Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

510(k)

# 510(K) Summary

FEB - 5 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091757 .

1. Submitter's Identifications:
   Well Life Healthcare Limited
   1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 23455,
   Taiwan, ROC

   Contact: Jenny Hsieh

   Date of Summary Preparation: December 08, 2009

2. Name of the Device:

   OTC TENS for Arm & Leg Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):
   1> The Prizm 5000-Z system (K033122)
   2> Endurance Therapeutics T1040 (K060846).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. Basically the stimulation model WL-2407 is completely identical to that of model as mentioned in the Well-Life K063660- 510(K) cleared device. To change the indication for use for the treatment location as the chosen predicate devices, Well-Life change the design of electrode.

   For the device included in this submission, we use the following third party 510(K) legally marketed predicate components:
   <1>K022494, the Home Care Jelly.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:

   <1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).
   <2> For the stimulation electrode, Well-Life uses upper arm belt as well as snap type adhesive electrode as standard accessories.
   <3> The output waveform is selectable pre-programming change among P1~P8.
   <4> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.

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

5. Intended Use:

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Power level testing comparison and acknowledge of comparison result with Prizm 5000Z system:

For the substantial equivalent comparison, the power level testing comparison with the chosen 510(K) cleared device, Prizm 5000-Z system was conducted via using 1K ohm loading resistance for the garment electrodes . Testing set up with comparison result is as the following table :

Current comparison: (Unit: $mA/cm^2$)

| Electrode Type | Glove | Sleeve& Knee | Sock | Silicone Pad |
|---|---|---|---|---|
| Well-life WL-2407 | 0.00337 | 0.00386 | 0.00271 | 0.11728 |
| Prizm 5000-Z | 0.00340 | 0.00385 | 0.00274 | 0.11817 |

Power Density Comparison : (Unit: $W/cm^2$)

| Electrode Type | Glove | Sleeve & Knee | Sock | Silicone Pad |
|---|---|---|---|---|
| Well-life WL-2407 | 0.00032 | 0.00036 | 0.00025 | 0.01098 |
| Prizm 5000-Z | 0.00064 | 0.00072 | 0.00051 | 0.02222 |

Based on this comparison result, we made a acknowledge that the model WL-2407 has a lower output power and power density than that of Prizm 5000-Z system while using the same electrode, and that the garment electrode for prescription use will not be packed or sold with WL-2407 model. In case the garment electrode is to be used with WL-2407 model , the effectiveness is to be determined by the physician who prescribes the use of that electrode.

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

8. Conclusions

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of Prizm 5000-Z system (K033122) and Endurance Therapeutics T1040 (K060846). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that

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the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

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

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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

FEB - 5 2010

Well Life Healthcare Ltd
c/o Ms. Jenny Hsieh
Official Correspondent
1FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
China (Taiwan) 234

Re: K091757
Trade/Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: NUH
Dated: December 10, 2009
Received: December 11, 2009

Dear Ms. Hsieh:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat 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 # 2015-813; Released by CDRH on 9-10-2015

# Indications For Use

510(k) Number (if known): K091757

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091757

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

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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

FEB - 5 2010

Well Life Healthcare Ltd
c/o Ms. Jenny Hsieh
Official Correspondent
1FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
China (Taiwan) 234

Re: K091757
Trade/Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407
Regulation Number: 21 CFR 882.5890
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
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Enclosure



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# Indications For Use

510(k) Number (if known): K091757

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091757



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**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 19, 2009

510k Number: K091757
Product: OTC TENS FOR ARM AND LEG PAIN

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.



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

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



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

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**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 15, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757
Product: OTC TENS FOR ARM AND LEG PAIN

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The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.



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

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

July 29, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757
Product: OTC TENS FOR ARM AND LEG PAIN

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.

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

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (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

June 18, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757
Received: 6/17/2009
Product: OTC TENS FOR ARM AND LEG PAIN

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 a draft guidance titled: "Certifications To Accompany Drug, Biological

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

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. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

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
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

June 16, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757
Received: 6/16/2009
User Fee ID Number: 6043345
Product: OTC TENS FOR ARM AND LEG

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

| By Regular Mail | By Private Courier(e.g.,Fed Ex, UPS, etc.) |
|---|---|
| Food and Drug Administration | U.S. Bank |
| P.O. Box 956733 | 956733 |
| St. Louis, MO 63195-6733. | 1005 Convention Plaza |
| | St. Louis, MO 63101 |
| | (314) 418-4983 |

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma. In addition, the 510k Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

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, or 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.

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

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Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

K091757

# Special 510(k) Submission

PREMARKET NOTIFICATION 510K SUBMISSION
For Device Modification based on K063660

Device Name: OTC TENS For Arm & Leg Pain Relief

Model Number: WL - 2407

*Presented by*

K97
NE
II

**Well Life Healthcare Limited**

Taiwan Branch: 1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

FDA CDRH DMC

JUN 16 2009

Received

Department of Heath and Human Services
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Subject: OTC TENS For Arm & Leg Pain Relief/ Model: WL-2407.

This 510(k) notification is to inform FDA of the intent to market the products of OTC TENS for Arm & Leg Pain Relief, models WL-2407. Basically this product was developed via changing the electrode from the models OTC TENS For Low Back Pain Relief/ Model: WL-2407 (K063660), distributed and manufactured by Well Life under his quality management system.

The degree of modification is mainly as the following brief description:
<1> The change for the use of garment electrodes as standard accessories.
<2> The change for the use of upper arm belt and snap type adhesive electrode as optional accessories.
<3> The change on device labeling to change the description of indication for use based on the change of electrode as mentioned in <1> and <2>.

These changes are basically intended to provide the same indication use as the model being modified, but with only the difference on the treatment location, the arm and leg for new device instead of low back area for K063660. According to the FDA guidance, a Special 510(k) Notification may be submitted for the new model via comparison with the 510(K) cleared predicate models which claim the OTC indication for use of pain relief for arm & leg before it is placed on US market. This special 510(K) submission was prepared according to this general FDA guidance. The information of this special 510(K) submission is:

Classification name: Stimulator, Nerve, Transcutaneous, for pain relief.
Common / Usual name: OTC TENS For Arm & Leg Pain Relief.
Proprietary name: WL-2407.
Classification: Class II.
Performance standard: Parts of ANSI/AAMI NS-4 1985.
Substantial equivalence : Prizm 5000-Z system(K033122) and Endurance Therapeutics T1040(K060846)

Since this new model was designed and is to be manufactured by Well Life according to his quality management system, the declaration of conformity for the design change will be signed by the quality representative of Well Life.

For this 510(K) submission, the followings is the official correspondent:

Company Name : Well Life Healthcare Limited
Contact person: Jenny Hsieh
Address : 1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C
TEL No. : 886-2-2928-2112
Fax No. : 886-2-2928-1880
E-mail address : jenny@welllifehealthcare.com.tw

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

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Identical to the other general 510(k) submission, we separate our submission into two parts:

- Part I: Documentation for the 510(k) submission.
- Part II: 510(k) summary.

For this special 510(k) application, we have completed the payment of 510(k) review fee, the payment identification number is MD6043345-956733. The information of our payment was attached to this letter. Please feel very free to review our special 510(k) application.

Sincerely yours,

Jenny Hsieh
Official Correspondent



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

(b) (4) [redacted]

Form Approved: OMB No. 0910-511 Expiration Date: Janu

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION<br>**MEDICAL DEVICE USER FEE COVER SHEET** | PAYMENT IDENTIFICATION NUME<br>Write the Payment Identification num [redacted] |
|---|---|

A completed cover sheet must accompany each original application or supplement subject to fees. If payme [redacted] courier, please include a copy of this completed form with payment. Payment and mailing instructions can b [redacted] http://www.fda.gov/oc/mdufma/coversheet.html

| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) | 2. CONTACT NAME |
|---|---|
| WELL LIFE HEALTHCARE LTD<br>1F, No.16, Lane 454, Jungjeng Rd.,<br>Yunghe City 234<br>TW | Jenny Hsieh |
| 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) | 2.1 E-MAIL ADDRESS<br>jenny@welllifehealthcare.com.tw<br>2.2 TELEPHONE NUMBER (include Area code)<br>8862-29282112<br>2.3 FACSIMILE (FAX) NUMBER (Include Area code)<br>8862-29281880 |

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

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

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

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] 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

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

(b) (4) [redacted]

SUBMITTED FOR THIS PREMARKET APPLICATION
07-Jun-2009

"Close Window" Print Cover sheet

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(b) (4)

[redacted]

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

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**PREMARKET NOTIFICATION**

**TRUTHFUL AND ACCURATE STATEMENT**

**[ As required by CFR/Title 21, Part 807.87 ]**

I certify that, in my capacity as Official Correspondent of Well Life Healthcare Limited I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.

Submitter: Jenny Hsieh

Qualification: **Official Correspondent**

Signature: Jenny Hsieh

Date: 2009-6-10

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

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**Part II. 510(k) Summary**


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# Part I. Documentation for the special 510(k) submission



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

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# Chapter 1. Statement of "Indication for use"

## 1.1 Device Name

Trade name : OTC TENS For Arm & Leg Pain Relief / Model : WL- 2407.

Common name : OTC TENS For Arm & Leg Pain Relief / Model : WL- 2407.

Classification name : Stimulator, Nerve, Transcutaneous For Pain Relief.

## 1.2 Classification

Trade/Device Name: OTC TENS For Arm & Leg Pain Relief; Model : WL -2407.
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve, Transcutaneous For Pain Relief.
Regulatory Class: II
Product Code: NUH

## 1.3 Indication for use.

- The OTC TENS For Arm & Leg Pain Relief; Model : WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

For the statement of indication for use, please see the following page.

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# Indications For Use

510(k) Number (if known):

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS For Arm & Leg Pain Relief; Model : WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (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)



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

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# Chapter 2. Description of Device

## 2.1 General Description about the device.

The Well Life OTC TENS For Arm & Leg Pain Relief; Model : WL -2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkailne battery) operated TENS device with the following features:

<1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).

<2> The stimulation electrode is garment electrodes as standard accessories and upper arm belt and snap type adhesive electrode as optional accessories.

<3> The output waveform is selectable pre-programming change among P1~P8.

<4> The output strength is adjustable at 0~80 mA, with variable setting time 0~60 minutes counting from switching ON.

<5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.

Basically the hardware and software design of device is completely identical to that of previous 510(k) cleared models OTC TENS for Low Back Pain Relief / Model WL-2407(K063660) except for the use of electrode. Due to the reason that we are intended to change the indication for use, we made some new design on the electrodes.

The photos for the WL-2407 was provided in section 2.2, the wave form was provided in section 2.3, and the new design of electrode was provided in section 2.4.

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

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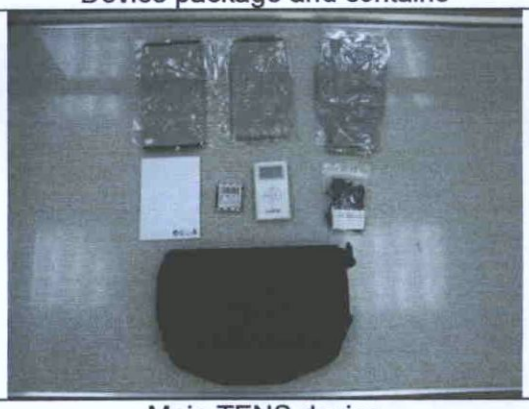
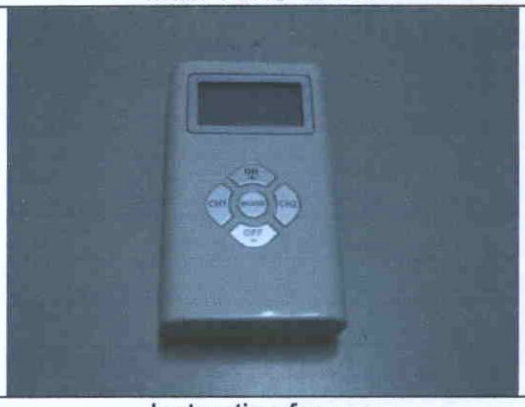
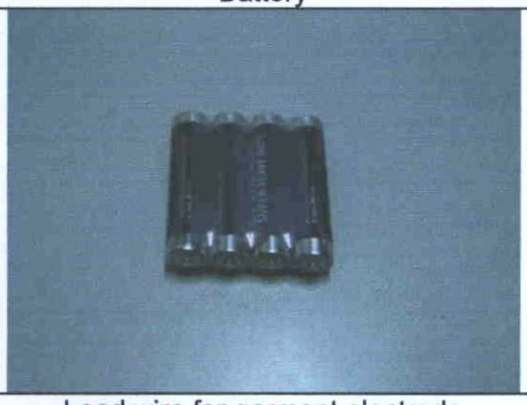
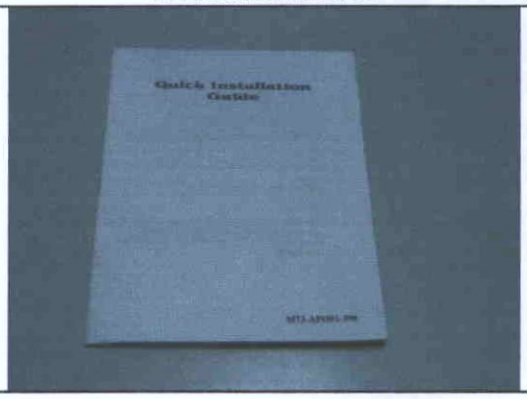
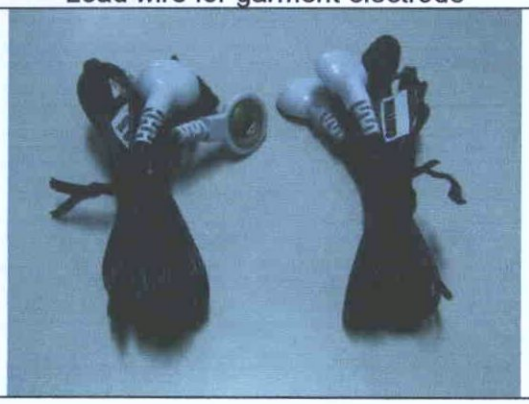
## 2.2 Device Photos.

