the foot switch to the connector labeled "Foot Switch" on the rear panel, if desired.
3. Set the desired power output power by rotating the rotary power knob on the front panel. Power is adjustable over the range from 40 Watts to 100 Watts in 5 Watt increments.
4. Place the Applicator in the holster provided on the front right side of the cart. Connect the microwave cable of the Applicator to the "Microwave Power Output" quick-connect QMA style connector on the front panel of the Generator.
5. Connect the vacuum tubing of the Applicator to the "Vacuum" connector on the front panel of the Generator.
6. Connect the temperature cable of the Applicator to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator.
7. Connect the antenna control cable of the Applicator to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator.
8. Select the desired Applicator antennas by pushing the "Antenna Select" push button switches located at the bottom left corner of the front panel of the Generator.

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9. Connect the cooling flow tubing of the Applicator into the Chiller/Circulator
   a. Connect the “into chiller” tubing into the “flow-in” receptacle of the Chiller/Circulator.
   b. Connect the “out from chiller” tubing into the “flow-out” receptacle of the Chiller/Circulator.
   c. Ensure the applicator fluid tubing is not placed over or on the equipment in order to prevent fluid ingress into the generator, chiller/circulator or isolation transformer, especially when disconnecting the applicator fluid tubing connectors from the chiller/circulator.
   d. Turn on the power to Chiller/Circulator, set the cooling temperature, and run until temperature is stabilized on the applicator cooling fluid temperature readout (depending on the set temperature, this can take up to 30 minutes).
   e. Only use de-ionized water in the Chiller/Circulator. Check the fluid level in the Chiller/Circulator before starting each therapy session. Coolant should be added until the fluid level is visible at the base of the reservoir neck. If the coolant level can be seen lower than halfway down the illuminated fluid level window, more coolant should be added.
10. Turn on the power to the Generator using the switch located on the AC inlet module located on the rear panel of the Generator by switching the on/off switch to the on (I) position.
11. Ensure that the “Start” and “Ready” lights are illuminated, that the two temperature displays show temperatures, that the three timers illuminate, that any selected Applicator “Antenna Switches” are illuminated and that the “Vacuum” gauge shows a vacuum level.
12. Set the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration by pressing the rocker buttons immediately below each digit display on the appropriate timer module and then pressing the reset button on that timer module. Each timer can be set to a time range of 0.00 to 99.99 seconds.
13. **WARNING:** The FAULT LED is illuminated if the system detects a malfunction (see Troubleshooting, section 0).
14. Position the system close to the patient.
15. Ensure all air vents on the equipment are not obstructed.

7.3. OPERATION

1. Confirm that the Pre-Cool duration, Energy Delivery duration, and Post-Cool duration settings on the Timer Controller are correct. If adjustments need to be made for any of the three durations, press the rocker buttons to the desired time on the appropriate timer panel and press the Reset button. ⚠ Important note regarding the Pre-Cool cycle: In order to assess proper tissue acquisition into the Applicator vacuum chamber prior to energy delivery, do not set the Pre-Cool timer to less than 3 seconds.

2. Adjust vacuum control knob to the desired setting. Use the lowest setting necessary to get adequate tissue acquisition into the Applicator vacuum chamber. Note that vacuum will not be applied to the Applicator until the “Start” button is pressed. A vacuum level tissue acquisition test can be performed by setting the “Energy” timer to 0 seconds to confirm that the vacuum level is adequate to engage the tissue in the Applicator.

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3. Place the DTS applicator on the target tissue. **CAUTION**: DO NOT operate if the applicator is not connected or if the applicator is not correctly positioned on the patient. See Applicator Instructions for Use for correct positioning of the applicator on the patient.

4. Push the "START" button on the Generator (or depress the foot switch). An audible buzzer will indicate when microwave energy is being delivered. Another sound (1 second duration) will indicate when the entire therapy cycle has been completed, at which time the vacuum will also be turned off to the Applicator. During the pre cool, energy and post cool cycles, each of the associated timers will count down from the user selected values to zero. If more than one antenna has been selected, the energy timer will count down the number of times that corresponds to the number of antennas selected before transitioning into the post cool cycle.

5. Press the "Stop" switch (or depress the foot switch) to abort the procedure.

6. Repeat steps 1-4 for additional treatments.

7.4. SYSTEM SHUTDOWN PROCEDURE

1. Turn off the power to all of the components of the system.
2. Disconnect the cable plugged into the isolation transformer from the AC mains source and coil cable on back of the Generator shelf.
3. Place foot switch in location provided on back of Generator shelf and coil excess cable on back of Generator shelf.
4. Disconnect DTS Applicator from the Generator and Chiller/Circulator and remove/dry up any fluids that may have dripped out of the tubing or chiller.

8. CLEANING AND MAINTENANCE

8.1. CLEANING

- Components of the DTS G2 cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter connectors on Generator.
- Make sure power to the DTS G2 components are turned OFF and the power cord unplugged before cleaning.
- Do not spray or pour cleaning agents or any other liquids on the DTS G2 components.
- Dampen a clean dry cloth with a multi-purpose hospital grade detergent.
- Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into the housing or electrical components.
- Gently dry the entire Generator, including cords.
- Do not soak any of the cords or cables, especially the connectors, since this can affect electrical performance.

8.2. STORAGE

The DTS G2 system components should be stored in a cool, dry place out of direct sunlight.

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8.3. SERVICE INFORMATION

The DTS G2 has been Manufacturer tested. There are no serviceable parts inside the DTS G2 components. Contact Miramar Labs for service.

9. HOW SUPPLIED

The Miramar Labs DTS G2 is supplied with the following components:

9.1. DESCRIPTION OF DTS G2 COMPONENTS

Item	Description	Qty
1	DTS G2 Generator User Manual (this document)	1
2	DTS G2 Generator	1
3	Nanotherm Chiller/Circulator and User Manual	1
4	Isolation Transformer	1
5	Cart (assembly required, see section 8.1)	1
6	Various cables and adapters, foot switch	As Required

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10. TROUBLESHOOTING GUIDE

Problem	Troubleshooting Tips
No, or irregular system operation or no power.	1. Ensure that power switches of the isolation transformer, Generator and Chiller are all turned on (I). 2. Ensure that power cords from Generator and Chiller are plugged into the isolation transformer. 3. Ensure that the isolation transformer is plugged into a proper electrical outlet matching its electrical specification. 4. Ensure that fuses in isolation transformer, Generator and Chiller are intact and have Miramar Labs personnel replace fuses if needed (see How to Change Fuses, section 2.3). 5. If problem persists, contact Miramar Labs representative.
Red "Fault" light on right side of Generator front panel is illuminated; preventing initiation of therapy cycle with the "Start" button.	1. Ensure that the antenna control cable of the applicator is properly connected to the 14 contact quick-connect circular "Antenna Switch" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Ensure that the temperature cable of the applicator is properly connected to the 24 contact quick-connect circular "Temperature" connector on the front panel of the Generator. After the connector has been properly connected, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator.. 7. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates immediately after initiation of therapy cycle with the "Start" button.	1. Ensure that the chiller temperature is set properly. 2. Ensure that the chiller is not in standby mode. 3. Ensure that the coolant level in the chiller is adequate. 4. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 5. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 6. If problem persists, contact a Miramar Labs representative.
Red "Fault" light on right side of Generator front panel illuminates during the energy delivery cycle and the energy delivery cycle terminates prematurely	1. Ensure that the microwave cable of the Applicator is properly connected to the QMA quick-connect "Microwave Power Output" connector on the front panel of the Generator. Turn the generator power off and back on. After the connector has been properly connected and after the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 2. Check the Applicator for any visible indication of a damaged or kinked microwave cable and replace Applicator if damage is suspected. Turn the generator power off and back on. After the applicator microwave cable has been checked or the applicator has been replaced (if needed) and the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 3. Ensure that the chiller temperature is set properly. 4. Ensure that the chiller is not in standby mode. 5. Ensure that the coolant level in the chiller is adequate. 6. Ensure that there are no kinks in the fluid delivery or return tubes that would prevent coolant flow to the applicator. 7. Turn the generator power off and back on. After the AC mains power has been turned off and turned back on, the red "Fault" light should no longer be illuminated and the green "Ready" light should be illuminated. 8. If problem persists, contact a Miramar Labs representative.