**Overall Device Photos (Standard parts)**

| Device package | Device package and contains |
|---|---|
| |  |
| **Device contains in standard package** | **Main TENS device** |
| |  |
| **Battery** | **Instruction for use** |
|  |  |
| **Lead wire for garment electrode** | |
|  | |

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

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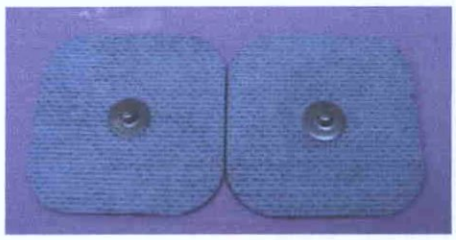
## Optional Accessories

| Upper Arm Belt | Upper Arm Belt (the other view) |
|---|---|
| | |
| **Conductive Gel (used with upper arm belt)** | **Adhesive Electrode(Snap Type)** |
| |  |



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

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## 2.3 Device Wave Forms.

## WL-2407 Stimulator Technical Specifications

Power Source: 4.5Volt (3xAAA/Alkaline battery)
Dimension: 90 x 5.08 x 12.7mm
Weight: Approx. 100 gram (battery not included)

| Program | Max. | Phase duration | Rate | Function mode | Wave form Type |
|---|---|---|---|---|---|
| P1 | 80mA | 260uS | 15Hz | Constant | A |
| P2 | 80mA | 260uS | 15Hz | Modulated | A |
| P3 | 80mA | 260uS | 120Hz | Constant | A |
| P4 | 80mA | 260~150uS | 2 ~ 100Hz | Modulated | B |
| P5 | 80mA | 260uS | 100Hz | Modulated | A |
| P6 | 80mA | 260uS | 80 <->7 Hz | Modulated | C |
| P7 | 80mA | 260uS | 60Hz | Modulated | A |
| P8 | 80mA | P1 ~P7 | | Cycle | A/B/C |

Time: 1~60 minutes.

**Note : 1. The specification of WL-2407 stimulator is completely identical to that of stimulator of Well-Life K063660.**

**2. For the wave form about the model of this submission, please see the information provided in K063660.**



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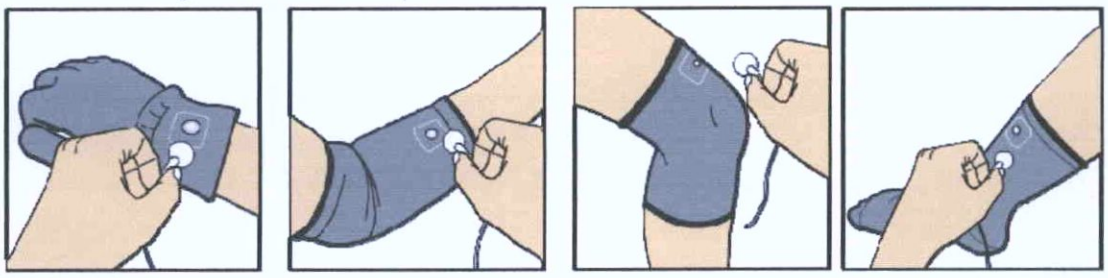
## 2.4 The new construction of electrodes for Arm & Leg.

1) The use of garment electrode



Glove | Elbow Sleeve | Knee Sleeve | sock

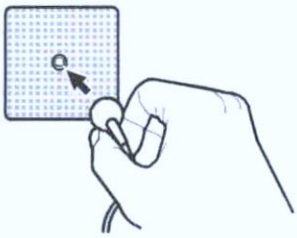
2) The use of Support Belt + Conductive gel

Before use, dampen the integrated silicon electrodes with water or a conductive gel.

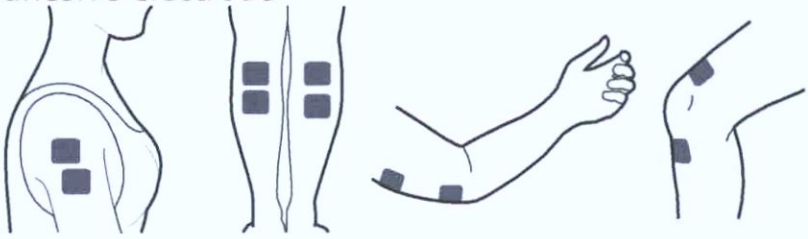
Insert the belt through the square ring, stretch the ends of the cuff, and press the electrodes firmly against your skin

Connecting the cable to the device.

3) The use of Snap type adhesive electrode



Preparing treatment site and accessories connect the lead wires to the electrodes before applying the electrodes to the skin.



(a) (b) (c) (d)

Place the electrodes *(a) shoulder (b) leg (c) elbow (d) Knee*



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

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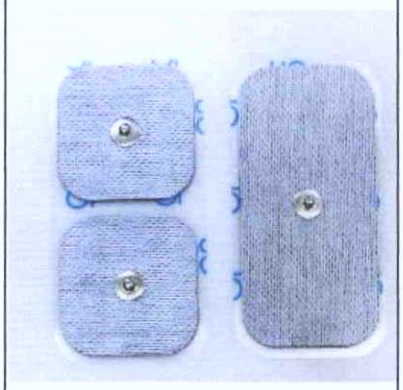
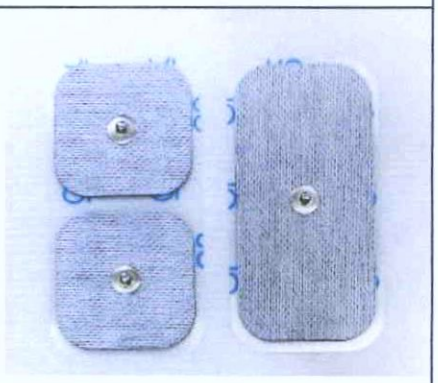
As mentioned on the description of "Intended Use", user could choose from System arm /Leg accessories pack , optional choices by individual from the followings :

| Indication for Arm use | | | |
|---|---|---|---|
| Conductive Mesh Garment Electrode Glove | Conductive Mesh Garment Electrode Elbow Sleeve | Support belt + Conductive Silicone pad with gel tube | Self Adhesive Electrodes |
| | | |  |
| Size indication:<br><br>Theraknit Part no, measured by Palm Width .<br><br>Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm | Size indication:<br><br>Theraknit Part no, measured by elbow circumference<br><br>Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 301 0: over 30 cm | One size fit all neoprene belt (adjust by Velco according to arm circumference 24~3 6 cm ) , W ell-Life p art no. TB-0040<br><br>Size of conductive silicone pad is - 25x50mm, 2 pcs ; Well-Life part no. SP2550 , or bigger size 50x50mm available | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |

| Indication for Leg use | | |
|---|---|---|
| Conductive Mesh Garment Electrode Socks | Conductive Mesh Garment El ectrode Knee Sleeve | Self Adhesive Electrodes |
| | |  |
| Size indication:<br><br>Theraknit Part no, measured by shoe size.<br><br>Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size | Size Indication :<br><br>Theraknit Part no, measured by Knee circumference .<br><br>Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |

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

## 2.5 Assessment for the Use Safety of Electrode.

As drawing shown in clause 2.4, there exists the following possibility for the use of electrodes:

For Arm:

1. The use of conductive mesh garment.
2. Adhesive electrode (Well-Life CM5050 or CM50100)
3. The Neoprene + Conductive silicone pad with conductive gel.

For Leg:

1. The use of conductive sock (garment electrode)
2. The use of conductive knee sleeve (garment electrode)

According to 510(k) guidance for TENS devices, the application shall prove the safety for the electricity characteristics concerning the use of every type of electrodes used. For this safety consideration, it is very clear that the use of garment electrodes is safe while comparing with the traditional use of adhesive electrode because of the following two reasons:

1. The skin contact surface of garment electrode is greater than that of adhesive electrode. The section area of electrodes is listed as the following table.

| Location | Electrode use condition | Possible size | Minimum Size |
|---|---|---|---|
| Arm | The use of glove garment or elbow garment. | Glove : S/M/L<br>Wristlet Sleeve:10*18 | 435 $cm^2$ |
| | Adhesive electrode (Well-Life CM5050 or CM50100) | 50 mm x 100mm, or 50mm x 50mm | 5.0mm * 5.0mm = 25 $cm^2$ |
| | The Neoprene + Conductive silicone pad with conductive gel. | 25mm x 50mm, or 50mm x 50 mm | 2.5mm * 5.0mm = 12.5 $cm^2$ |
| Leg | The use of conductive sock (garment electrode) | S/M/L/XL | 540 $cm^2$ |
| | The use of conductive knee sleeve (garment electrode) | 10*27 | 380 $cm^2$ |

This information table clearly indicated that the size of conductive silicone pad used with upper arm support belt is smaller than that of garment electrode. So the current density and power density for the garment electrode is smaller than that of electrode for the same TENS device. Therefore, it is very reasonable to state that the use of garment electrode from electricity point of view is safer than the use of adhesive as specified by Well-Life.

2. For the skin contact material, the "Theraknit Garment Electrode"(K053214), the Well-Life choose the 510(k) cleared electrode(K082065) , and skylark conductive gel(K983964) which is to be used with legally marketed TENS stimulating device were chosen to be used together with the device of this submission.

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

For the 510(K) clear information of the garment electrodes and adhesive electrode, please see the following appendix.

- Appendix 1: 510(K) cleared information for garment electrode: K053214/S1.
- Appendix 2. 510(K) cleared information for Well-Life electrode: K082065.
- Appendix 3. 510(K) cleared information for conductive gel: K983964.

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

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**Appendix 1: 510(K) cleared information for garment electrode: K053214/S1.**

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

K053214

DEC 2 0 2005

# 510(k) Summary

Trade Name: **TheraKnit**

Common/Classification Name: Electrode, Cutaneous (84GXY) 21 CFR 882.1320

Neurotron Medical, Inc.
800 Silvia Street
West Trenton, NJ 08628
800-367-1238

Contact: Jack Guldalian, President

Prepared: August 24, 2005

## A. LEGALLY MARKETED PREDICATE DEVICES

K932299 Electro-Mesh Glove Electrode Prizm Medical, Inc.

K944487 Electro-Mesh Sock, Wrap and Sleeve Electrodes Prizm Medical, Inc.

K943009 SMD Glove, Sock and Sleeve Electrodes Scientific Medical Devices, Inc.

## B. DEVICE DESCRIPTION

The TheraKnit Garment Electrodes are conductive garments knitted from a continuous silver coated Nylon yarn into the form of gloves, socks, sleeves and flat fabric used for pads. The conductivity is derived from the silver content of the Nylon yarn. The garment electrodes are available in a variety of sizes ranging from small to extra large for gloves and small to large for socks and sleeves. The elongation property of the nylon yarn provides some elasticity which ensures firm skin contact. The devices can be used dry or wet when in contact with the skin. The entire surface of each garment electrode is very conductive having a resistance of less than 7 ohms per inch. This low resistance provides low current density with uniform current distribution.

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## C. INTENDED USE

TheraKnit garment cutaneous electrodes as glove, socks, sleeves and pads are intended for use with legally marketed electrostimulation devices such as TENS and NMES to deliver stimulation current for pain relief. They can be used on body parts such as hands, feet, arms, legs, low back and shoulder for pain relief using electrostimulation.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

The TheraKnit Garment Electrode is a medical device that has the same indication, intended use and target population as the legally marketed predicate devices.

TheraKnit has the same technological characteristics as the predicate devices. Both the TheraKnit and the predicate devices are made with a silver plated nylon yarn. The resistance of the knitted garment for both TheraKnit and the predicate devices are less than 7 ohms/inch which is very low relative to the delivery of the stimulation current.

Both TheraKnit and the predicate devices receive the electrostimulation signal from a legally marketed TENS or NEMS device through a lead wire with a 0.080" pin connection connected to a snap connector on the knitted garment device.

Both TheraKnit and the predicate devices are washable and intended for single patient use.

## E. TECHNOLOGICAL CHARACTERISTICS

The TheraKnit garment electrodes are made from a silver plated nylon yarn using a conventional knitting process. The fabric is highly conductive and provides less than 7 ohms resistance per inch. The device can be used with either positive or negative polarity, a second electrode is necessary to direct the stimulator current to the target tissue and complete the electrical circuit. The device is washable using conventional detergents without adverse effect on the conductivity of the device.

The garment electrodes provide a snug elastic fit based upon the 37% elongation characteristic of the yarn used in the construction.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## F. TESTING

Bench testing has been done with this device demonstrating that it meets design controls.

Comparative testing was done between the TheraKnit garments and the predicate devices for resistance measurement and comparison.

## G. CONCLUSIONS

Design specifications, comparison to predicate device specifications and testing has demonstrated that this TheraKnit device meets design requirements and is equivalent to the predicate devices.

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

Records Processed under FOIA Request # 2015-813; 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 2 0 2005

Neurotron Medical, Inc.
c/o Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo Minnesota 55313

Re: K053214/S1
Trade/Device Name: Theraknit Garments
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: December 2, 2005
Received: December 5, 2005

Dear Mr. Job:

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 # 2015-813; 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) 276-0120. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting 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 # 2015-813; Released by CDRH on 9-10-2015

# Indications for Use

510(k) Number (if known): K053214

Device Name: TheraKnit

Indications For Use:

The TheraKnit Garment Electrodes are cutaneous electrodes to be used with legally marketed TENS stimulating device. The knitted garment electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include hand (glove), feet (socks), elbow or knee (sleeve), arm, leg, shoulder, back (pads).

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page 1 of 1

**510(k) Number** K053214

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

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**Appendix 2. 510(K) cleared information for Well-Life electrode: K082065.**

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

Records Processed under FOIA Request # 2015-813; 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

Well-Life Healthcare Ltd.
% Ms. Jenny Hsieh
1 FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
Taiwan, R.O.C

APR 10 2009

Re: K082065
Trade/Device Name: Well-Life Self Adhesive Electrodes/CM, FA, PU, and SP models
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 7, 2009
Received: March 9, 2009

Dear Ms. Hsieh:

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

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

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



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) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 # 2015-813; Released by CDRH on 9-10-2015

# Indications For Use

510(k) Number (if known):

Device Name: Well Life Self Adhesive Electrode / CM, FA, PU and SP series

Indications For Use:

The Well Life Self Adhesive Electrode / CM, FA, PU and SP series are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Well Life Self Adhesive Electrode / AP, CM, FA, PU and SP series are designed and intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Prescription Use √ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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510(k) Number K082065



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**Appendix 3. 510(K) cleared information for conductive gel: K983964.**

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

Records Processed under FOIA Request # 2015-813; 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 9 1998

Mr. George K.C. Chen
President and CEO
Skylark Device Company Limited
12th Floor, 34 Section 3
Chung Shan North Road Taipei
Taiwan ROC

Re: K983964
Trade Name: Batch #6060 Conductive Gel
Regulatory Class: II
Product Code: IKC
Dated: November 2, 1998
Received: November 6, 1998

Dear Mr. Chen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

500



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

510(k) Number (if known): K983964

Device Name: BATCH #6060 CONDUCTIVE GEL

Indications For Use:

**FOR USE WITH TENS (TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS) AND EMS (ELECTRICAL MUSCLE STIMULATORS). CONDUCTIVE GEL IS USED WITH EXTERNAL ELECTRODES TO REDUCE THE IMPEDACE OF THE CONTACT BETWEEN THE ELECTRODE SURFACE AND THE SKIN.**

(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 Devices
510(k) Number K983964

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Chapter 3. Information of device specification

| *Model* | *WL-2407* |
|---|---|
| Manufacturer | Well-Life |
| Classification | Class II |
| Waveform | Asymmetrical<br>Monophasic<br>Square |
| Channels | Dual |
| Power supply | 4.5 volt (3xAAA/Alkaline battery) |
| Circuit designed | Digital & Pre-program |
| Software | Yes |
| Amplitude (mA) | 0-80 (Adjustable) |
| Pulse rate (Hz) | 120 max |
| Width (μs) | 260 fixed |
| Power ON indicator | LCD |
| Timer (min) | 0~ 60 |
| Weight (grams) (batt. not include) | 100 |
| Size (mm) | 90×5.08×12.7 |
| Prescription or OTC | OTC |
| Maximum Output Voltage (V) (±10%)<br>@ 500Ω<br>@ 1kΩ<br>@ 2kΩ | <br><br>40<br>68<br>92 |
| Maximum Output Current (mA) (±10%)<br>@ 500Ω<br>@ 1kΩ<br>@ 2kΩ | <br><br>80<br>68<br>46 |
| Pulse Width (μS) | 30-260 |
| Frequency (Hz) | 1-150 |
| Maximum Phase charge (μC) @500Ω | 20.8 |
| Maximum Current Density ($mA/cm^2$) @500Ω | 0.1 |
| Maximum Power Density ($W/cm^2$) @500Ω | 0.004 |

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Chapter 4. Labeling

Basically the labeling for the new models include the labeling on the product package and user manual. The labeling on the product package is as indication of section 4.1, and the detail labeling of user manual for each new models are as indication of section 4.2.

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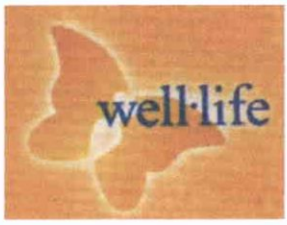
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## 4.1. Example for the product Labeling

Brand Name (logo).




Product label

WL-2407 S/N:

OTC TENS For Arm & Leg Pain Relief.

Made by Well-Life Healthcare Ltd. Taiwan

CE 0434



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## Photos of product labeling

636. Package label.

637. Devices contained in package.

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

639. WL-2407 interior package & Contents

638. WL-2407 & Standard Accessories.

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

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## 4.2. WL-2407 OTC TENS for Arm & Leg Pain Relief User Manual

See the following details.

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Operation Manual

Model: WL-2407

WELL LIFE HEALTHCARE LTD.

1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# WELL LIFE

# Arm and Leg Pain Management System

## Intended Use

The WELL LIFE Arm & Leg Management System WL-2407 is intended for temporary relief of p ain associated with sore and aching muscles in the upper and lower extremities ( arm and/or leg) due to strainfrom exercise or normal household and work activities.

## Table of Contents


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## SAFETY INSTRUCTIONS

Read instruction manual before operation. Be sure to comply with all "CAUTIONS" and "WARNINGS" in the manual. Failure to follow instructions can cause harm to user or device.

Please read the following information carefully before using the **WELL LIFE Arm & Leg Pain Management System.**

**Contraindications: Do not use this System if any of the following conditions are present.**

- Do not use this System if you have a cardiac pacemaker, implanted defibrillators or any other implanted metallic or electronic device.
- Do not use this System if you have undiagnosed chronic pain.

**Warnings for proper use and safety**

**If you have numbness, tingling or loss of feeling/sensation in your arms, hands, legs or feet this may represent a more serous problem like diabetic neuropathy. Consult your physician before using the device.**

**If you have swelling of the arm or leg, it may be more serious than simple muscle pain from overuse. Consult your physician before using the device.**

**Use the glove or stocking only on healthy skin. Do not use on open wounds or rashes, or over swollen, red, infected or inflamed skin.**

- If you are under the care of a Physician, consult with your Physician before using this System.
- The long-term effects of this System are not known.
- Do not place the pads on or close to your heart.
- Do not place the pads around or close to your neck. Do not apply stimulation over the neck. Severe spasm of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck could also have adverse effect hearing or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart.
- Do not place the pads on or around your head. The efects of stimulation of the brain are unknown.
- Do not use the pads over or close to sores.
- Do not use this System while sleeping.
- Do not use if you feel numbness.
- Do not use this System in or close to water.
- Use the pads only on normal, healthy, clean and dry skin. Do not use the pads on open wounds or rashes, or over swollen, red, infected or inflamed skin.
- If you have ever had back surgery, consult your Physician before using this System.



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## Precautions for the safe use of this WELL LIFE Arm & Leg Pain Management System

- Read User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- The System is intended for individual person use.
- The System is not effective for pain associated with Central Pain Syndromes, such as headaches.
- The System is for pain caused by muscle soreness, and should be placed only around muscles where pain originates.
- The pain may indicate that you have some other health problem. You should know the reason and source of your pain before using this System. Do not solely rely on the treatment of this System for pain.
- The safety of using the System during pregnancy or birth has not been established.
- The effectiveness of the System depends greatly on a person's individual physical condition. It may not always be effective for every user.
- If you have had medical or physical treatment for your muscle pain, consult with your treatment provider before using this System. You should contact your physician prior to using the System following recent surgical procedures. Stimulation may disrupt the healing process.

⚠ **Use Caution and consult your Physician before using System if any of the following conditions apply to you:**

- If you have suspected or diagnosed heart problem.
- If you have suspected or diagnosed epilepsy.
- If you have a tendency to bleed internally following an injury.
- If you recently had surgery, or have ever had surgery on your back.
- If areas of skin lack normal sensations, such as skin that tingles or is numb.
- During menstruation or during pregnancy.
- Some people may feel skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using your System and consult your Physician.
- If skin under one of more pads feels irritated after using the stimulator for a long period of time, use the stimulator for a shorter period of time.
- Minor redness at stimulation placement is a normal skin reaction. It is not considered as skin irritation, and it will normally disappear within 30 minutes after the electrodes are removed. If the redness does not disappear after 30 minutes from the removal of electrodes, do not use the stimulator again until after the excessive redness has disappeared.
- Turn off the stimulator if the stimulation feels unpleasant or does not provide pain relief.
- Keep your System out of the reach of children.
- Use your stimulator only with the pads, snap cables and accessories recommended by the manufacture.
- Do not use this System when driving, operating machinery or when swimming.
- Before removing the belt and pads, be sure to turn OFF both power knobs to avoid unpleasant stimulation.
- **If your pain does not improve, becomes more than mild or if it continues for four to six days, stop using this System and consult your Physician.**

## Adverse Reactions

- Skin irritation and burns under the pads have been reported by some people who have applied electronic stimulators to their skin.



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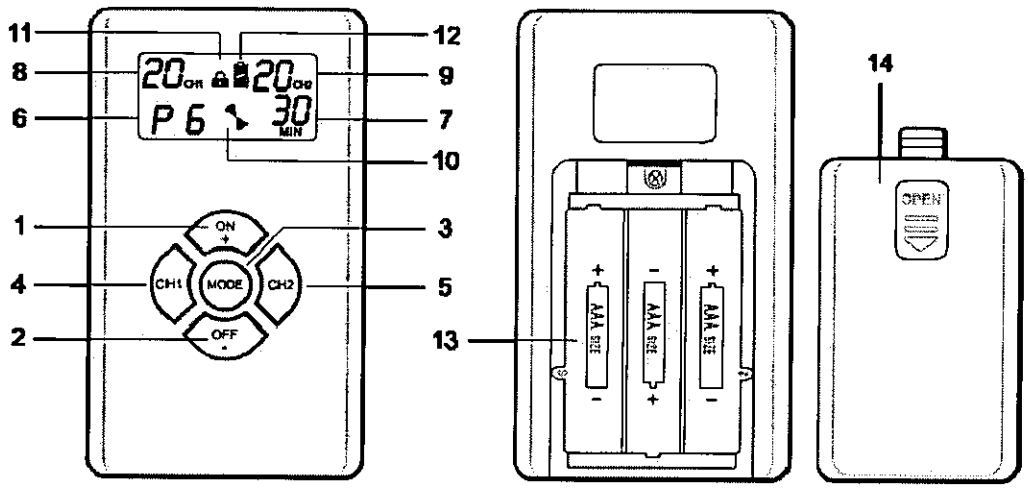
# Introduction to your WELL LIFE Arm & Leg Pain Management System

## ABOUT THE DEVICE




Front View

Rear View

1. Power on / adjust / increase setting key
2. Power off / adjust / decrease setting key
3. Program / therapy time selection
4. CH1 key
5. CH2 key
6. Program number
7. Therapy time remaining
8. CH1 intensity level
9. CH2 intensity level
10. Therapy duration status
11. Lock status indicator
12. Battery status indicator
13. Batteries compartment
14. Battery cover



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## How Your WELL LIFE Arm & Leg Pain Management System works

The main function of p ain relief comes fr om the continuous stim ulation pulse generated from the dual channels stimulator. We can not ensure that the pain relief is 100% effective for everyone. However , when used according to our instruction, it can be a safe, non-addictive, non-invasive pain reliever.

## Conditions that may affect your WELL LIFE Arm & Leg Pain Management System

Since the stimulator is a battery-operated electronic System, its output performance and safety may be affected greatly in extreme humidity. Therefore, it is very important to keep the stimulator dry to ensure the safety and performance of the stimulator.



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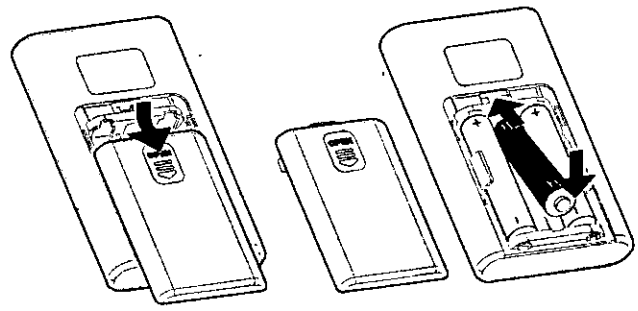
# Operation Instruction

## Inserting/Changing the Batteries

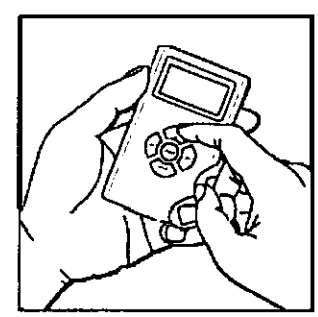


1. Open the battery compartment at the back of the device by pushing the battery cover labelled "Open" downward (this area features raised marks for easy identification).
2. Insert 3 AAA (1.5 V) batteries in the battery compartment; make sure to match up the symbols (+/–).
3. Close the battery cover by carefully placing the stud into the slot in the rear area and sliding it upward, applying slight pressure.
4. Follow the same procedure when replacing the battery at a later date.

**Note** : for important precautions regarding the batteries ,please be informed:

- Always use only 3x1.5V(AAA) batteries.
- Keep away from children.
- Do not recharge.
- Do not short-circuit.
- Do not throw into a fire.
- Please recycle. Do not dispose of old batteries with your household waste; dispose of them safely at your
- recycling centre or business where the batteries were purchased.

## Turning On the Device



1. Press and hold the ON+ button for two (2) seconds to turn on the device.
2. The most recently selected treatment time and program will flash when the unit is turned on.

## Turning Off the Device

1. The device turns off automatically after the therapy session time has elapsed.
2. To turn the unit off manually, press the OFF- button for three (3) seconds. The display will blank and the device will turn off.
3. In an emergency you may also pull the connector(s) from the device and then remove the cuff or belt.

**Note**: To prevent unpleasant electric shocks, never remove the device while it is still turned on.



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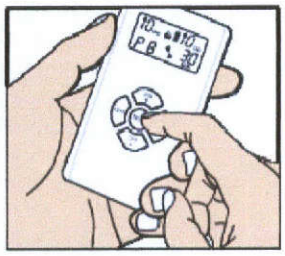
## Selecting the Treatment Time



1. Press MODE. The preset (default) treatment time will flash on the display.
2. To increase or decrease the treatment time, press the button ON + (to increase) or the button OFF – (to decrease) repeatedly until the desired duration appears on the display.
3. Press MODE again to save your selection. The treatment time you selected will appear on the display the next time you turn the device on.

**Note**: If you change programs during the course of a therapy session, the treatment time will not reset unless you manually reset it by performing the steps described above.

## Selecting the Program

The stimulator WL-2407 offers eight different preset treatment programs. The programs differ with respect to varying pulse widths and frequencies. The user may choose suitable stimulation mode depending on hips personal condition, as the following trail and determination steps :

1. Start from P1, change every mode for a couple of seconds, and sense the stimulation of each mode.
2. Choose the suitable mode in which you feel most comfortable, and set the device at that model.
3. In case you feel senseless about the determined mode before the end of stimulation, repeat 1 & 2 steps to change the operation to the other suitable stimulation model.

## Selecting the Therapy Intensity Level

1. Intensity is adjustable according to the channel selected. Select the channel you wish to adjust by pressing CH1 or CH2. "CH1" or "CH2" will flash on the display.
2. To increase or decrease the intensity, press ON +(to increase) or OFF – (to decrease) repeatedly until the desired intensity level flashes on the display.