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11. SPECIFICATIONS

Dimensions	40" H x 25" W x 25" D
Weight	125 lbs
AC input voltage	100-115V AC, 60 Hz
Protection	Protectively earthed, Class I
Microwave Output Frequency	5800MHz ± 50 MHz
Microwave Output Power	Adjustable from 40 to 100 Watts in 5 Watt increments
Integrated Vacuum setting range	0 to -28 inHg
Timer setting range	Pre-Cool 0 – 99.99 sec Energy 0 – 9.999 sec Post-Cool 0 – 99.99 sec
Patient Isolation	Class BF (body floating) for applied parts
Duty Cycle	Continuous
Environmental Operating Temperature/Humidity	Ambient Temperature: +60˚F to +80˚F (+16˚C to+26˚C) Relative Humidity (Non-condensing): 30% - 60%
Environmental Storage/Shipping Temperature/Humidity	Ambient Temperature: 0˚C to +50˚C Relative Humidity (Non-condensing): 20% to 85%
CONFORMS TO	Safety: UL 60601-1 Issued:2006/04/26 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety CSA C22.2#601.1 Issue:1990/01/11 (R2005) Medical Electrical Equipment - Part 1: General Requirements for Safety-General Instruction No 1; Update No 2 IEC 60601-1 Issue: 1998 + A1:1991 + A2: 1995. Medical Electrical Equipment Part 1: General Requirements for Safety EMC: IEC 60601-1-2 Issued:2004/11/01 Ed:2.1 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests-Edition 2.1; Consolidated Reprint –

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199 Jefferson Drive
Menlo Park
CA 94025
United States

1-650-326-2656 (telephone)
1-650-326-3108 (fax)

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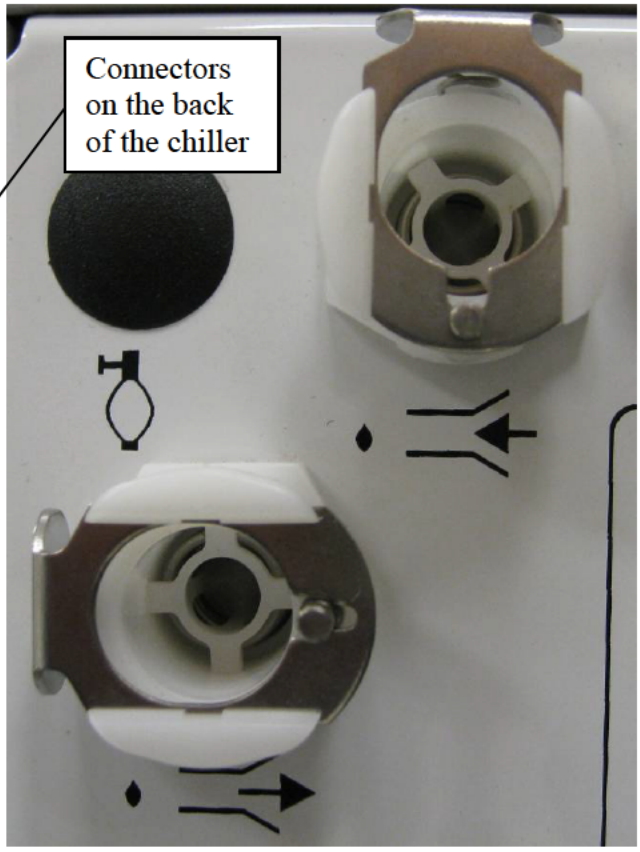
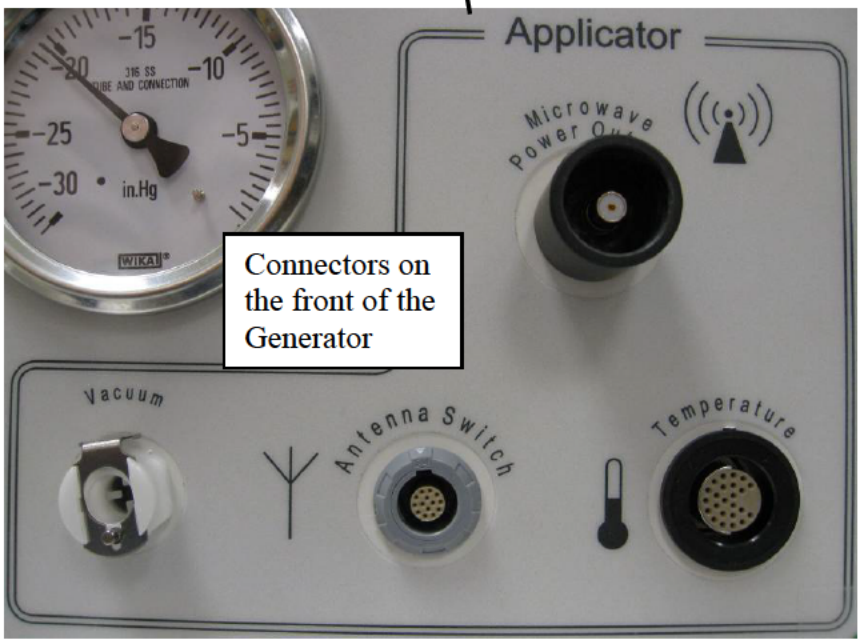
ATTACHMENT D

Photos of the connectors for the DTS G2 System

See also pages 5 and 6 of the DTS G2 User Manual for a more complete description of each connector, filed as attachment K of the response dated November 17, 2008.

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





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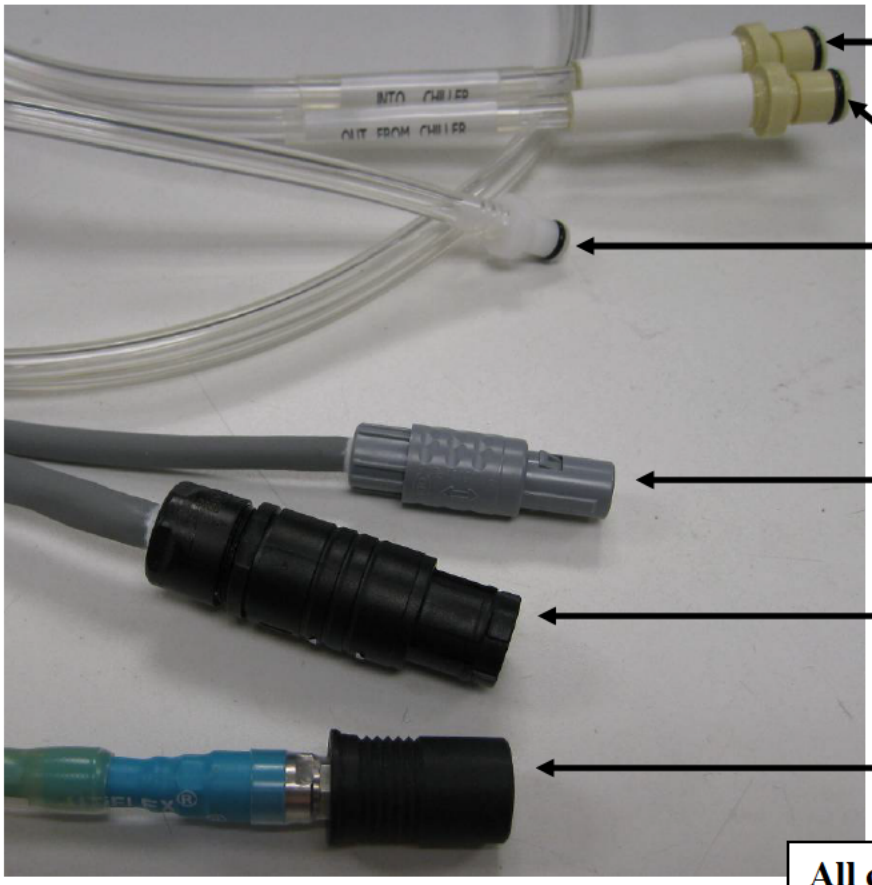


Coolant inflow connector (7/16" diam; to back of chiller)

Coolant outflow connector (7/16" diam; to back of chiller)

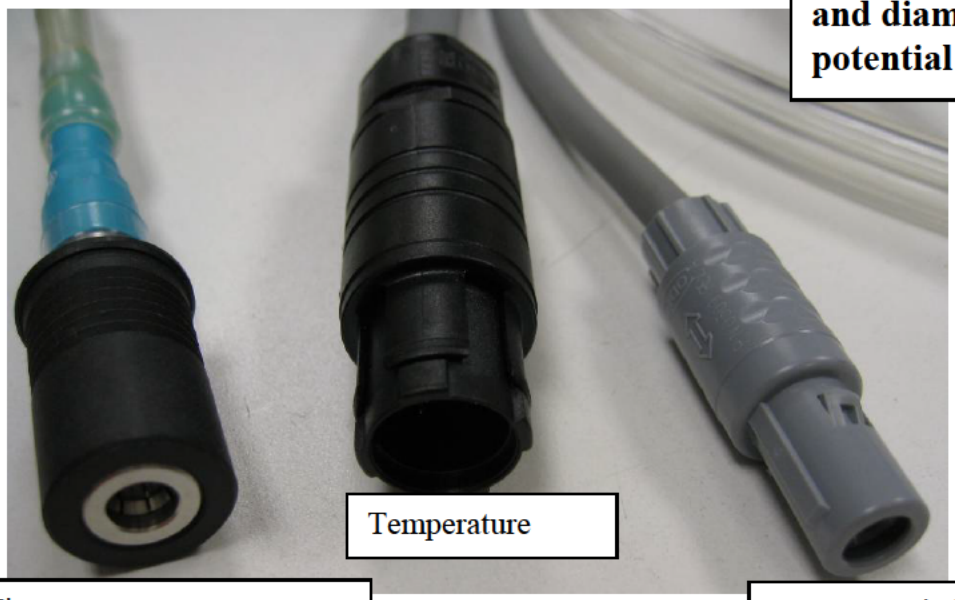
Vacuum connector (5/16" diam)

Antenna switch (14 pin)

Temperature (24 pin)

Coaxial microwave power connector

All connectors have different pins and diameters to remove the potential for misconnections.