**Note**: You will feel the intensity increase or decrease as you select the intensity level. You can use this as a guide to select a level that is comfortable for you.

3. Press MODE to save your selection.



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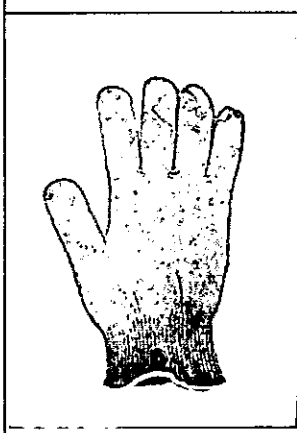
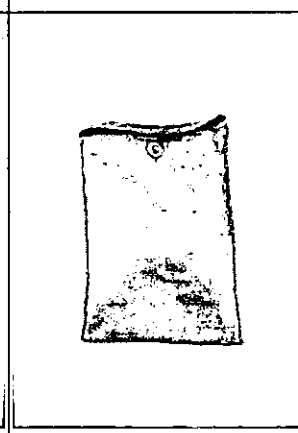
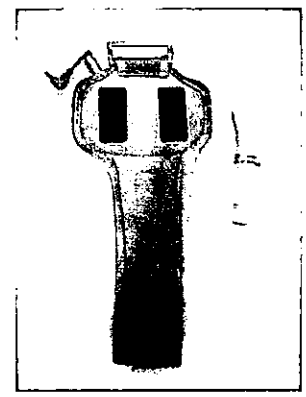
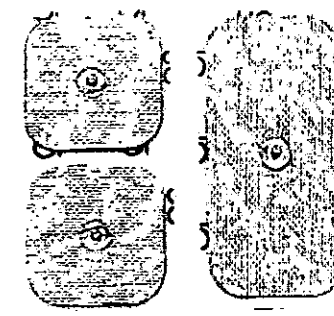
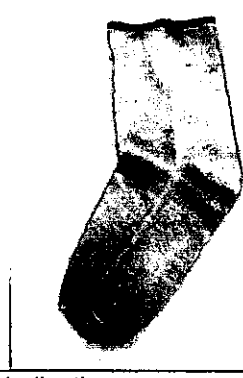
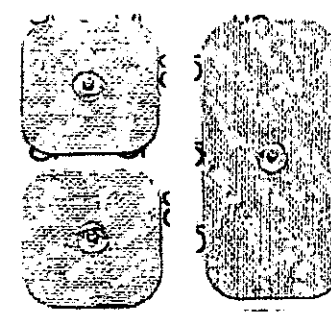
## Putting on Accessories

As mentioned on the description of "Intended Use", user could choose from System arm /Leg accessories pack , optional choices by individual from the followings :

| Indication for Arm use | | | |
|---|---|---|---|
| Conductive Mesh Garment Electrode Glove | Conductive Mesh Garment Electrode Elbow Sleeve | Support belt + Conductive Silicone pad with gel tube | Self Adhesive Electrodes |
|  |  |  |  |
| Size indication:<br><br>Theraknit Part no, measured by Palm Width .<br><br>Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm | Size indication:<br><br>Theraknit Part no, measured by elbow circumference<br><br>Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 3010: over 30 cm | One size fit all neoprene belt (adjust by Velco according to arm circumference 24~36 cm ) , Well-Life part no. TB-0040<br><br>Size of conductive silicone pad is - 25x50mm, 2 pcs ; Well-Life part no. SP2550 , or bigger size 50x50mm available | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |

| Indication for Leg use | | |
|---|---|---|
| Conductive Mesh Garment Electrode Socks | Conductive Mesh Garment Electrode Knee Sleeve | Self Adhesive Electrodes |
|  | |  |
| Size indication:<br><br>Theraknit Part no, measured by shoe size.<br><br>Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size | Size Indication :<br><br>Theraknit Part no, measured by Knee circumference .<br><br>Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |



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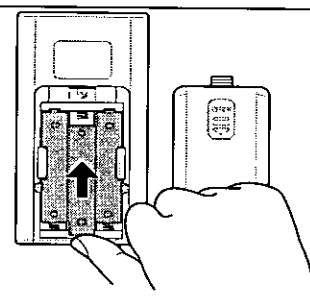
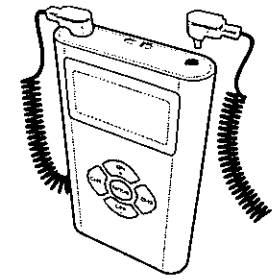
## Quick reference Guide

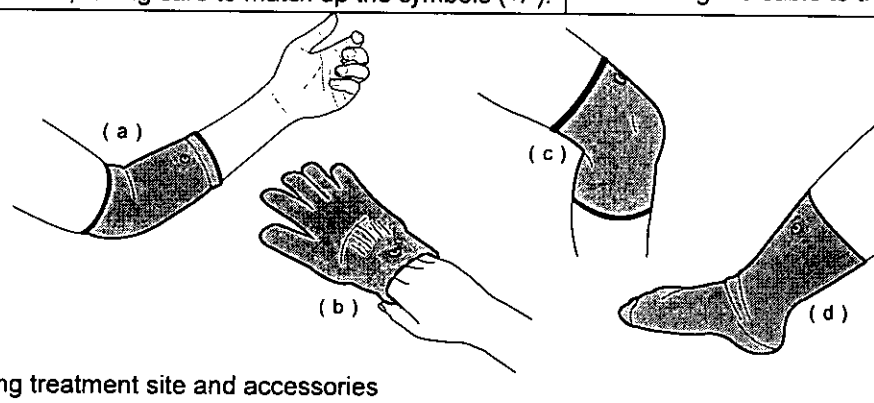
### i. How to attach conductive mesh garment electrode (Glove, Sock, Elbow/Knee )



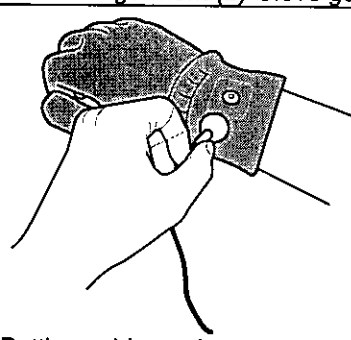
Step 1:
Insert 3AAA batteries, taking care to match up the symbols (+/-).



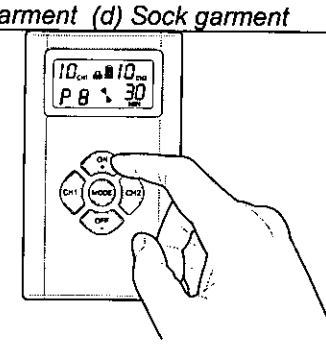
Step 2:
Connecting the cable to the device.




Step 3: Preparing treatment site and accessories
*(a) Elbow Sleeve garment (b) Glove garment (c) Knee Sleeve garment (d) Sock garment*

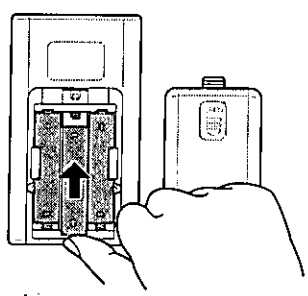


Step 4: Putting cable on the garment

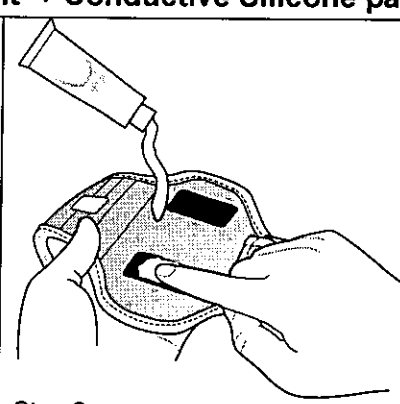


Step 5:
Power On / Select Program / Timer / Intensity Level

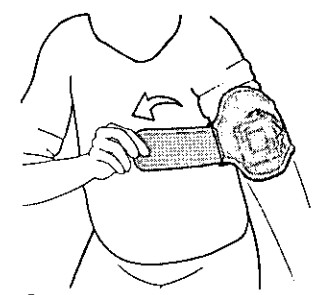
### ii. How to attach Support belt + Conductive Silicone pad with gel tube on the arm



Step 1:
Insert 3AAA batteries, taking care to match up the symbols (+/-).



Step 2:
Before use, dampen the integrated silicon electrodes with water or a conductive gel.



Step 3:
Insert the belt through the square ring, stretch the ends of the cuff, and press the electrodes firmly against your skin



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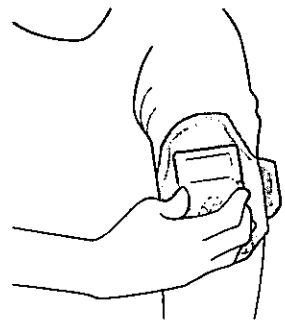
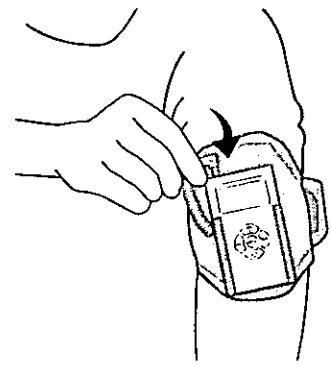


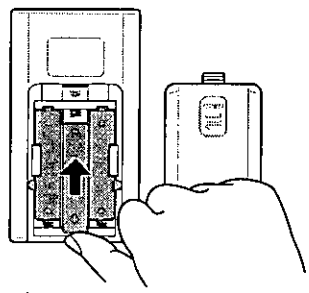
Step 4:
Insert the device into clip holder



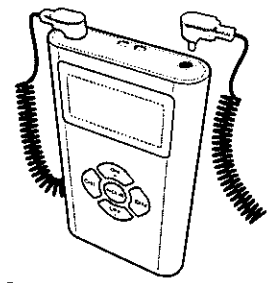
Step 5:
Connecting the cable to the device.

Step 6:
Power On / Select Program / Timer / Intensity Level

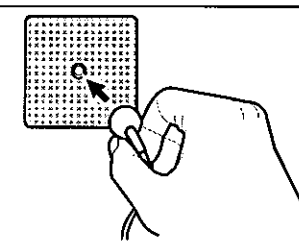
## iii. How to attach self adhesive electrodes



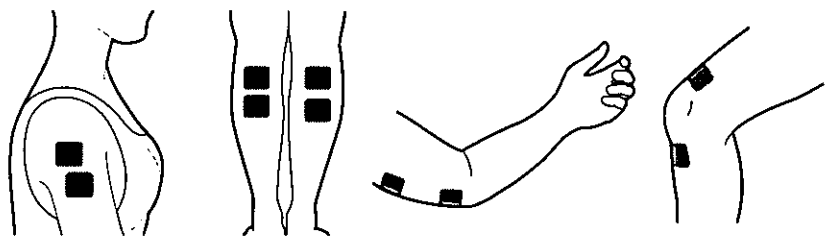
Step 1:
Insert 3AAA batteries, taking care to match up the symbols (+/-).



Step 2:
Connecting the cable to the device.

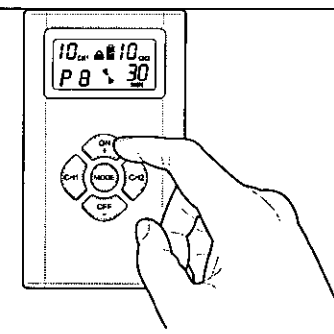


Step 3:
Preparing treatment site and accessories connect the lead wires to the electrodes before applying the electrodes to the skin.



( a ) ( b ) ( c ) ( d )

Step 4:
Place the electrodes *(a) shoulder (b) leg (c) elbow (d) Knee*



Step 5:
Power On / Select Program / Timer / Intensity Level



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## How to clean Your WELL LIFE Arm & Leg Pain Management System

**Stimulator**

The stimulator may be wiped clean with a small amount of soapy water on a clean cloth. **Do not submerge the stimulator in liquids or expose it to ANY amounts of water.**

**Snap Cables**

Disconnect the snap cables from the belt and the stimulator. Then snap cables may be wiped with a clean, damp cloth. When re-connecting,take one snap cable, and snap its two connectors onto the metal snaps on one side of the thumbhole. Repeat for other side of thumbhole. Tuck lower snap cable under tension strap toward the top of the belt.

**Conductive Mesh Garment Electrode & Support Belt**

Before washing the belt, remove the pads and put them on the storage liners. Remove the snap cables and the stimulator from the belt. Hand-wash your Support Belt in cool water. Do not wash the belt in the washing machine.

The support belt should be air-dried, lying flat or hanging. **Do not put the belt in clothes dryer.**

## Maintaining Your WELL LIFE Arm & Leg Pain Management System

1. Your Stimulator uses the standard AAA battery. If stimulation seems to be weak, or the stimulator will not turn on, check battery. To replace the battery, make sure both power knobs are turned OFF. Slide the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert the AAA/1.5Volt battery according to the diagram in the battery compartment. To close the cover, slide from the bottom up.

2. Be sure to put the storage liners on the pads when not using your Low Back Pain Management System. You may use the larger storage liners provided. Replace the pads on your support belt if they no longer stick to your skin or to the belt.

3. If your support belt is damp after use, allow it to air-dry before re-applying.

4. When connecting and disconnecting a snap cable, hold it by the molded end and pull. Do not pull on the cable itself. Replace snap cable if worn or broken.



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## How to Store Your WELL LIFE Arm & Leg Pain Management System

1. S tore your Pain Management System at room temperature in a dry place, out of the reach of children.
2. If the stimulator will not be used for more than a week, remove the battery from the stimulator.

## When To Order New Pads

The electrode pads are disposable and use an adhesive that will dry after prolonged usage or storage. Pads should be replaced when they lose their adhesive quality, or you sense a change in stimulation sensation. If you're in doubt about the integrity of the pads, order fresh pads.

To order new pads see Replacement Parts page .

## Check the WELL LIFE Arm & Leg Pain Management System before using

Before using your WELL LIFE Arm & Leg Pain Management System, always check all of the parts to be sure they are in good working order. Make sure of the following:

1. The battery still has power and it is not corroded.
2. All four pads are in the proper place on the support belt, covering the metal snaps.
3. Both snap cables are in good condition.
4. Both snap cables are properly connected to the belt and the stimulator.

## Warranty

This WELL LIFE Arm & Leg Pain Management System carries a one-year warranty from the date of purchase.

The warranty applies to the WELL LIFE Arm & Leg Pain Management System and necessary parts and labor relating thereto. The distributor reserves the right to replace or repair the unit at their discretion.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## Replacement Parts

Contact WELL LIFE for ordering information for replacement parts, Be sure to use only WELL LIFE Arm & Leg Pain Management System parts.

Conductive Mesh Garment Electrode:

| | |
|---|---|
| **Socks**<br><br>Theraknit Part no, measured by shoe size. | Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size |
| **(Gloves)**<br><br>Theraknit Part no, Measured by Palm Width . | Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm |
| **Elbow Sleeve**<br><br>Theraknit Part no, measured by elbow circumference | Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 3010: over 30 cm |
| **Knee Sleeve**<br><br>Theraknit Part no, measured by Knee circumference. | Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm |

Snap Cable (set of 2): Part # LE-WS-0012

Self -adhesive Pads (set of 4): Part # CM5050 , CM50100

Support belt: Part # TB-0040 + Conductive Silicone pad (set of 2): Part # SP2550

## Conformity to Standards

The Stimulator is in compliance with:

- EN 60601-1: 1990 - Safety of medical device; electrical equipment - General safety.
- ANSI/AAMI NS 4 –1985; Transcutaneous Electrical Nerve Stimulators.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## Troubleshooting Guide

If you have a problem using your Low Back Pain ManagementSystem, review the following table find a solution.

| Problem | Solution |
|---|---|
| The stimulator will not turn on. | Check the battery – be sure it is firmly in place. Change the battery if necessary. |
| The stimulator has new AAA battery, but will not turn on. | Call Customer Service |
| The stimulator turns on and then off quickly | Replace the battery. |
| The stimulator is on, but there is no stimulation | Check the snap cables for breakage. If broken, replace. |
| The stimulator is on, but there is no stimulation | Make sure the snap cables are securely snapped onto the support belt and into the stimulator socket. |



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

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## WL-2407 Stimulator Technical Specifications

Power Source: 4.5Volt (3xAAA/Alkaline battery)

Dimension: 90 x 5.08 x 12.7mm

Weight: Approx. 100 gram (battery not included)

| Program | Max. | Phase duration | Rate | Function mode | Wave form Type |
|---|---|---|---|---|---|
| P1 | 80mA | 260uS | 15Hz | Constant | A |
| P2 | 80mA | 260uS | 15Hz | Modulated | A |
| P3 | 80mA | 260uS | 120Hz | Constant | A |
| P4 | 80mA | 260~150uS | 2 ~ 100Hz | Modulated | B |
| P5 | 80mA | 260uS | 100Hz | Modulated | A |
| P6 | 80mA | 260uS | 80 <->7 Hz | Modulated | C |
| P7 | 80mA | 260uS | 60Hz | Modulated | A |
| P8 | 80mA | P1 ~P7 | | Cycle | A/B/C |

Time: 1~60 minutes.



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

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# Chapter 5. List the name and 510(k) number of the device being modified and if applicable

Basically the information for the name and 510(k) number of the device being modified are listed as the followings:

Re: K063660.

Classification Name: Transcutaneous Nerve Stimulator.
Trade/Proprietary Name: OTC TENS for Low Back Pain Relief/ model WL-2407.
Classification: Class II (21 CFR 882.5890)
Product Code: NUH
Performance standard : ANSI/AAMI NS-4 1985.

In addition, to prove the substantial equivalence of the indication for use of our new design of electrode, we chose the following two additional 510(K) cleared model for comparison, in which the garment electrode, and snap type adhesive electrodes were used on the arm & leg treatment location:

Re: K033122.

Classification Name: Transcutaneous Nerve Stimulator.
Trade/Proprietary Name: Prizm Medical, Inc. 5000-Z System.
Classification: Class II (21 CFR 882.5890)
Product Code: NUH
Dated : February 10, 2005.

Re: K060846.

Classification Name: Transcutaneous Nerve Stimulator.
Trade/Proprietary Name: Endurance Therapeutics T1040.
Classification: Class II (21 CFR 882.5890)
Product Code: NUH, NGX, GZJ
Dated : December 03, 2007.

For the significant information of the device being modified, please see the following attachment.

- Attachment 1. SE information for K063660.
- Attachment 2. SE information for K033122.
- Attachment 3. SE information for K060846.



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

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Attachment 1. SE Information for K063660



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

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K063660

# 510(K) Summary

FEB 7 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:
   Well Life Healthcare Limited
   5Fl., Ste 504, Empire Centre, 68 Mody Road, Tsimshatsuim, Kowloon, Hong Kong

   Contact: Jenny Hsieh

   Date of Summary Preparation: January 31, 2007.

2. Name of the Device:

   OTC TENS for Low Back Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):

   WL-2402 (K040512), and WL-2406 (K052785).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:
   <1> The stimulation electrode is dual channels electrode.
   <2> The output waveform is selectable pre-programming change among P1~P8.
   <3> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <4> The LCD display is provided for the indication of operation status including operation mode, output wave form, output strength, time to cut-off, and battery low warning.



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

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5. Intended Use:

The model WL-2407 TENS is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The OTC TENS for low back pain relief/ model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of WL-2402 (K040512), and WL-2406 (K052785). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.



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

Records Processed under FOIA Request # 2015-813; 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

Well-Life Healthcare Limited
% Ms. Jenny Hsieh
68 Mody Road, Empire Centre, Suite 504
Tsimshatsuim, Kowloon
Hong Kong

FEB 7 2007

Re: K063660
Trade/Device Name: OTC TENS for Low Back Pain Relief/Model WL-2407
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH
Dated: December 6, 2006
Received: December 8, 2006

Dear Ms. Hsieh:

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 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 (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

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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: OTC TENS For Low Back Pain Relief / Model WL-2407.

Indications For Use:

- The model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063660

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Attachment 2. SE Information for K033122



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

K033122



## 510(k) SUMMARY of SAFETY and EFFECTIVENESS

### I. GENERAL INFORMATION

| | |
|---|---|
| **Trade or (Proprietary) Name:** | 5000Z System (OTC) |
| **Common or usual name:** | Transcutaneous Electronic Nerve Stimulator (TENS) |
| **Classification Name:** | FDA has classified Transcutaneous Electronic Nerve Stimulator (TENS) as Class II devices. (21 C.F.R. § 882.5890) |
| **Submitter's Name And Address:** | Cathryn N. Cambria<br>for Prizm Medical, Inc.<br>Regulatory Resources Group<br>5536 Trowbridge Drive<br>Dunwoody, GA 30338 |
| **Submission Date:** | September 29, 2003 |

### II. INDICATIONS FOR USE

The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs).

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## III. DEVICE DESCRIPTION

The 5000Z System (OTC) is a compact battery operated transcutaneous electrical stimulator that delivers a micro-current to the surface area of our patented conductive Silver-Thera E.M. garment electrodes to provide electrical stimulation for pain. It is designed not to exceed 100 volts across the garment electrodes. The technical Specifications for the 5000Z Stimulator can be found in Exhibit E. It is microprocessor controlled, allowing for easy setup of the treatment parameters and precise control of each setting, with a garment electrode dedicated to the upper or lower extremities. The system incorporates a proprietary connection from the stimulator to the electrodes that renders the device unusable without the dedicated electrodes. It is designed for ease of patient use with clearly marked intensity buttons.

Please refer to the Operations Manual (Exhibit A) for photographs and a more thorough description of the device.

The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs).

The primary function of the 5000Z System (OTC) is the same as the Micro-Z™ Stimulation System, Axelgaard Mfg. Co. UltraStim Kit and Woodside Biomedical ReliefBand® and raises no new questions of safety and effectiveness.

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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 MD 20850

Prizm Medical, Inc.
c/o Ms. Cathryn N. Cambria
Regulatory Resources Group, Inc.
5536 Trowbridge Drive
Dunwoody, GA 30338

APR 15 2005

Re: K033122
Trade Name: Prizm Medical, Inc. 5000-Z System
Regulatory Name: 21 CFR 882.5890
Regulatory Class: II
Product Code: NUH
Dated: February 10,2005
Received: February 10,2005

Dear Ms. Cambria:

We have reviewed your Section 510(k) preinarket 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Warnings section of the device labeling immediately following the indications for use section:

1. Warning: If you have numbness, tingling or loss of feeling/sensation in your arms, hands, legs or feet. this may represent a more serious problem like diabetic neuropathy. Consult your physician before using the device.

2. Warning: If you have swelling of the arm or leg, it may be more serious than simple muscle pain from overuse. Consult your doctor before using the device.

3. Warning: Use the glove or stocking only on healthy skin. Do not use on open wounds or rashes, or over swollen, red, infected or inflamed skin.



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

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Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device'and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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-Bea Tillman, Ph.D.
Director
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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# Indications for Use

510(k) Number (if known): K073122

Device Name: Prim Medical, Inc. 5000

Indications For Use: "To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities."

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use x (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

4/15/05

Page 1 of ___



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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 3. SE Information for K060846



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

K060846



## 510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92(c)

**1.0 Submitter's Name and Address:**

Endurance Therapeutics
122B First Street, NE
Dauphin, Manitoba Canada
R7N 1B5

**Contact Name:**
Brad Brezden
122B First Street, NE
Dauphin, Manitoba
Ph. / Fax 1-877-274-4962

DEC 0 3 2007

**Date Prepared:** August 27, 2007

**2.0 Name of Device and Classifications**

**Trade/Device Name:** T1040:
**Common Name:** TENS
**Regulation Number:** 21 CFR 882.5890
Transcutaneous Electrical Nerve Stimulator for Pain Relief
**Classification Name:** Stimulator, Nerve, Transcutaneous, Over-the-Counter.
**Regulatory Class:** Class II
**Product Code** NUH, NGX, GZJ

**3.0 Predicate Devices**

| | | |
|---|---|---|
| K011880 Compex Sport | Sport Muscle Stimulator | 21CFR890.5850 OTC |
| K033122 Prizm Medical inc. | 5000Z OTC TENS | 21CFR882.5890 OTC |
| K050174 Bio Stim Kit, | Back Pain Relief System | 21CFR882.5890 OTC |

**4.0 Device Description:**

The T1040 is a portable; battery powered (4.5 VDC) multi function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device.

Independent channel (two pads) that effectively transfers your desired choice of pre-programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. A garment belt is used to hold the electrode pads to treat the lower back muscles. There are 10 modes of operation, 6 manual and 4 automatic.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



**Electrical Parameter Comparisons**

**Table 14 – Comparison Table**

| Quantity | T1040 | Bio-Stim | Compex | 5000Z |
|---|---|---|---|---|
| Max. Voltage over 10kΩ, V | 154.1 | 132 | 126.8/103.3 | 226 |
| Max. Current over 10kΩ, mA | 15.4 | 13.2 | 12.7/10.3 | 22.6 |
| Max. Voltage over 2.2kΩ, V | 105.1 | 90 | 167.8/153.5 | 218 |
| Max. Current over 2.2kΩ, mA | 47.8 | 41 | 76.3/69.8 | 99 |
| Max. Voltage over 500Ω, V | 40.7 | 29.5 | 48 | 208 |
| Max. Current over 500Ω, mA | 81.4 | 59 | 96.1 | 416 |
| Pulse Width, μseconds | 210 | 30 - 225 | 270 | 100 |
| Pulse Period, msec | 4.1 - 500 | 9 – 12.5 | 125 | 10 |
| Max. Pulse Frequency, Hz | 245 | 110 | 118 | 120 |
| Max. Charge per Phase over 500Ω, μC | 16.9 | 7.6 | 32.3 | 3.4 |
| Max. Current Density over 500Ω, $mA/cm^2$ | 2.71 | 3.93 | 3.84 | 16.64 |
| Max. Average Power Density over 500Ω, $mW/cm^2$ | 5.35 | 1.1 | 10.2 | |

## 5.0 Intended Use:

To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto1 or Auto 4

Is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2

## 6.0 Substantial Equivalence:

The electrical stimulation provided by the T1040 is substantially equivalent to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling; i.e., for OTC sale. The pulses in the waveform combinations are restricted in amplitude and duration to values consistent with other devices quoted above.(see Appendix 4)

Technological characteristics, features, specifications, materials and intended uses of the T1040 are substantially equivalent to the quoted predicate devices.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



The T1040 has modes that offer substantially equivalent technical specifications, features and effective results as each of the predicates listed.

## 7.0 Non-Clinical Tests Performed:

Compliance to applicable voluntary standards includes AAMI NS-4 1985, as well as EN 60601-1, EN 60601-1-2, ISO 9001;2000 and ISO 13485:2003

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

## 8.0 Conclusion:

The electrical stimulation provided by the T1040 is similar to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling.

The T1040 has the same intended uses and the similar technological characteristics as these OTC cleared predicates. Moreover, verification and validation tests contained in this submission demonstrate that the differences in the T1040 still maintain the same safety and effectiveness as that of the cleared devices.

In other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Concerns of safe and proper use of electrodes and electrode pad placements have been fully addressed by making the user conscious of the proper placement of electrodes and proper operations of the device through detail in the User's Instruction Manual.

We believe that there are no new safety or effectiveness issues concerning this device to be introduced.

The safety of the device, to be used for the proposed indications without medical prescription or supervision, is established by the fact that no adverse events have been reported since 2002 with over 300,000 units sold with out a prescription in 20 countries.

Over 300 000 units sold with no adverse effects reported, proves its specific technical, safety measures and features are safe and effective when used without medical supervision. An even greater and more detailed user instruction manual regarding safe operation and adhesive pad placements is proposed for the USA marketplace and consumers.

The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrate that electrical stimulation does improve muscle performance as well as temporary pain reduction.



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

Records Processed under FOIA Request # 2015-813; 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 0 3 2007

Endurance Therapeutics
% Mr. Brad Brezden
CEO
122 B – First Street, NE
Dauphin, Manitoba, Canada
R7N 1B5

Re: K060846
Trade/Device Name: T1040
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH, NGX
Dated: August 27, 2007
Received: September 4, 2007

Dear Mr. Brezden:

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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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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



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## 13.0 Statement of Indication for Use

510(k) Number (if known): K060846

Device Name: T1040

Indications for Use:

To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto1 or Auto 4

Used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2

| Prescription Use (Part 21 CFR 801 Subpart D) | ——— | AND/OR | Over-The-Counter Use (21 CFR 801 Subpart C) | XX |
|---|---|---|---|---|

(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 General, Restorative, and Neurological Devices**

**510(k) Number** K060846



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# Chapter 6. Comparison information for the new device and the device being modified

In general the stimulation model WL-2407 is completely identical to that of the Well-Life model being modified : the OTC TENS for Low Back Pain Relief/ model WL-2407 (K063660). To help you clear about this stimulation model, we provided the following description for WL-2407.