Temperature

Microwave power

Antenna switch

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ATTACHMENT E

DTS-LT Applicator Instructions for Use

(Draft dated February 27, 2009
Revised to add information regarding effect of cooling temperature)

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

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INSTRUCTIONS FOR USE

DTS-LT APPLICATOR

DRAFT 02/27/09

Deleted: 11/14/08

Miramar Labs, Inc.

199 Jefferson Dr.
Menlo Park, CA 94025
Phone: 650-326-2656
Fax: 650-326-3108

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

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DTS-LT APPLICATOR INSTRUCTIONS FOR USE

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

BEFORE USING THE SYSTEM:

Please refer to DTS G2 Generator User Manual for detailed instructions on connecting and operating the entire system. Components of the DTS G2 System are designed to be used together as a single unit.

Failure to understand and follow provided instructions may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

- The DTS G2 System is indicated for use for coagulation of soft tissue.

IMPORTANT:

- The procedures should only be performed by physicians and operating room staff familiar with the equipment and techniques involved.

WARNINGS AND CAUTIONS:

- ONLY use power/time settings that are within the bounds listed in the guidance tables below. Using higher power/time settings could cause injury to the patient.
- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
- DO NOT apply power with Applicator not in contact with the target tissue
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

- Refer to DTS G2 Generator User Manual for detailed instructions on how to activate system generator and properly connect associated components.
- Refer to the NanoTherm Chiller/Circulator User Manual for detailed instructions on how to set chiller temperature and activate the flow.
- Connect the Applicator Disposable Head to the DTS Applicator LT (see Figure 1 below)
- Inspect the film on the Applicator Disposable Head to ensure no rips/tears/holes are present.

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

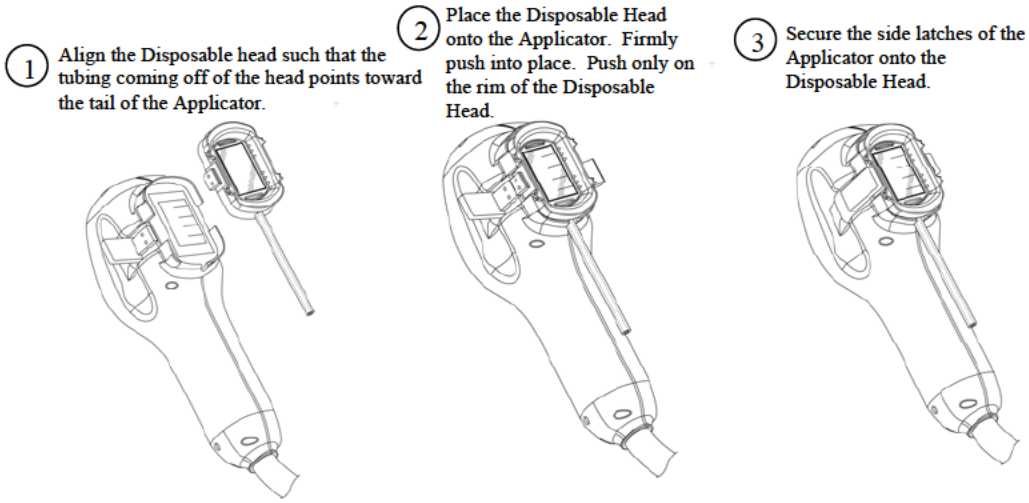

Figure 1. Connecting the Disposable Head onto the Applicator

STARTING THE PROCEDURE

- Activate the cooling flow for surface cooling.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level.
- Set power, cooling temperatures and durations of pre-cool, energy delivery, and post cool to desired levels.
  - Energy delivery times and cooling temperature settings can be chosen based on the tables below and the desired lesion size.
  - Recommended setting for Pre-cool time is 3.0 sec and post-cool time is 20.0 sec. Settings can be varied if more surface cooling is desired.
- Place the Applicator on the target tissue (see Figure 2 below for proper technique of holding the handle).
- Confirm the generator settings before proceeding with the procedure.

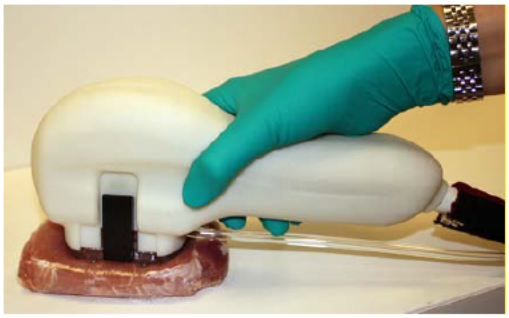

Figure 2. Proper technique for holding the handle of the Applicator

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ANTENNA SELECTION

The DTS Applicator LT contains four antenna that are arranged in a row along the Applicator body (see Figure 3 for the location and numbering scheme). The antenna are spaced 9 mm apart.

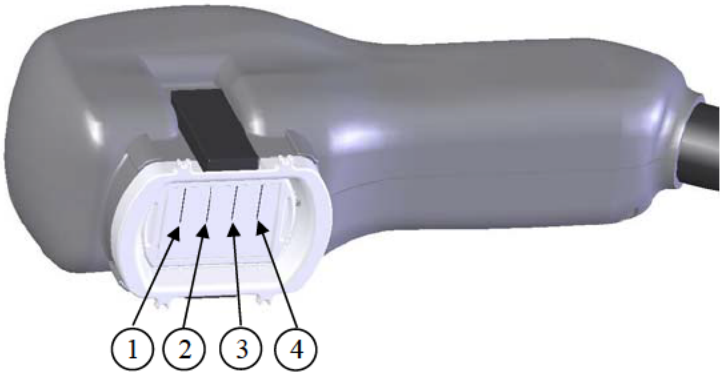

Figure 3. Location and numbering of antenna for the DTS Applicator LT.

Figure 4 shows a comparison between single antenna activation (4A) compared to having four antennas activated (Figure 4B). The DTS G2 Generator sends power to only one antenna at a time. Similar lesions are created under each antenna.

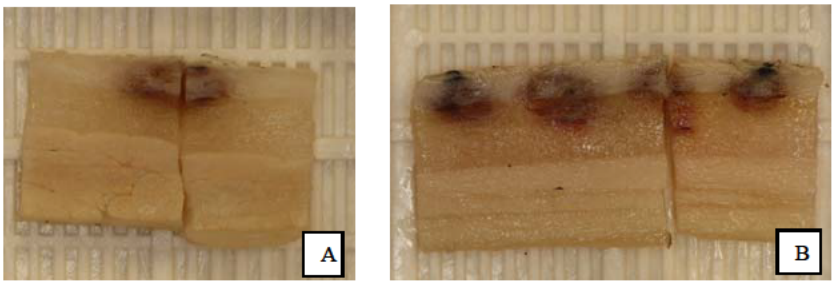

Figure 4. Cross-sectional view of lesions created by single antenna activation (A) versus lesions created with 4 antennas activated (B) in an In-Vivo porcine skin model.

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GENERAL SOFT TISSUE

NOTE:
The following tables show the approximate lesion size created by the DTS LT Applicator at various power and energy time settings with a single antenna activated for different tissues. A second table shows the variation in lesion size with different cooling temperature choices. If more than one antenna is activated, it is reasonable to expect a repeat of the lesion created with a single antenna as shown in Figure 4 with a skin model. The results below are from Ex-Vivo porcine tissue models. Lesion sizes may vary in clinical setting.

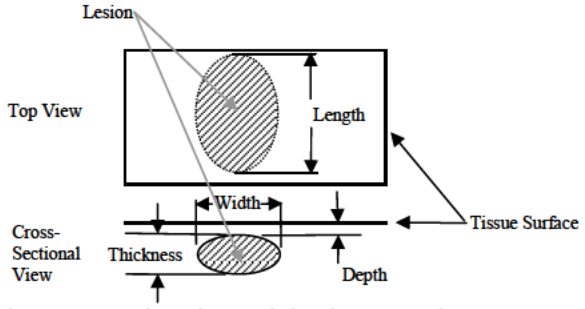

Figure 5. Lesion size and depth nomenclature.

Power (W) @ 10 °C	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length**	—	—	—	—	**6.1**
	Width					2.8
	Thickness					**1.8**
	Depth					0.6
60	**Length**	—	—	**7.6**	**7.6**	**8.8**
	Width			3.8	4.8	5.3
	Thickness			**1.9**	**3.0**	**3.1**
	Depth			0.3	0.6	0.4
80	**Length**	—	**7.8**	**8.4**	**9.5**	—
	Width		4.1	5.9	6.6	
	Thickness		**2.5**	**2.9**	**3.1**	
	Depth		0.5	0.3	0.3	
100	**Length**	**8.1**	**9.3**	**10.0**	—	—
	Width	5.4	6.6	7.4		
	Thickness	**2.5**	**2.9**	**3.4**		
	Depth	0.3	0.3	0.0		

Table 2. Approximate lesion sizes created in Ex-Vivo muscle tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

Lesion Dimension (mm)	5 °C	10 °C	20 °C
Length	**8.4**	**8.4**	**10.4**
Width	5.8	5.9	6.4
Thickness	**3.1**	**2.9**	**2.9**
Depth	0.3	0.3	0.0

Table 3. Approximate lesion sizes created in Ex-Vivo muscle tissue with variable cooling temperature settings. Power set at 80W and energy delivery time at 6 sec. All lesion size dimensions are in **millimeters**.

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Power (W) @ 10 ºC	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length** Width **Thickness** Depth	–	–	–	–	**7.4** 2.6 **1.8** 0.9
60	**Length** Width **Thickness** Depth	–	–	**7.5** 2.5 **1.6** 0.8	**7.8** 3.3 **2.6** 0.6	**9.4** 3.8 **2.9** 0.6
80	**Length** Width **Thickness** Depth	–	**7.1** 3.3 **2.0** 0.5	**8.5** 3.9 **2.5** 0.5	**8.8** 5.4 **2.9** 0.3	–
100	**Length** Width **Thickness** Depth	**7.6** 3.8 **1.5** 0.6	**8.9** 5.0 **2.9** 0.3	**9.3** 5.5 **2.6** 0.3	–	–

Table 4. Approximate lesion sizes created in Ex-Vivo liver tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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Lesion Dimension (mm)	5 ºC	10 ºC	20 ºC
Length	**8.4**	**8.5**	**8.8**
Width	3.6	3.9	5.8
Thickness	**2.5**	**2.5**	**2.8**
Depth	0.6	0.5	0.3

Table 5. Approximate lesion sizes created in Ex-Vivo liver tissue with variable cooling temperature settings. Power set at 80W and energy delivery time at 6 sec. All lesion size dimensions are in **millimeters**.

Power (W) @ 10 ºC	Lesion Dimension (mm)	4 sec.	5 sec.	6 sec.	7 sec.	9 sec.
40	**Length** Width **Thickness** Depth	–	–	–	–	**7.1** 2.3 **2.1** 1.0
60	**Length** Width **Thickness** Depth	–	–	**8.1** 2.3 **2.3** 0.8	**8.4** 3.0 **2.6** 0.8	**9.0** 4.1 **3.6** 0.3
80	**Length** Width **Thickness** Depth	–	**8.9** 4.2 **2.5** 0.5	**9.0** 4.3 **3.0** 0.6	**9.5** 5.4 **4.0** 0.3	–
100	**Length** Width **Thickness** Depth	**8.9** 3.7 **3.1** 0.5	**9.5** 5.6 **3.9** 0.3	**10.1** 6.1 **3.9** 0.4	–	–

Table 6. Approximate lesion sizes created in Ex-Vivo kidney tissue. Coolant set at 10°C. All lesion size dimensions are in **millimeters**.

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Lesion Dimension (mm)	5 ºC	10 ºC	20 ºC
Length	**8.4**	**9.0**	**9.6**
Width	5.4	4.3	5.5
Thickness	**2.8**	**3.0**	**2.8**
Depth	0.6	0.6	0.3

Table 7. Approximate lesion sizes created in Ex-Vivo kidney tissue with variable cooling temperature settings. Power set at 80W and energy delivery time at 6 sec. All lesion size dimensions are in **millimeters**.

PROCEDURE NOTES

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to DTS Generator User Manual for troubleshooting.

AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from Generator and Chiller/Circulator.
- Open the side latches on the Applicator and remove the Disposable Head. Discard the Disposable Head and the attached vacuum tubing. Do not re-use the Disposable Head.
- Turn off Generator after procedure.

STORAGE:

- Store Applicator away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:

⚠.....**Read Instructions**

Applicator Technical Specifications

Energy Modality:	Microwave
Frequency of Operation:	5.8GHz
Power Handling Capability:	0-100 Watts
Number of Active Antennas:	1-4
Applicator Head Footprint:	5cm x 7cm

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

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ATTACHMENT F

NanoTherm User Manual

(Repeat of manual that was submitted as part of Attachment B of the original submission dated September 23, 2008)

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

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NanoTherm™ Industrial **User Manual**

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

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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

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1. Introduction

Please read the entire manual carefully before trying to operate the NanoTherm™ system. It is unsafe to start using the NanoTherm system before reading the entire user manual.

At ThermoTek, we pledge to provide the highest quality product with excellent support and service. If we can do anything to make your NanoTherm experience better, please do not hesitate to contact us.

User Assistance Information:

The NanoTherm System is manufactured by:

ThermoTek, Inc.
1454 Halsey Way
Carrollton, TX 75007
(972) 242-3232
(877) 242-3232 (toll free service number)

Visit us on the web at www.thermotekusa.com

Icons Used for Warnings and Cautions:

Electrical Shock Risk
Burn Risk
Frostbite or Cryogenic Burn Risk
General Caution

Do not drink or ingest the coolant mixture.

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

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

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2. General Warnings and Cautions

2.1 Precautions:

When using the NanoTherm system, basic safety precautions should always be followed to reduce the risk of fire, electric shock and personal injury. Please read the entire manual carefully before trying to operate the unit. Precautions include:

2.2 Warnings:

- Never push objects of any kind into the unit through the air filter or frame.
- Never spill liquid of any kind on the unit.
- Do not overfill the reservoir of the unit.
- If the unit gets wet, unplug the unit from the wall and allow the unit to dry before use.
- The unit must be operated with the supplied power cord and plugged into a 3-prong grounded outlet.
- Do not operate the unit if it has any noticeable or physical damage or is leaking fluid.
- Do not operate the unit with a damaged or frayed power cord.
- The unit is not intended to be used in a wet environment or when relative humidity is greater than 60%.
- Do not spray the unit with any water solvents or cleaners.
- Do not drop the unit or cause impact to the unit.
- Do not use this device without the supplied air filter.
- Do not use near equipment that generates electromagnetic or other interferences as this may be harmful to the unit.
- Do not touch the heat sink fins on the sides of the unit during or immediately after operation.
- Do not stick a finger or any other foreign objects into the reservoir.
- Do not attempt to sterilize this device by any means.
- Use only the approved coolant in the NanoTherm unit.

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

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Slots and openings in the cabinet are provided for ventilation to protect the unit from overheating. These openings must not be blocked or covered at any time except by the supplied air filter.

Observe all warning labels. Never remove the warning labels.

Do not drink or ingest the coolant.

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

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3. NanoTherm Device Description

The NanoTherm system is an electronic heating and cooling system. The NanoTherm system provides precisely controlled fluid temperature for cooling and heating applications. This lightweight, portable system utilizes solid-state thermoelectric heat pumps that heat and cool with electricity in a safe and environmentally friendly manner.

3.1 Features:

- Fluid Temperature Range between 10ºC – 40ºC
- Lightweight and Portable Package
- User-Friendly Interface
- 110 VAC Power Input
- Illuminated Fluid Level Indication
- Easy to read Liquid Crystal Display
- Quiet Operation
- Flow Switch
- RS232 Communication

3.2 General Specifications:

- Weight: 15 lbs.
- Hose Length: 7 ft.
- Hospital Grade Power Cord
- Dimensions: 5.25”W x 8.75”H x 14.25”D
- Operating Fluid: 90% Distilled Water/10% Isopropyl Alcohol
- Safety: UL Medical Listing 60601, CE