WL-2407 is a selectable single/ dual channel, 4.5V (3xAAA /Alkaline battery) operated TENS device with the following features:

<1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).

<2> The stimulation electrode is garment electrodes as standard accessories and upper arm belt and snap type adhesive electrode as optional accessories.

<3> The output waveform is selectable pre-programming change among P1~P8.

<4> The output strength is adjustable at 0~80 mA, with variable setting time 0~60 minutes counting from switching ON.

<5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.

Since the stimulation model for this submission is completely identical to that of K063660, it is not necessary to provide comparison for these two identical stimulation model.

As clear description of Chapter 5, we chose another two 510(K) cleared models, the prizm Medical, Inc.5000-Z system (K033122) and Endurance Therapeutics T1040(K060846) to support the change of indication for use as claimed in this 510(K) submission. Because there exists some difference between the two chosen 510(K) cleared models (5000-Z system and T1040 and our new application model as mentioned in this 510(K) submission, we provided the following comparison table based upon the comparison table as mentioned on the 510(K) summary of Endurance Therapeutics T1040(K060846).

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## 6.1 Comparison table between new models and cleared model

| Quantity | WL-2407(Well-life) | 5000Z (Prizm) | T1040(Endurance) |
|---|---|---|---|
| Max. voltage over 10kΩ, V | 94 | 226 | 154.1 |
| Max. Current over 10kΩ, mA | 9.4 | 22.6 | 15.4 |
| Max. Voltage over 2.2kΩ, V | 56 | 218 | 105.1 |
| Max. Current over 2.2kΩ, mA | 18.18 | 99 | 47.8 |
| Max. Voltage over 500Ω, V | 40 | 208 | 40.7 |
| Max. Current over 500Ω, mA | 80 | 416 | 81.4 |
| Pulse Width, μseconds | 260 | 100 | 210 |
| Pulse Period, msec | No specified | 10 | 4.1-500 |
| Max. Pulse Frequency, Hz | 120 | 120 | 245 |
| Max. Charge per Phase over 500Ω, μC | 20.8 | 3.4 | 16.916.9 |
| Max. Current density over 500Ω, mA/cm$^2$ | 0.1 | 16.64 | 2.71 |
| Max. Average Power Density over 500Ω, mW/cm$^2$ | 4 | | 5.35 |

Note: 1. The technical information for WL-2407 is based on the testing waveform and calculation of Clause7.2.
2. According to the information in the comparison table, the technical specification for all of three models are within the acceptable limit as specified by FDA guidance for TENS devices.
3. The information of 5000z(Prizm) and T1040(Endurance)comes from the 510(K) summary of T1040(Endurance/K060846) released on FDA web-site.

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In addition to the output characteristics comparison as stated above mentioned, the use of stimulation electrode as well as the indication for use are also the very significant consideration for the choice of Prizm 5000-Z system(K033122) and Endurance Therapeutics T1040(K060846). For the comparison concerning these features, please see the following comparison table.

| Comparison Features | Models to be Compared | | |
|---|---|---|---|
| | WL-2407 (Well-life) | 5000Z (Prizm) | T1040 (Endurance) |
| Prescription or OTC | OTC | OTC | OTC |
| Indication for use | Pain relief for Arm and leg | Pain relief for Arm and leg | Pain relief for Arm and leg |
| FDA product code | NUH | NUH | NUH & NGX |
| Electrode Used | 1. Garment electrodes<br>2. Adhesive electrode<br>3. Arm belt with conductive gel | Garment electrode | adhesive electrode |

Form this comparison table, it is very clear that all of models are claimed for the OTC use of pain relief for arm and leg, and are all within the scope of "NUH" product classification code. Regarding the use of electrode type, our new model WL-2407 used the same garment electrode with Prizm 5000-Z system, and the same type of adhesive electrode as Endurance T1040 model. Therefore , it is very reasonable to claim that our new device WL-2407 for pain relief of Arm and Leg is substantial equivalent to Prizm 5000-Z System & Endurance T1040.

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## 6.2 Different Features.

Form the comparison table as above mentioned, it is very clear that there exist the following main difference for the stimulator.

<1> The treatment time.
<2> The intensity amplitude.
<3> The waveform.
<4> The power supply.
<5> The No of Channel.
<6> The weight and dimension.
<7> The use of electrodes.



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# Chapter 7. Variation comparison between modified device and the device being modified.

Based on the detail information and comparison as above mentioned, the following analysis for the possible impact concerning the comparison difference as well as its conclusion are presented:

## 7.1. The Issue of Specification difference and risk assessment

According to the specification comparison described in chapter 6, the main specification difference may be listed hereafter.

| No | Difference | Brief Description of Difference | Evaluation of difference and/or justification |
|---|---|---|---|
| 1 | Treatment time | ⅄ Prizm 5000-z is 15 minutes ~ 24 hours.<br>⅄ Unknown for Endurance T1040 .<br>⅄ WL-2407 is 1~ 60 minutes | This difference does not cause any impact on operation function |
| 2 | Intensity amplitude | ⅄ Prizm 5000-z is 0~200 Volts<br>⅄ Endurance T1040 is 0~150 Volts.<br>⅄ WL-2407 is 0~160 Volts | WL-2407 provided higher safety operation level than prizm 5000-z device |
| 3 | Wave form | ⅄ Prizm 5000-z is mono-phase pulse with 100μs fixed pulse duration.<br>⅄ Endurance T1040 provide 210 μs pulse duration.<br>⅄ WL-2407 is monophase pulse with 260 μs fixed pulse duration | For the WL-2407 wave form, Well-life has proven the effectiveness in K063660, so reasonable to claim the same clinical effectiveness, even there exist some diffence in wave form between two models. |
| 4 | Power Supply | ⅄ Prizm 5000-z use 3V (2*AAA battery) power<br>⅄ WL-2407 use 4.5V (3*AAA battery)power<br>⅄ Endurance T1040 use 4.5V (3*AAA)battery. | The difference on the use of power specification does not cause any impact on the performance and safety of device. |
| 5 | No. of output channel | ⅄ Prizm 5000-z provides only single output channel.<br>⅄ WL-2407 provide 2 independent output channels<br>⅄ Endurance T1040 provide 2 indendent output channels. | The difference in the No. of output channel dose not cause any impact on the performance and safety of device. |
| 6 | Weight and dimension | ⅄ For prizm 5000-z, the weight is 2.5 ounce,and the dimension is 2"X2.4"X0.65" mm.<br>⅄ For WL-2407, the weight is 100 g, and the dimension is 90X5.08X12.7 mm<br>⅄ Unknow for Endurance T1040. | The difference in the weight and dimensions of device does not cause any impact on the performance and safety of device |
| 7 | The use of electrodes | ⅄ Prizm 5000-z use only garment electrode.<br>⅄ For WL-2407, not only garment electrode but also | ⅄ WL-2407 provides more operation options on Arm and Leg stimulation.<br>⅄ The safety for the use of |



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| | | | |
|---|---|---|---|
| | | arm cuff with gel and adhesive electrode are used for Arm and leg.<br>➢ Endurance T1040 use only adhesive electrode for Arm & Leg pain relief. | electrodes for WL-2407 model was assessed with acceptable result in Clause 7.2. |

As comparison evaluation on the above mentioned table, the only technical issue needs justification is the use of electrode. For this technical issue, we have conducted and completed the assessment for the major output characteristis concerning the use of new electrode on our device WL-2407 in clause 7.2, and get the conclusion of acceptable results. For the details of evaluation, please see clause 7.2.

For the main difference as above mentioned, Well-Life have completed the risk assessment according to ISO 14971 and their quality management system. The assessment result indicated that the new models OTC TENS for Arm & Leg Pain Relief / model WL-2407 have the same safety level as well as the same indication for use, while compared with the cleared model Prizm 5000-Z (K033122) and Endurance Therapeutics T1040(K060846).



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## 7.2. Major output characteristics comparison

As previous discussion, the use of garment electrode is the most significant change for this new 510(k) submission. In order to prove that the safety for the use of garment electrodes is still within the acceptable range of TENS device, we make assessment as this clause.

According to the safety requirement as mentioned in FDA guidance for the TENS device, the current density and power density delivered from the TENS device shall be within the acceptable range as specified in the FDA guidance.

Practically speaking, this issue could be easily ensured by comparing the cross-section area of the electrode use. In section 2.4, we have given very clear information to make comparison for the cross section area for each type of electrode. We would like to repeat it again as the following table.

| Location | Electrode use condition | Possible size | Minimum Size |
|---|---|---|---|
| Arm | The use of glove garment or elbow garment. | Glove : S/M/L<br>Wristlet Sleeve:10*18 | 435 $cm^2$ |
| | Adhesive electrode (Well-Life CM5050 or CM50100) | 50 mm x 100mm, or 50mm x 50mm | 5.0mm * 5.0mm = 25 $cm^2$ |
| | The Neoprene + Conductive silicone pad with conductive gel. | 25mm x 50mm, or 50mm x 50 mm | 2.5mm * 5.0mm = 12.5 $cm^2$ |
| Leg | The use of conductive sock (garment electrode) | S/M/L/XL | 540 $cm^2$ |
| | The use of conductive knee sleeve (garment electrode) | 10*27 | 380 $cm^2$ |

From the information of table, it is very clear that the cross section area of adhesive electrode is far smaller than any one of garment electrode. Therefore it is also clear without any additional approval that the maximum output current density and power density happens in the condition of using adhesive. (Note: The minimum cross-section of the new well-life electrode is 2.5 cm * 5.0 cm =12.5$cm^2$)

Therefore, it could be reasonable foreseen that the use of garment electrode is safer than the use of adhesive electrode for the same output specification of TENS device. And the comparison of output characteristics is only required for the condition of using adhesive electrode.

Based on this conclusion, we would like to provide the comparing calculation for WL-2407 in the condition of using adhesive electrode of the same dimension as the followings.



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The major output characteristics are compared hereafter:

1. Maximum charge per pulse.
   Maximum charge per pulse = maximum current x maximum pulse width
   Maximum charge per pulse of WL-2407 = 0.26s X 80mA = 20.8 micro coulomb,

   All the maximum charge per pulse of above devices are smaller than 25 micro coulomb.

2. Maximum average current density.
   Maximum average current density = $I^2$x R / Area
   = (Ix Duty cycle)$^2$ / Area
   In here, R = 500ohm, electrode area = 12.5 cm$^2$ ; The calculation is as hereafter.
   Maximum average current density of WL-2407 = 0.0998 mA/cm$^2$ $\cong$ 0.1 mA/cm$^2$

3. Maximum peak power density.
   Maximum peak power density = I x V / Area; The calculation is as hereafter.
   Maximum peak power density of WL-2407 = 3.99 mW/cm$^2$ $\cong$ 0.004 W/cm$^2$

   For the calculation of the data as above mentioned, please see NS4 test report.

Based on the comparison information as above mentioned, the major output characteristics for the new model and the predicated cleared model are within the acceptable range of ANSI/AAMI NS4.



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## 7.3. Analysis for the other conformity issues.

### A. Design control actives

As mentioned in clause 6 and clause 7.1, the different hardware circuit and different power supply voltage was used for the new device and 510(K) cleared device. Basically the new device and Endurance Therapeutics T1040(K060846) used 4.5V (3xAAA battery) power. Prizm 5000-Z (K033122) used 3V (2xAAA battery) power.
For this difference, we have carried out the following tests to prove that our new devices were still in compliance with the requirement of the following two standards:

- Performance test according to ANSI/AAMI NS-4 1985.
- EMC test according to EN 60601-1-2: 2001
- Electrical Safety Test according to EN 60601-1:1990/A13:1996.

(Note : The test reports as above mentioned have been provided during FDA review for the WL-2407 OTC TENS for Low Back Pain relief(K063660)).

All the design control actives were performed in accordance with the design control procedures of Well Life. Therefore; we believe it is appropriate to address that the new device, OTC TENS for Arm & Leg Pain Relief / model WL-2407 is substantial equivalent to our predicated model Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846).

### B. Materials and Composition

Basically the materials used for the construction of the different mechanical parts are completely identical for the new device and the device being modified.

The garment electrode is the only new material used for our new device OTC TENS for Arm & Leg Pain Relief / model WL-2407. Since the garment electrode used for OTC TENS for Arm & Leg Pain Relief / model WL-2407 is the 510(k) cleared electrodes which has been claimed for the use of TENS device, it may be considered adequate to use this garment electrode for our new device from the material and composition point of view. The 510(K) cleared information for the garment electrode has been provided in clause 2.4.

Therefore, in terms of materials and composition, the OTC TENS For Arm & Leg Pain Relief / model WL-2407 do not involve any changes or modifications which could significantly affect the safety or effectiveness of the modified device, as compared to the cleared models: Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846)..



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## C. Chemical Composition

Neither the function of OTC TENS for Arm & Leg Pain Relief / model WL-2407 nor the function of cleared models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846) are based on chemical composition. Therefore, there are no issues associated with chemical composition for this analysis.

## D. Energy Source

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 and Endurance Therapeutics T1040 (K060846) obtain their energy from one 4.5V battery (3xAAA battery) and the model Prizm 5000-Z (K033122) obtains its energy from 3V (2xAAA battery) power.

All of the new and cleared models are supplied from DC battery. It will not cause any difference and impact on the performance and safety features of device. And the use safety of power supply has been clearly approved according to the relevant electrical safety standard, EN 60601-1.

Therefore, in terms of energy source, the OTC TENS for Arm & Leg Pain Relief / model WL-2407 do not involve any changes or modifications which could significantly affect the safety or effectiveness of the modified device, as compared to the cleared models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846)..

## E. Manufacturing Process and Sterilization

The models OTC TENS for Arm & Leg Pain Relief / model WL-2407 was manufactured using manual assembly of molded plastic and metal parts and electrical components. The device is not sterilized prior to use.