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

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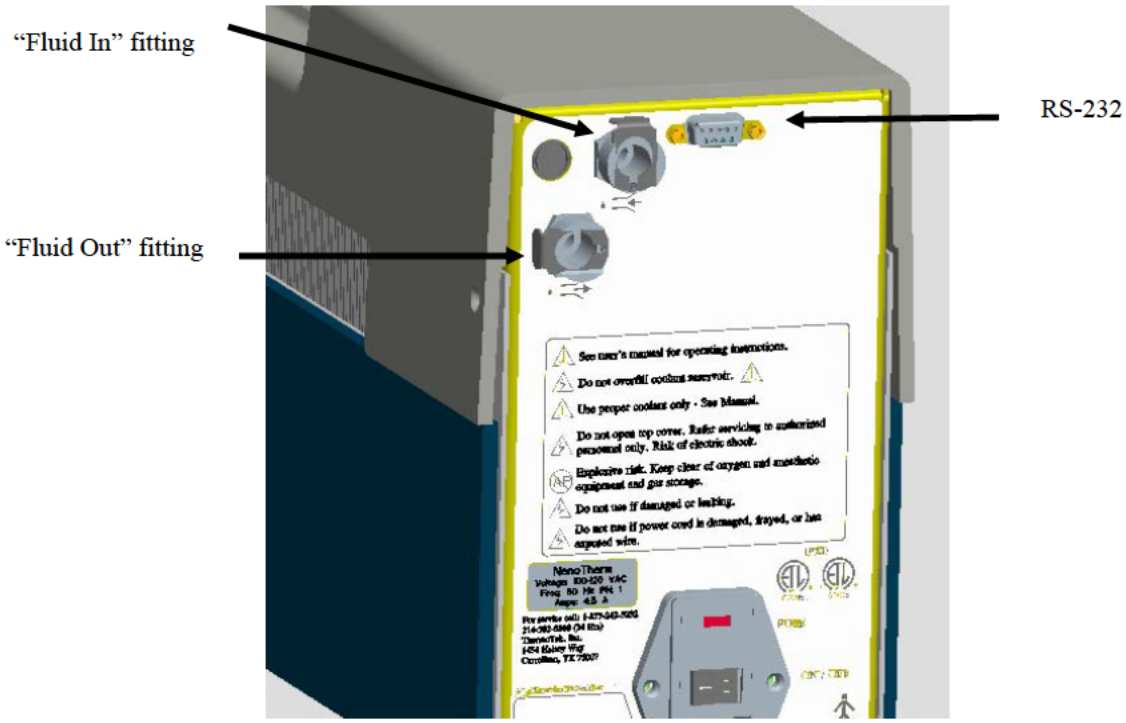
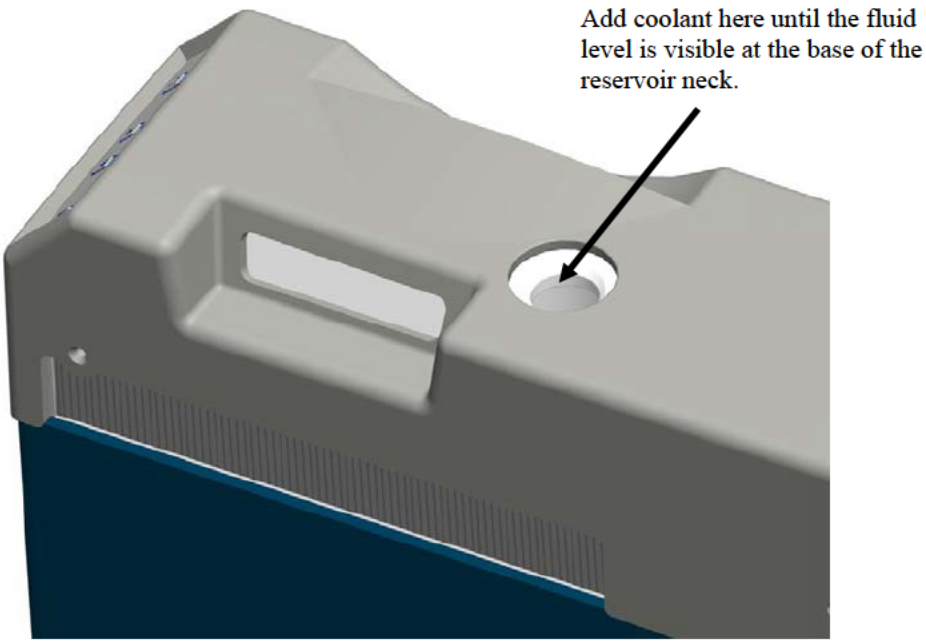
3.3 Device Description:

Rear Panel Connections



Coolant Reservoir Fill Location



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

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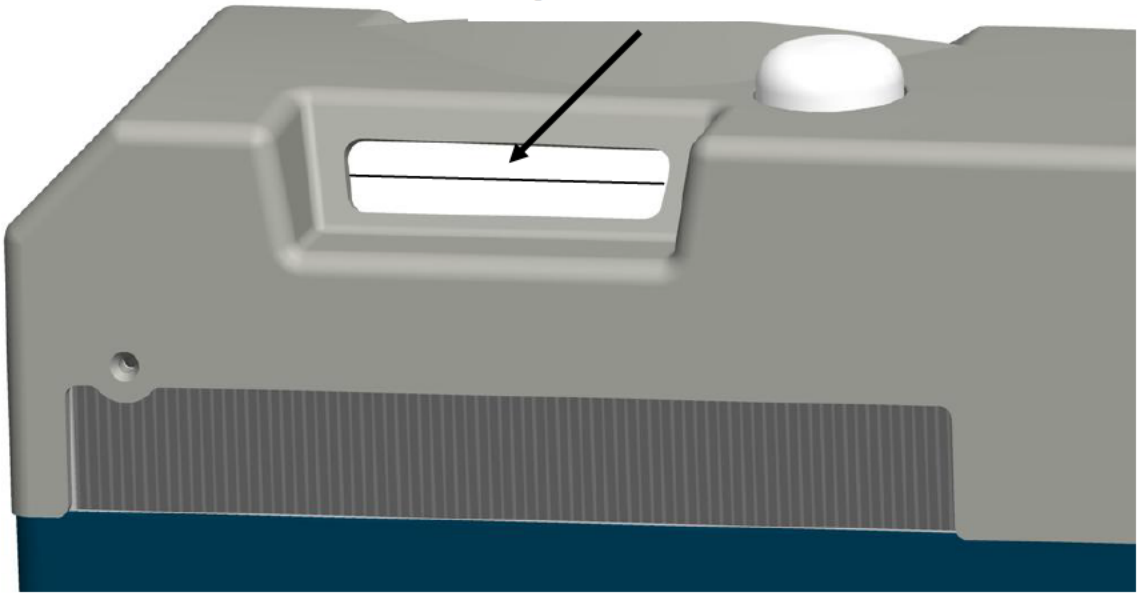
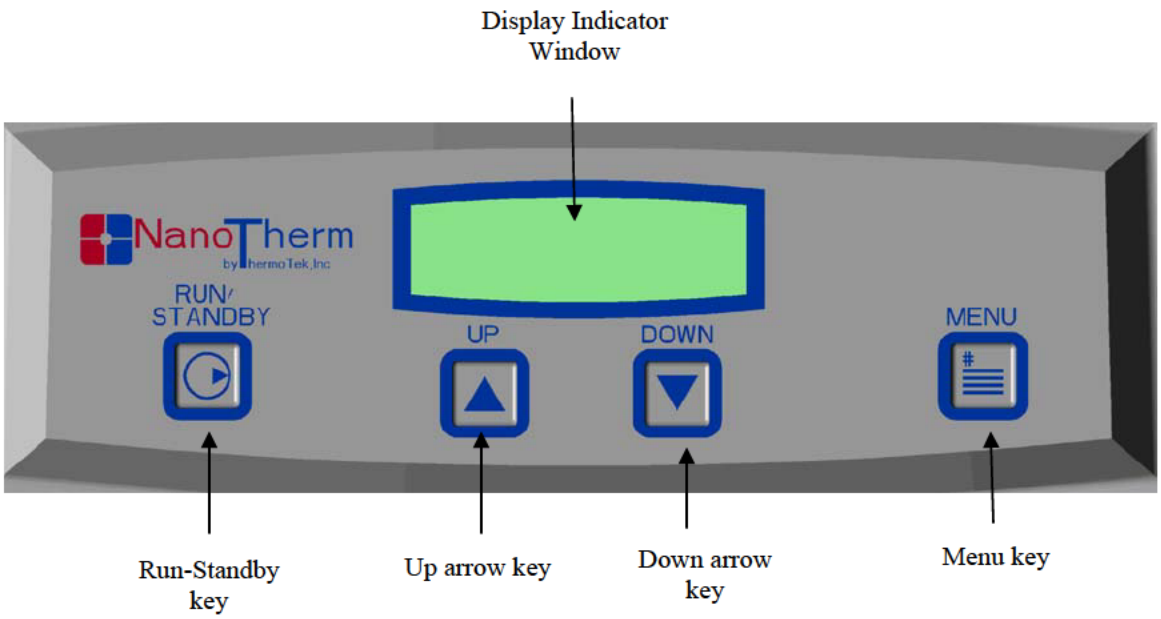
Reservoir Coolant Level Window

If the coolant level can be seen lower than halfway down the window, more coolant should be added. See Chapter 6 for instructions on how to add more coolant.



Keypad Interface and Illuminated Display



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

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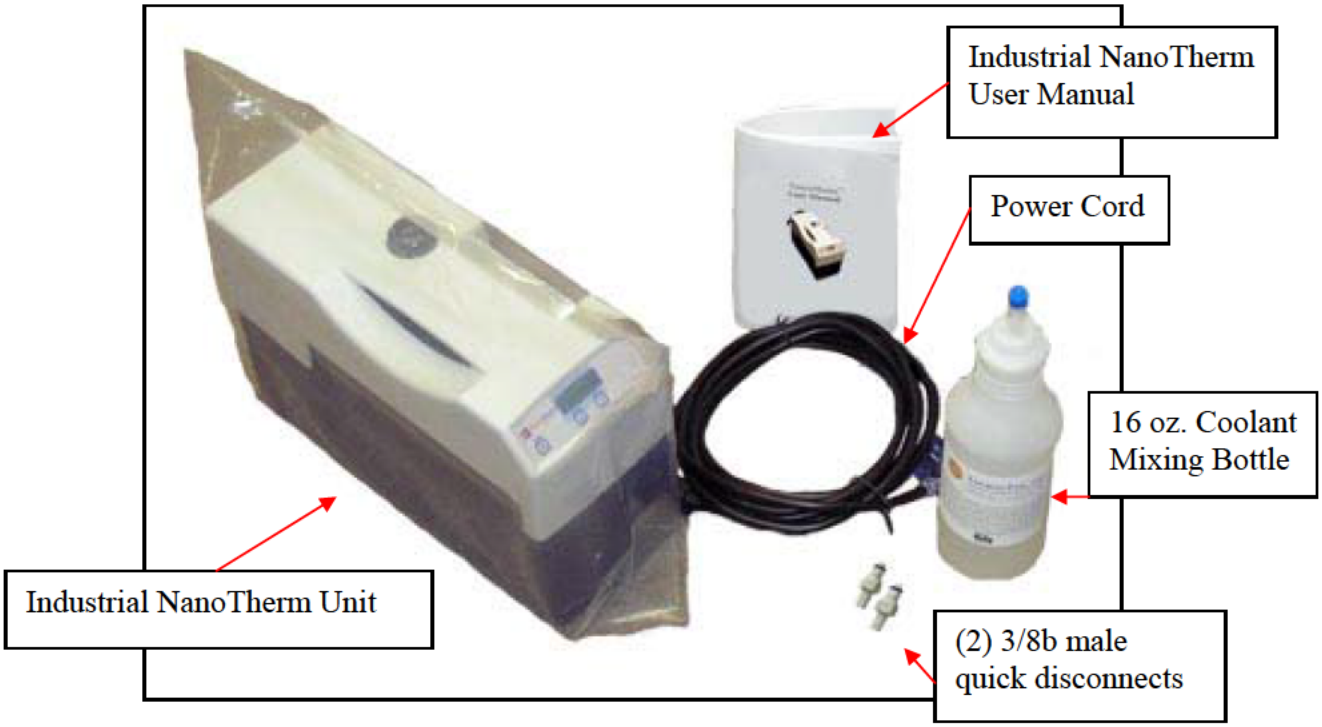
4. Unpacking Your NanoTherm System

When you first unpack the carrying case you should have the following items:



All of these items are needed for safe system operation. If any of these items are missing from the carrying case or shipping container, please contact ThermoTek Customer Service at 877-242-3232.

Immediately upon unpacking your NanoTherm System, inspect your unit. If the unit shows shipping damage, contact the transportation company and file a freight damage claim. **Be sure to retain all packing material and the original box or case.**

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

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5. Environmental Conditions You Should be Aware of Before Operating Your NanoTherm Device

The NanoTherm system is intended for indoor use only.

Do not operate the NanoTherm system in or near a wet environment.

The NanoTherm system is not to be used in a confined space. Adequate air flow distance from the unit sides must be maintained during operation. Inadequate air flow can result in overheating of internal electrical components and undesirable or excessive noise.

Only use the NanoTherm system in an ambient environment between 60-80 ºF (degrees Fahrenheit) and a relative humidity below 60%.

Failure to meet these operating environment conditions may result in:

Condensate buildup inside the unit.

Overheating or freezing of the unit.

Internal electronics malfunction

- A reduction in the heating or cooling capabilities of the unit
- A potential to blow the unit's electrical fuse due to an internal electrical overload.
- The inability of the unit to properly regulate and administer fluid temperature during system operation.

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

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6. How to Set Up Your NanoTherm System

1. Connect the unit to the application using a fluid transport from ThermoTek, or hoses using Colder PLC or PLCD insert fittings.

2. Keep unit upright and on a level surface.

3. Make sure there is a 6-inch clearance and free path for flow of air entry and exit around the unit prior to operation.

4. Verify the power switch is in the OFF position.

5. Remove the reservoir cap and add coolant to the reservoir until the fluid level reaches the bottom of the neck. **See Recommended Coolants (Section 8.3).**

6. DO NOT overfill the reservoir.

7. Install the appropriate end of the power cord into the unit. Plug the male end into the appropriate AC voltage within the specified voltage.

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

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7. Operating Instructions for Your NanoTherm System

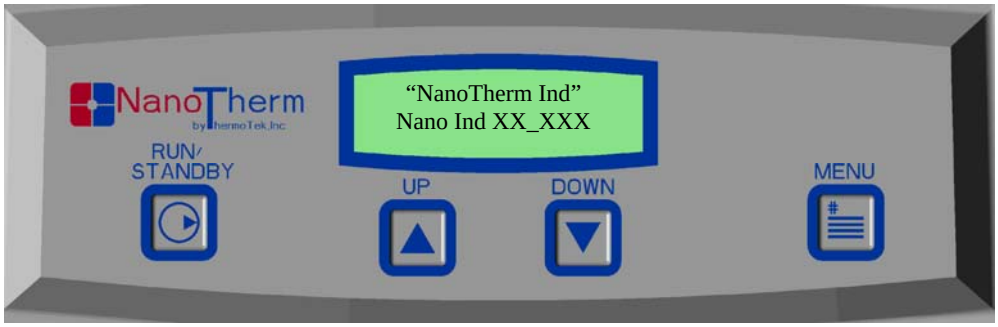
Refer to Chapter 6 “How to Set Up Your NanoTherm System” before beginning any application.

7.1. Start Up and Operating Position:

1. Verify the unit is plugged into the appropriate AC voltage outlet.

2. Turn the unit to the ON position. The ON/OFF switch is located on the rear panel of the unit.

3. When the unit is first powered up, a green back light will illuminate the display screen located on the front panel of the unit and the fans will turn on. The message **NanoTherm Ind, Nano Ind_XX_XXX** will appear on the display screen.



4. Once the unit is powered up, it may be necessary to add more fluid to the reservoir. The system will display a low coolant flow alarm if coolant is low. Press the RUN/STANDBY key to clear the alarm.

Note: Optional External Flow switch detection is disabled for 5 seconds during initial system prime.

5. During the power up sequence, there will be a moment when the keypad is disabled and you will hear the pump being powered up and brought up to speed. The fans will be initiated at this time. This sequence will be repeated each time the unit is powered up or taken from standby to operation.

6. The unit will automatically control to the last set temperature.

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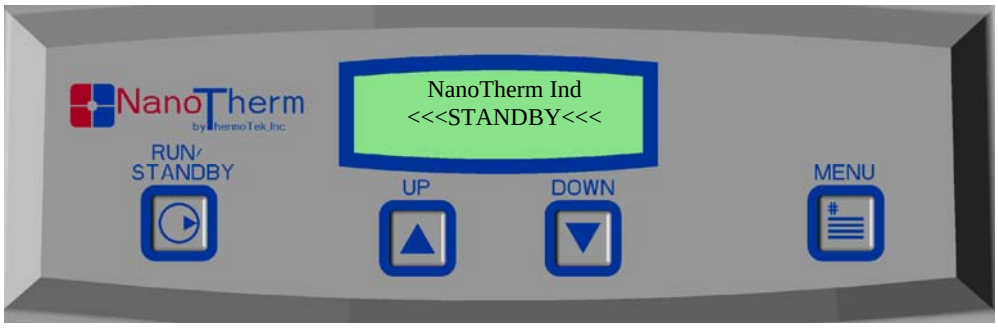
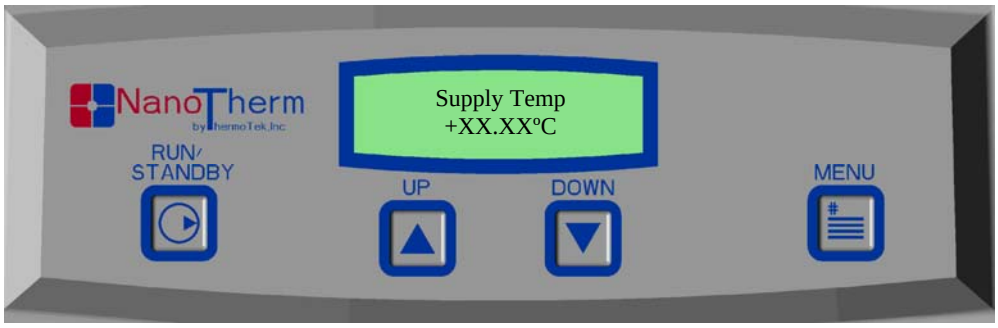
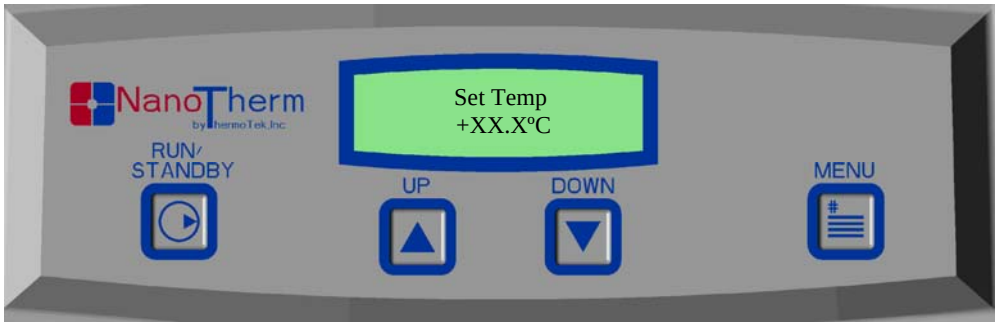
7. To stop the coolant flow to your application, press the RUN/STANDBY key on the keypad. A display message will read “STANDBY”. The unit will stop running. The pump will stop and after a few seconds the fans will turn off.