The cleared models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846) were also manufactured using manual assembly of molded plastic and metal parts and electrical components. The device is not sterilized prior to use.

Therefore, in terms of manufacturing process and sterilization, the OTC TENS for Arm & Leg Pain Relief / model WL-2407 do not involve any changes or modifications which could significantly affect the safety or effectiveness of the modified device, as compared to the cleared models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846).



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## F. Intended Use and Indications for use

For OTC TENS for Arm & Leg Pain Relief / model WL-2407, the indications for use is as the followings:

- The OTC TENS for Arm & Leg; Model : WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

For the cleared model Prizm 5000-Z (K033122), the indications for use is as the followings:

- Indication For Use : To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Therefore, the OTC TENS for Arm & Leg Pain Relief / model WL-2407 do not involve at changes or modifications in the intended use and indications for use of the device as compared to the cleared models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846).

## 7.4. Conclusion

The information provided above supports a conclusion that the changes or modifications associated with the development of the OTC TENS for Arm & Leg Pain Relief / model WL-2407 are such that neither significantly affect the safety or effectiveness of the cleared models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846) nor constitute major changes or modifications in the fundamental scientific technology and its intended use of the cleared model Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846)..



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# Chapter 8. Design Control Activities Summary.

## 8.1. Risk Analysis method(s):

In general the method for the risk assessment according to the standard ISO 14971: 2000 as mentioned on the report of software validation, verification and testing of our previous 510(k) submission are also available for the risk analysis of all new devices.

## 8.2. Impact and result of risk analysis for the modification

As statements above mentioned, the hardware and software of the main stimulation device of WL-2407 is completely identical as that of the Well-live existing model, the OTC TENS for Low Back Pain Relief/model WL-2407.

And the effectiveness and safety for the use of new electrode on the WL-2407 device could be ensured via the assessment report as mentioned in Clause 7.2.

Based on these two reasons, we concluded that the existing risk assessment report for the OTC TENS for Low Back pain Relief/model WL-2407(K063660) is still available for the model of this 510(K) submission, the OTC TENS for Arm & Leg / model WL-2407.



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## 8.3. Methods to ensure the conformity of new device

As mentioned in the previous sections, the new devices were designed, constructed and distributed in US market by Well-Life.

The basic methods to ensure the conformity of new device is to follow the general FDA assessment rule for the 510(K) submission of new device. As current FDA administration rules for the application of 501(K), the applicant is requested to submit FDA-3514 form to clearly present the substantial equivalent to the 510(K) cleared device, and FDA-3654 form to present the appropriate standards to ensure the safety and good performance of device. For these two basic requirements, we have completed the detailed information of Form-3514 and Form-3654.

Because that the hardware and software for our new models were completely identical to the model being modified, we do not provide any further new test reports for the standards as mentioned in Form-3654 for this 510(K) submission. In case of required, you could make reference to the testing reports submitted included in our previous 510(K) submission documents.

Since Well-Life has set up a full quality control system according to the international standard of ISO 9001 and ISO 13485, and this quality control system is under the periodical surveillance of DNV, the qualified European Notified Body for medical device directive (93/42/EEC), the verification and validation for this design change of new device was implemented according to the design control procedure of Well-Life's quality control system.

The appropriate methods to ensure the conformity of new device are as the following four attached information:

1> Form FDA-3514 form to clearly present the substantial equivalent to the 510(K) cleared device .
2> Form FDA-3654 form to present the appropriate standards to ensure the safety and good performance of device.
3> The valid ISO-9001+ISO-13485(Well-Life) certificate issued by DNV.

These three conformity evidence are provided in Appendix 1 ~Appendix 3.



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**Appendix 1. FDA Form-3514.**



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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)* |
|---|---|---|
| 06/10/2009 | (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: Well-Life Healthcare Limited | Establishment Registration Number *(if known)*: | | |
| Division Name *(if applicable)*: | Phone Number *(including area code)*: ( ) 886-2-29282112 | | |
| Street Address: 1F, No.16, Lane 454, Jungjeng Road | FAX Number *(including area code)*: ( ) 886-2-29281880 | | |
| City: Yunghe City, Taipei County | State / Province: | ZIP/Postal Code: 234 | Country: Taiwan |
| Contact Name: Chin-Chih Hsieh | | | |
| Contact Title: Official Correspondent | Contact E-mail Address: jenny@welllifehealthcare.com.tw | | |

## 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: | | |

FORM FDA 3514 (9/07)

PAGE 1 OF 5 PAGES

PSC Graphics: (301) 443-1090 EF

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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 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

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## SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | K063660 | 2 | K033122 | 3 | K060846 | 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 | K063660 | 1 | Well-Life OTC TENS of Low Back Pain Relief/model 2407 | 1 | Well-life Health care Limited |
| 2 | K033122 | 2 | Prizm 5000-Z system | 2 | Prizm Medical, Inc. |
| 3 | K060846 | 3 | Endurance T1040 | 3 | Endurance Therapeutics |
| 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 | OTC TENS for Arm & Leg Pain Relief | 1 | WL-2407 |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

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

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

Data Included in Submission

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

## SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

| Product Code | C.F.R. Section *(if applicable)* | Device Class |
|---|---|---|
| NUH | Unclassified | [ ] Class I [x] Class II |
| Classification Panel: Division of General Restorative and Neurological Devices | | [ ] Class III [ ] Unclassified |

Indications *(from labeling)*

The OTC TENS for Arm & Leg Pain Relief; Model:WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

FORM FDA 3514 (9/07)



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| | |
|---|---|
| ***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 | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ 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 | |

| | | | | |
|---|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifer (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ 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 | |

| | | | | |
|---|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifer (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ 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

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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 | EN/IEC 60601-1 | IEC | Medical Electrical Equipment - Part 1: General requirements for safety | 1990 + A1/A2/A13: 1996 | |
| 2 | EN/IEC 60601-1-2 | IEC | Medical Electrical Equipment - Part 1-2: General requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests | 2001 | |
| 3 | ANSI/AAMI NS4 | ANSI | American National Standard for Transcutaneous Electrical Nerve Stimulators | 1985 | |
| 4 | | | | | |
| 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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**Appendix 2. FDA Form-3654.**



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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

***(To be filled in by applicant)***

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI NS4, American National Standard for Transcutaneous Electrical Nerve Stimulators, 1985

| ***Please answer the following questions*** | *Yes* | *No* |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☐ | ☑ |
| FDA Recognition number [3] # | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☑ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☑ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☑ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☑ | ☐ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☑ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☑ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☑ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☑ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☑ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☑ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html



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

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS***

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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



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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirments for Safety, 1990+A1/A2/A13:1996

| *Please answer the following questions* | *Yes* | *No* |
|---|---|---|
| Is this standard recognized by FDA [2] ? | ☑ | ☐ |
| FDA Recognition number [3] # 5-4 | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☑ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☑ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☑ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☑ | ☐ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☑ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☑ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☑ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☑ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☑ |
| If yes, was the guidance document followed in preparation of this 510k? | | ✔ |
| Title of guidance: | | |

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS***

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

***(To be filled in by applicant)***

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-1-2, Medical Electrical Equipment - Part 1-2: General Repuirments for Safety - collateral Standard.2001

| ***Please answer the following questions*** | *Yes* | *No* |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☑ | ☐ |
| FDA Recognition number [3] # 5-34 | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☑ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☑ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☑ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☑ | ☐ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☑ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☑ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☑ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☑ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☑ |
| If yes, was the guidance document followed in preparation of this 510k? | | ✔ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED * | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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**Appendix 3. ISO 13485 Certificate**



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

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# DET NORSKE VERITAS

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 2004-OSL-AQ-0137

*This is to certify that the Management System of*

## Well-Life Healthcare Limited

**(with sites as per attachment)**

*at*

**Suite 405, 5F., Empire Centre, 68 Mody Road, Tsimshatsui, Kowloon, Hong Kong**

*has been found to conform to*

**ISO 13485:2003**

*This Certificate is valid for the following product or service ranges:*

**Manufacture and supply of Transcutaneous Electrical Nerve Stimulators (TENS), Powered Muscle Stimulators (EMS), Interferential Stimulators (IF), and Electrode Pads.**

*Initial Certification date:*
25 October 2003

*This Certificate is valid until:*
19 August 2010

*The audit has been performed under the supervision of*
Fred Cheng
*Lead Auditor*

NORWEGIAN ACCREDITATION
QUAL 002

*Place and date:*
Hovik, 10 September 2007

*for the Accredited Unit:*
DET NORSKE VERITAS CERTIFICATION, NORWAY

Aud Løken Eiklid
*Management Representative*

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

66

HEAD OFFICE: Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 · www.dnv.com



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

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# DET NORSKE VERITAS

# APPENDIX TO CERTIFICATE

This Appendix refers to Certificate No. 2004-OSL-AQ-0137

## Well-Life Healthcare Limited

locations included in the certification are as follows:

1. **1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei county 234, Taiwan, R.O.C.**
   **Scope:**
   ***Manufacture and supply of Heating and Cooling Therapeutic Devices.***

2. **No. 20, Lane 145, An-Ping Road, Chung-Ho City, Taipei County 235, Taiwan, R.O.C.**
   **Scope:**
   ***Supply of Blood Pressure Monitors and Clinical Thermometers.***

3. **6F-9, No. 502, Yuanshan Road, Chung-Ho City, Taipei County 235, Taiwan, R.O.C.**
   **Scope:**
   ***Sales and Distribution of Medical Equipment.***

*Initial Certification date:*
25 October 2003

*This Certificate is valid until:*
19 August 2010

*The audit has been performed under the supervision of*
Fred Cheng
*Lead Auditor*

NORWEGIAN ACCREDITATION
QUAL 002

*Place and date:*
Hovik, 10 September 2007

*for the Accredited Unit:*
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## 8.4. Summary of Design Control Activities

Based on the statement and information provided in this chapter, we would like to draw up the following summaries for the design control activities:

1> The new device, models OTC TENS for Arm & Leg/ model WL-2407 comply with the standard of ANSI/AAMI NS4: 1985 –American National Standard for Transcutaneous Electrical Nerve Stimulators

2> All verification and validation activities were performed by designate individual(s) and the results demonstrated that predetermined acceptance criteria and manufacturing facility are in compliance with the design control procedure requirements as specified in 21 CFR820.30.

3> All the detail design control information about the new models OTC TENS for Arm & Leg Pain Relief / model WL-2407 was maintained as the quality records according to the requirement of quality system, and are available for review any time.

4> The declaration of conformity with design control requirement in the quality system regulation was signed by the R&D department of Well Life as mentioned hereafter.



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

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# Chapter 9. Special 510(K) Statement & Declaration of conformity with design control requirement in the Quality System Regulation.

As required by FDA, the following two statement are provided as the conclusion of this special 510(K) submission :

- Statement for special 510(K) document.
- Declaration of conformity( from the manufacturer)



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

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# Statement for special 510(k) document

The undersigned, Jenny Hsieh, representing the official correspondent of **Well-Life Healthcare Ltd. / 1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County Taiwan, R.O.C**, states that

"The indication for use and the intended use of the device as described in its labeling (including instruction for use, packaging labeling, and marketing literature) for our new submission OTC TENS for Arm & Leg Pain Relief / model WL-2407 have no significant change which is liable to cause impact on the performance and safety change of device"

Submitter: Jenny Hsieh

Qualification: Official Correspondent

Signature:



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

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# Declaration of Conformity

The undersigned, Jenny Hsieh , representing **Well-Life Healthcare Ltd. / 1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County Taiwan, R.O.C.;** manufacturer declares that.,

Our modified device, model OTC TENS for Arm & Leg Pain Relief / model WL-2407, to be distributed in US market, complies with the standard of ANSI/AAMI NS4: 1985 –American National Standard for Transcutaneous Electrical Nerve Stimulators.

And that all verification and validation activities were performed by the designate individual(s) and the results demonstrated that predetermined acceptance criteria were met and the manufacturing facility is in compliance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Well-Life Healthcare Ltd.

Quality Representative of Well Life



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

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# Part II. 510(k) Summary

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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) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:
   Well Life Healthcare Limited
   1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C

   Contact: Jenny Hsieh

   Date of Summary Preparation: June 10, 2009.

2. Name of the Device:

   OTC TENS for Arm & Leg Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):

   1> The Well-Life OTC TENS for Low Back Pain Relief/model WL-2407 (K063660).
   2> The Prizm 5000-Z system (K033122)
   3> Endurance Therapeutics T1040 (K060846).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:
   <1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).
   <2> The stimulation electrode is garment electrodes as standard accessories and upper arm belt and snap type adhesive electrode as optional accessories.
   <3> The output waveform is selectable pre-programming change among P1~P8.
   <4> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.



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

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5. Intended Use:

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of Well-Life OTC TENS for Low Back Pain Relief/model WL-2407 (K063660), and Prizm 5000-Z system (K033122) and Endurance Therapeutics T1040 (K060846). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.