8. To restart the unit, press the RUN/STANDBY key. The unit display will read “Supply Temp + XX.XXºC”. Set the unit to the desired temperature.



9. To change the set temperature, press the MENU key on the keypad until the display reads “SET TEMPERATURE”. To lower the fluid temperature, press the DOWN key on the keypad. To raise the fluid temperature, press the UP key on the keypad.



Note: If you hold the appropriate key down, the set point will scroll in tenths of degrees and then change to full ºC increments.

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10. To determine the current fluid temperature in your application, press the MENU key until the display reads “SUPPLY TEMP”.

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8. Display Messages and Alarm Indicators

8.1. Normal Operation

The following list contains display messages that you may encounter during normal operation:

- **RUN/STANDBY:** Standby mode indicates that the pump is OFF and the unit is ready for use. Press the pump RUN/STANDBY key to begin the heating/cooling application.
- **SUPPLY TEMP:** Indicates the unit is controlling to set temperature.
- **SET TEMPERATURE:** Shows the current set temperature. This can be adjusted by pressing the UP and DOWN keys to the desired temperature setting.
- **LIFE TIMER:** Displays total system hours.
- **FLOW SWITCH:** Enabled or Disabled.
- **HEAT SINK TEMP:** Internal heat sink temperature reading.
- **PLATE TEMP:** Internal reservoir plate temperature reading.

8.2. Warnings, Alarms, and System Errors

The NanoTherm System has many internal software safeguards to help protect the unit from unsafe operation. In this section you will find a list of possible system warnings and alarms that may occur if a potentially unsafe situation arises while using the NanoTherm unit.

Warnings indicate that an unsafe condition could or is about to occur. Warning notifications combine the use of a flashing description on the upper line of the display and a fast beeping noise.

Alarms indicate that an unsafe condition is currently present and halts all current applications to protect the user. The alarm state must be corrected before any application can be restarted. Alarm notification combines the use of “ALARM ACTIVE” text on the upper line and an alarm description on the lower line of the display. An audible notification is also initiated by a slow beeping noise. Press the RUN/STANDBY key to clear the active alarm. If the alarm state is still present, the alarm message will reappear and prevent the start of any application.

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System Errors indicate that an internal software or hardware error has occurred and that an unsafe condition is currently present and all current applications are halted to protect the user. An example of this is when there is a problem reading from one of the internal sensors. System errors typically require service to the unit to identify and correct the problem. If you encounter a system error, please write down the 3-digit number indicated on the display and contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time.

Below is a list of common user-related warnings and alarms that may occur during application operation of the unit.

!!ALARM ACTIVE!! HIGH H-SINK TEMP: Anytime the unit is turned ON, the software constantly monitors the temperature of the heat sink fins visible on either side of the unit. If the software determines that the heat sink fin temperature is hotter than a safe level this alarm activates.

!!ALARM ACTIVE!! HIGH TEMP ALARM: Anytime the unit is turned ON, the software constantly monitors the temperature of the internal coolant manifold. If the software determines that the temperature of the manifold is hotter than a safe level this alarm activates.

!!ALARM ACTIVE!! LOW H-SINK TEMP: Anytime the unit is turned ON, the software constantly monitors the temperature of the heat sink fins visible on either side of the unit. If the software determines that the heat sink fin temperature is colder than a safe level this alarm activates.

!!ALARM ACTIVE!! LOW TEMP ALARM: Anytime the unit is turned ON, the software constantly monitors the temperature of the internal coolant manifold. If the software determines that the temperature of the manifold is colder than a safe level this alarm activates.

SYSTEM ERROR XXX: This alarm indicates that an internal software or hardware error has occurred. The unit potentially requires service by an authorized technician. If you encounter a system alarm, please write down the 3-digit number indicated on the display and contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time.

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

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8.3. Recommended Coolants:

1. Distilled water: For operation from 10ºC to 40ºC only. Replace monthly to prevent biological growth.

2. 95% distilled water and 5% alcohol mixture prevents bacterial growth. Replace every 90 days.

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

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9. Things You Can Do To Keep Your NanoTherm System Performing

Do not use abrasive or solvent-based cleaners on the unit.

There are no user serviceable internal parts. The system warranty is voided if the tamper seals are breached or removed.

Keep water away from vents, power ON/OFF switch and the power cord connection of the unit.

To avoid possible electric shock, do not remove the cover of the unit.

Do not immerse the unit in water or any liquid.

- **Check the fluid level weekly.**
- **Wipe the exterior of the unit with a damp cloth.**

  Do not use abrasive or solvent-based cleaners on the unit.

- **Cleaning the filter:**

  1. The filter is attached to the unit with Velcro strips. Carefully remove (separate) the filter from the Velcro strips installed to the unit.
  2. Use warm, soapy water to clean the filter.
  3. Allow the filter to air dry completely before re-installing to the unit.

- **Re-installing the filter:**

  The air filter must be completely dry before installing on the unit. Using a wet air filter has a strong risk of causing an internal electrical short and is hazardous to both the user and the unit.

  1. Turn the unit OFF and disconnect the power cord.
  2. Starting at the rear of either side of the unit, begin attaching one end of the air filter towards and around the front of the unit using the Velcro strips.
  3. Continue attaching the air filter around to the opposite side of the unit.
  4. The filter should be taught without bulge across the top and bottom of the filter to prevent bypassing of air.

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

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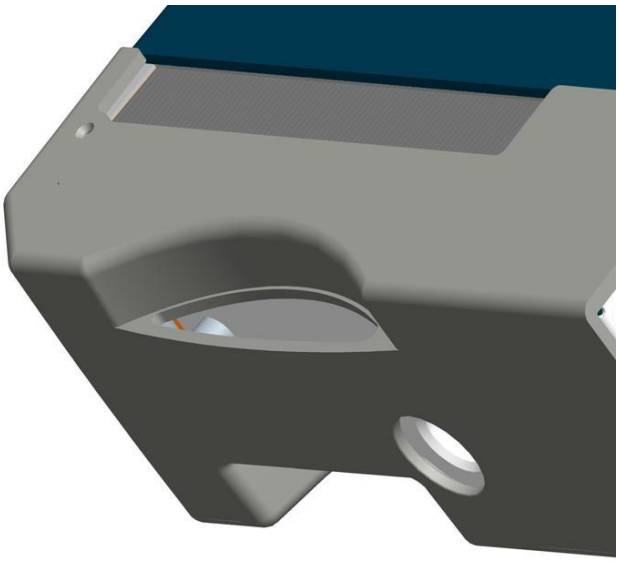
10. Draining the Fluid from the Unit

If the unit is going to be stored for a long period of time or periodically between uses, the unit should be drained of fluid.

1. Turn the unit OFF and unplug from electrical source.

2. Remove the reservoir cap from the unit by twisting the cap counter-clockwise.

3. Lift the unit on both ends and tip backward to empty the fluid from the reservoir into a bucket or sink.



4. Continue to tip the unit until the reservoir is completely empty of all fluid.

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

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11. Storage and Re-Packing the Unit

When user application is complete and it is time to return or store the NanoTherm system, you can use the transport box.

1. Turn the unit OFF and unplug from the electrical source
2. Disconnect all fittings from the rear panel of the unit.
3. Follow the "Draining the Fluid from the Unit" instructions in Chapter 10.
4. Do not screw the unit's reservoir cap on, but rather leave it off to allow the unit to dry completely. This helps avoid the risk of microbial growth in the unit during storage or long transport.
5. Collect the following items together:
    - NanoTherm Unit
    - Reservoir Cap
    - Power Cord
    - User Manual
    - Coolant Mixing Bottle
    - Hand-carry Box with Package Inserts
6. Store the above items in the original packaging box or in the travel case you received.
7. Store indoors in an ambient environment between 40 ºF and 105 ºF.

Failure to properly store the unit may result in the following:

⚠ Damage to the unit.

⚠ Catastrophic system damage if the unit is not properly drained.

⚠ Microbial growth inside the unit if not properly drained.

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

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12. Troubleshooting Guide

Refer to Chapter 5 “Environmental Conditions You Should Be Aware of Before Operating Your NanoTherm Device” for a list of acceptable environmental conditions for safe operation.

This unit is NOT intended for field repair. Do not attempt to service the unit in any way other than using the instructions listed in this guide.

If the unit is displaying an alarm, warning, or system error not listed in the above Troubleshooting Guide, contact Customer Support. See the Customer Support contact information below.

If your issue cannot be resolved with the following scenarios, first contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time.

Problem	Cause	Suggested Actions
Nothing happens when I turn the unit to the ON position.	No AC Power to the unit.	Make sure the unit is plugged into the appropriate electrical outlet. Make sure the power cord is also plugged into the therapy unit.
	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

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

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Problem	Cause	Suggested Actions
My unit gives me a HIGH H- SINK alarm.	Dirty air filter.	Check the filter. If it is dirty, clean or replace with new filter. Refer to Chapter 9 for details.
	Unit operated in a place with restricted airflow.	Make sure the unit is operated in a location with adequate airflow from all sides. Make sure there is at least 6” of clearance around the unit.
	Unit is operated in a hot ambient environment	Make sure the unit is operated indoors in an ambient < 80° F
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a LOW H- SINK alarm.	Unit is operated in a cold ambient environment.	Make sure the unit is operated indoors in an ambient > 60° F.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a HIGH TEMP alarm.	The unit was filled with hot coolant.	Make sure the unit is filled with room temperature fluid.
	Unit is operated in a hot ambient environment.	Make sure the unit is operated indoors in an ambient < 80° F.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

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

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Problem	Cause	Suggested Actions
My unit gives me a LOW TEMP alarm.	The unit was filled with cold coolant.	Make sure the unit is filled with room temperature fluid.
	Unit is operated in a cold ambient environment.	Make sure the unit is operated indoors in an ambient > 60° F.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a SYSTEM ERROR XXX alarm.	Reservoir cap is not screwed tightly.	Make sure the unit is unplugged from the AC outlet. Check the reservoir cap and secure it tightly. Connect to AC power and restart unit.

Problem	Cause	Suggested Actions
The unit is leaking. **(cont'd on next page)**	The coolant ports are not connected / seated properly.	Make sure the unit is unplugged from the AC outlet. Check the coolant connections; disconnect and reconnect the ports to make sure they are seated properly.
	Physical damage to the unit.	Inspect the unit for physical damage. . If the unit shows any cracks or dents and is leaking, the unit should not be used. Contact ThermoTek Customer Support.

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

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Problem	Cause	Suggested Actions
The unit is heating when it should be cooling (or cooling when it should be heating)	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	The unit is in Alarms Active state.	Check display for alarm events. If alarms are displayed use the trouble-shooting guide to resolve the issue.

Problem	Cause	Suggested Actions
Unit turns on, but it is not heating or cooling.	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists
	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.

Problem	Cause	Suggested Actions
The unit is noisy.	Foreign objects lodged inside the air filter.	Turn the unit off and unplug it from the power source. Remove the air filter and inspect the chassis vents for any foreign objects that may be lodged inside or present in the unit. If the foreign object cannot be removed, Contact ThermoTek Customer Support.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	Unit not connected to AC power.	Make sure the unit is connected to the AC outlet. Make sure the power switch on unit is switched to the ON position.

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

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Problem	Cause	Suggested Actions
The display is not functioning.	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	Unit not connected to AC power	Make sure the unit is connected to the AC outlet. Make sure the power switch on unit is switched to the ON position.

Problem	Cause	Suggested Actions
The keypad is not responding	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.
	Internal fault within the unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

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

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13. Service and Customer Support

ThermoTek, Inc. is committed to servicing our NanoTherm™ unit both during and after sale to the customer. If you have any questions concerning the operation of your NanoTherm™ unit, please refer to the following to contact us at our Carrollton, Texas facility:

- **Sales Organization:** (972) 242-3232
- **Toll Free Number:** (877) 242-3232
  (between 8:00am and 5:00pm CST, Monday through Friday)
- **ThermoTek Website:** www.thermotekusa.com

Do not drink or ingest the coolant mixture.

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

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14. Accessories and Replacement Parts

Boxes/Foam:

Part Number	Description
0P2HNTFSET	Packing Foam
0P2HNTSBX0	Shipping Box
0P7ANANTRC	Traveling Case, Single

Replacement Parts:

Part Number	Description
0P2CDMARFT	Washable Air Filter
0P2DDMRSPG	Reservoir Cap
0P3C12MGCP	Cord, Power 13A/110 VAC, Medical Grade
0P2HNAN0FL	Mixing Bottle, Thermoflow
0P2HNAN0SP	Mixing Bottle, Spout
0P2EBBMQKD	Fittings

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

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15. Specifications

NanoTherm Part Number	0P9TNAN001
Dimensions	5.25”W x 8.75”H x 14.25”D
Ambient Operating Range	60 – 80 ºF
Relative Humidity	< 60% RH
Set Temperature Range	10ºC – 40ºC
Centrifugal Pump	12-volt Brushless DC
Weight without Fluid	15-pounds
System Fluid Capacity	32-ounces
Power Consumption (Max)	450 Watts
Input Voltage (Nominal)	100-120 VAC, 60 Hz, Single Phase
Input Current (Max)	4.5 Amps
Accuracy	± 2 ºF
Refrigerant	None
Heating/Cooling Function	Yes, Standard
RS232 Interface	Yes, Standard
Recommended Coolants	90% distilled water, 10% alcohol

18.1 Calibration

The NanoTherm unit is comprised of components that are of high accuracy and low drift. Under normal operation, the unit does not require calibration. The end user has the option to send the unit to ThermoTek for calibration or request documentation from the factory, which details the calibration steps.

18.2 Product Listing

The NanoTherm unit has been tested and listed by ETL to meet or exceed the requirements for UL Medical Listing 60601 Standards. This product is classified as a Type B Medical Equipment, Class II

ThermoTek is a registered medical equipment manufacturer with The United States Food and Drug Administration (FDA).

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

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17. Warranty and Disclaimer Information

ThermoTek Inc. warrants for twelve months from the date of shipment to the end user, any ThermoTek NanoTherm™ unit according to the following terms:

All parts of the unit manufactured or supplied by ThermoTek Inc. shall be free from defects in material and workmanship for a period of one year from the date of shipment. ThermoTek Inc. shall repair or exchange the product within the warranty period when the unit has been found in the reasonable judgment of ThermoTek to have defective material or workmanship. The unit must be returned to an authorized ThermoTek Service Center. The buyer shall pay for the expense of returning the unit to the authorized ThermoTek Service Center for warranty service. ThermoTek Inc. will pay for the expense of returning the unit back to the buyer. Return units must be in the ThermoTek approved box and packing material to ensure safe transport. Removal of the warranty seals or other attempts of servicing the inside of the unit shall void this warranty.

The buyer shall be responsible and assessed a fee for test and calibration if no defects are found with the ThermoTek product.

In the event that the product or any portion thereof is not installed or used in accordance with the manufacturer's Operating Instructions, any and all warranties either expressed or implied shall be and are hereby voided. Only upon the proper installation and use of the items shall this warranty apply. This warranty does not cover any unit that has been altered or modified so as to change its intended use. In addition, this warranty does not extend to the use of parts, accessories, or fluids which are either incompatible with the unit or adversely affect its operation, performance, or durability.

Because ThermoTek Inc. constantly provides our customers with the latest technology, we reserve the right to change or improve the design of any unit without assuming any obligation to modify any unit previously manufactured.

All units returned for warranty claims must have a Returned Materials Authorization (herein referred to as RMA) number on the outside of the container. Please call ThermoTek Customer Service at 972-242-3232 for an RMA number. Before returning a system to the factory, it must be drained of all fluids and packed in the original packaging.

In order to quickly process your warranty repair request, your customer service representative will require the following information about your system:

- Model Number
- Serial Number
- Description of Problem
- Contact Name and Phone Number

This information is on the serial plate located on the back side of the unit.

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ThermoTek Inc. assumes no responsibility for the accuracy or completeness of the information presented which is subject to change without notice. Mention of non-ThermoTek products or services is for information purposes only and constitutes neither an endorsement nor a recommendation.

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

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For customer service information please see Section 13 of this manual.

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Revision: X3
9/07

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