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: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (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)



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

# COVER SHEET MEMORANDUM

**From:** Rahul Ram
**Subject:** 510(k) K091757/S3
**To:** The Record

1/13/10

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 |
|---|---|---|---|
| Indications for Use Pages | *Attach IFU* | | No |
| **510(k) Summary** /510(k) Statement | *Attach Summary* | Yes | |
| Truthful and Accurate Statement. | *Must be present for a Final Decision* | Yes | |
| Is the device Class III?<br>If yes, does firm include Class III Summary? | *Must be present for a Final Decision* | | No |
| Does firm reference standards? **FDA Forms 3654 Provided**<br>(If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) | | Yes | |
| Is this a combination product?<br>(Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC | | | No |
| Is this a reprocessed single use device?<br>(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) | | | No |
| Is this device intended for pediatric use only? | | | No |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) **OTC** | | | No |
| Is clinical data necessary to support the review of this 510(k)?<br>Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*?<br>(If not, then applicant must be contacted to obtain completed form.) | | | No |

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

| | | |
|---|---|---|
| Does this device include an Animal Tissue Source? | | No |
| All Pediatric Patients age<=21 | | n/a |
| Neonate/Newborn (Birth to 28 days) | | n/a |
| Infant (29 days -< 2 years old) | | n/a |
| Child (2 years -< 12 years old) | | n/a |
| Adolescent (12 years -< 18 years old) | | n/a |
| 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.) | | n/a |
| Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) | | n/a |
| Nanotechnology | | No |

| | | | |
|---|---|---|---|
| Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html) | *Contact OSB.* | | No |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) | *Contact OC.* | | No |

| Regulation Number | Class* | Product Code |
|---|---|---|
| **21 CFR 882.5890** | **II** | **NUH** |

(*If unclassified, see 510(k) Staff)

**Additional Product Codes:** ~~GXY~~ RKR 2/3/10

**Review:** [signature] OHDB
(Branch Chief) (Branch Code)

(Date) 2/1/10

**Final Review:** Kevin Alexander 2/5/10
(Division Director)

(Date) for

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Food and Drug Administration**
**Center for Devices & Radiological Health**

**Division of Ophthalmic, Ear, Nose, and Throat Devices**
**Diagnostic and Surgical Devices Branch**
**9200 Corporate Boulevard HFZ-460**
**Rockville, MD 20850**
**(240) 276-1498**

## Premarket Notification [510(k)] Review

**Date:** 1/13/2010
**To:** RECORD
**From:** Rahul Ram
**Subject:** K091757/S3

1/13/10

| | |
|---|---|
| **Company:** Well Life Healthcare, Ltd.<br>1 Fl., No. 16, Lane 454, Jungjeng Rd<br>Yunghe City, Taipei County, Taiwan, R.O.C | **Contact:** Jenny Hsieh<br>Official Correspondent, Well Life Healthcare, Ltd. |
| **Device Trade Name:** OTC TENS for Arm and Leg Pain Relief, Model WL-2407 | **Email:** jenny@welllifehealthcare.com.tw |
| **Description:** OTC TENS Device / Garment Electrodes | **Phone:** 886-2-29282112 |
| **510(k) Received Date:** August 28, 2009 | **Fax:** 886-2-29281880 |

**Sponsor-Identified Predicate Devices:**

| 510K # | Pro Code | Device Name | Company |
|---|---|---|---|
| K063660 | NUH | OTC TENS FOR LOW BACK PAIN RELIEF, MODEL WL-2407 | Well-Life Healthcare |
| K060846 | NUH, ~~GZX~~ NGF | Therapeutic Massage Companion | Endurance Therapeutics |
| K033122 | NUH | 5000Z System | Prism Medical |

**Recommendation**
The device requires NO additional information in order to be found substantially equivalent.

Therefore, I recommend that the file be found **substantially equivalent (SE).**

Regulation Number: **21 CFR 882.5890**
Regulation Name: **Transcutaneous electrical nerve stimulator for pain relief.**
Regulatory Class: **Class II**
Product Code: **NUH**

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

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Additional Product Codes: ~~GXY~~ FKR 2/3/2011

**IFU as specified in the submission:** ☐ **Pediatric** ☐ **Rx** ☒ **OTC**

"The OTC TENS for Arm and Leg Pain Relief /Model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities."



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

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## I Purpose and Background

The applicant would like to introduce **OTC TENS for Arm and Leg Pain Relief (Model WL-2407)** into interstate commerce. The original submission (K091757) was submitted as a Special 510(k), however due to the change in the Indications for Use it was determined (by the lead reviewer at the time, Dexiu Shi) that this submission did not qualify for being a Special 510(k). Dexiu requested additional information to meet the requirements of a Traditional 510(k), which the applicant provided in the previous submission (K091757 / S001). In the previous submission (K091757 / S002), the applicant attempted to address deficiencies related to electrical performance of their device, and the marketing of their device with a prescription device. In response to that submission, concerns were raised regarding the results of the electrical performance testing, lack of dispersion testing, and an issue regarding prescription electrodes. The current submission (K091757 / S003) attempts to address these concerns.

The scope of this review is limited to how the applicant addresses these deficiencies and furthermore whether resolution of these deficiencies mitigates all safety and effectiveness concerns required for being found substantially equivalent (SE).

## II i) Deficiencies Sent In Response to S2 ii) Responses to Those Deficiencies in S3 & Reviewer Comments to Responses

### i) Deficiency 1:

In response to deficiency 1, you identify another garment electrode / TENS device combination predicate (K033122, "5000Z System") and provide a comparison of overall impedance between the TheraKnit electrodes and the electrodes of the 5000Z system. Based upon this comparison, you reason that the TheraKnit garment electrode can be used with the WL-2407 stimulator. Because the TheraKnit device intended is for prescription use only, it is inappropriate to package or sell the TheraKnit with your device, as your device is for over-the-counter use. Therefore, please confirm that your device is not packaged or sold with the TheraKnit device (instead, it is only indicated to be used with the TheraKnit device). Furthermore, please revise your "Operation Manual" to include the following warning:

> "The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."

Alternatively, please remove all references to the TheraKnit Garment Electrodes from your submission and labeling.

### ii) Response to Deficiency 1 & Reviewer Comments

***In response to Deficiency 1,*** the applicant has declared that the TheraKnit electrodes are not packaged or sold with the applicant's device in the 510(k) summary. Furthermore, the applicant provided a revised instruction manual to inform the user that the TheraKnit electrodes are for prescription use only.



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

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***REVIEW COMMENT:*** **The applicant's actions to resolve Deficiency 1 are ADEQUATE. The applicant has made it abundantly clear that the TheraKnit electrodes are not packaged and sold with the device. Therefore, the prescription protection on these electrodes cannot be circumvented by purchase of the applicant's device. Furthermore, the included information in the instruction manual informs the user that to use the electrodes, it must be sanctioned by a licensed healthcare provider. This assures that the user of the device is informed as to how to obtain and appropriately use the device.**

**i) Deficiency 2 (A & B):**

In response to deficiency 2, you provide testing and calculations in Attachment 2 of the submission. The testing shows that the output power and power density is roughly half of the corresponding values for your predicate device. You claim that this is due to the fact that "the 5000Z is a high voltage stimulator, whilst WL-2407 is a typically asymmetrical biphasic TENS device." However, you have not stated why this does not significantly diminish the effectiveness of your device. Therefore, please revise your 510(k) summary to include the following:

a. The results of all comparison testing noted in Attachment 2, and;

b. An acknowledgement of the lower output power and power density of your device and a scientific rationale for how effectiveness is equivalent.

This information is important to ensure that your device is equivalent to your predicate devices.

**ii) Response to Deficiency 2 & Reviewer Comments**

***In response to Deficiency 2,*** the applicant has provided a revised 510(k) summary that includes comparison testing between the 5000Z and the WL-2407, including an acknowledgement that the power density is lower than the predicate.

***REVIEW COMMENT:*** **This is ADEQUATE. Additionally, the applicant neglected to put units on the current and power density tables in the 510(k) summary; because the information in the 510(k) summary is just a reproduction of the information provided in Supplement 2, Attachment 2, which had units ($mA/cm^2$ and $W/cm^2$ for current density and power density). PLEASE SEE EMAIL CORRESPONDENCE FOR FURTHER INFO.**

**i) Deficiency 3:**

In response to deficiencies 2 and 3, you have provided electrical performance testing. However, you have not provided dispersion testing for any of the electrodes. Please provide dispersion testing to ensure that current traveling through the electrodes does



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not congregate in "hot spots." This is important to ensure that your device is reasonably safe for its indicated use.

### ii) Response to Deficiency 3 & Reviewer Comments

***In response to Deficiency 3,*** the applicant has provided dispersion testing in Attachment 3-A of the submission.

***REVIEW COMMENT:*** **Upon review of the provided information, the test setup appears to be adequate: the output current was tested in four locations on the electrode. The results of this testing showed that output current deviated no more than 2% between locations. This is ADEQUATE.**

## III Substantial Equivalence Discussion

Needed only for SE decision

| | YES | NO | |
|---|---|---|---|
| 1. Is the product a device? | ✓ | | If **NO,** See 510(k) staff |
| 2. Is the device subject to 510(k)? | ✓ | | If **NO,** See 510(k) staff |
| 3. Same indications for use? | ✓ | | If **YES,** Go To 5 |
| 4. Do the differences alter the effect or raise new questions of safety and/or effectiveness? | | | If **YES,** Stop **NSE** |
| 5. Same technological characteristics? | ✓ | | If **YES,** Go To 7 |
| 6. Could the new characteristics affect safety and/or effectiveness? | | | If **YES,** Go To 8 |
| 7. Are the descriptive characteristics precise enough? | | ✓ | If **NO,** Go To 10<br>If **YES,** Stop **SE** |
| 8. Are there **new types** of safety or effectiveness questions? | | | If **YES,** Stop **NSE** |
| 9. Do accepted scientific methods exist for assessing the effects of the new characteristics? | | | If **NO,** Stop **NSE** |
| 10. Are performance data available to allow for assessment of equivalence? | ✓ | | If **NO,** Request Data |
| 11. Do the data demonstrate equivalence? | ✓ | | |

Final decision:

"Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device: **IT IS A DEVICE**

2. Explain why not subject to 510(k): **IT IS SUBJECT TO A 510(K)**

3. Explain how the new indication differs from the predicate device's indication:

   **THE NEW INDICATION DOES NOT DIFFER FROM THE PREDICATE'S INDICATION.**

4. Explain why there is or is not a new effect or safety or effectiveness issue:

   **NOT APPLICABLE, SINCE THE INDICATIONS FOR USE ARE THE SAME.**



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

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5. Describe the new technological characteristics:

   N/A

6. Explain how new characteristics could or could not affect safety or effectiveness:

   N/A

7. Explain how descriptive characteristics are not precise enough:

   ~~ELECTRICAL PERFORMANCE OF THE STIMULATOR / ELECTRODES NEEDS CLARIFICATION~~ (THE ELECTRICAL PERFORMANCE INFORMATION HAS BEEN CLARIFIED)

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

   N/A

9. Explain why existing scientific methods can not be used:

   NOT APPLICABLE

10. Explain what performance data are needed:

    IMPEDANCE TESTING AND CLARIFICATION OF PERFORMANCE TESTING ~~IS REQUESTED.~~ (HAS BEEN PROVIDED)

11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

    DISPERSION TESTING MITIGATES SAFETY CONCERNS REGARDING FOCAL AREAS OF CURRENT DISTRIBUTION; CLARIFICATIONS TO THE 510(K) SUMMARY ADEQUATELY INFORM THE USER OF ELECTRICAL PERFORMANCE OF THE DEVICE; CLARIFICATIONS TO THE 510(K) SUMMARY AND USER'S MANUAL ENSURE THAT CIRCUMVENTION OF THE ACCESSORY ELECTRODE'S PRESCRIPTION LIMITATION DOES NOT OCCUR.

## IV Recommendation

The device requires NO additional information in order to be found substantially equivalent.

Therefore, I recommend that the file be found **substantially equivalent (SE).**



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

**Lead Reviewer Signoff:** 1/13/10

Rahul Ram (ODE/DONED/ONDB)

**Branch Signoff:**

Brad Cunningham (ODE/DONED/ONDB)

Date 2/3/10. Concur: Yes ☑ No ☐

**Division Signoff:**

Kesia Alexander, Ph.D. (ODE/DONED)

Date 2/5/10. Concur: Yes ☑ No ☐



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## Ram, Rahul

**From:** jenny@welllifehealthcare.com.tw
**Sent:** Thursday, February 04, 2010 9:51 PM
**To:** Ram, Rahul
**Cc:** Cunningham, Bradley
**Subject:** Re: K091757/S2 , 510k summary revised, 2010-2-5
**Attachments:** Attachment 2 -510(K)-summary for K091757S2 dd. 20091208( R1).doc

Dear Dr. Ram :

Thank you for your comments on the K09157/S2 received of today. As informed, I revise accordingly the 510 summary accordingly as enclosed, please refer to.

Thank you ~

Sincerely yours,
Jenny

----- Original Message -----
From: Ram, Rahul
To: jenny@welllifehealthcare.com.tw
Cc: Cunningham, Bradley
Sent: Friday, February 05, 2010 4:24 AM
Subject: K091757/S2

Jenny:

Thank you for your most recent supplement to K091757/S2 (WL-2407, OTC TENS).

We have the following remaining deficiency that we would like you to resolve:

**In your 510(k) summary, you present two tables ("current comparison" and "power density comparison"). However, these tables do not have units (presumably, the units are "mA/cm^2" for the "current comparison" table and "W/cm^2" for the "power density comparison" table). Please email me a revised copy of the 510(k) summary with the appropriate units included. Please send your email to me by tomorrow, 5 PM EST at the latest.**

Thanks!

- Rahul

**Rahul K. Ram**
LTJG, USPHS
*FDA \ CDRH \ ODE*
***(NEW)*** *Division of Ophthalmic, Neurologic & ENT Devices (DONED),*

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

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*(NEW) Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch (ONDB)*
**rahul.ram@fda.hhs.gov**
***(NEW)* 301-796-6610 (v)**
***(NEW)* 301-847-8126 (f-1)**
***(NEW)* 301-847-8127 (f-2)**


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# Part II. 510(k) Summary



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

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# 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091757 .

1. Submitter's Identifications:
   Well Life Healthcare Limited
   1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 23455,
   Taiwan, ROC

   Contact: Jenny Hsieh

   Date of Summary Preparation: December 08, 2009

2. Name of the Device:

   OTC TENS for Arm & Leg Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):
   1> The Prizm 5000-Z system (K033122)
   2> Endurance Therapeutics T1040 (K060846).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. Basically the stimulation model WL-2407 is completely identical to that of model as mentioned in the Well-Life K063660- 510(K) cleared device. To change the indication for use for the treatment location as the chosen predicate devices, Well-Life change the design of electrode.

   For the device included in this submission, we use the following third party 510(K) legally marketed predicate components:
   <1>K022494, the Home Care Jelly.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:

   <1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).
   <2> For the stimulation electrode, Well-Life uses upper arm belt as well as snap type adhesive electrode as standard accessories.
   <3> The output waveform is selectable pre-programming change among P1~P8.
   <4> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.



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5. Intended Use:

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Power level testing comparison and acknowledge of comparison result with Prizm 5000Z system:

For the substantial equivalent comparison, the power level testing comparison with the chosen 510(K) cleared device, Prizm 5000-Z system was conducted via using 1K ohm loading resistance for the garment electrodes . Testing set up with comparison result is as the following table :

Current comparison: (Unit: $mA/cm^2$)

| Electrode Type | Glove | Sleeve& Knee | Sock | Silicone Pad |
|---|---|---|---|---|
| Well-life WL-2407 | 0.00337 | 0.00386 | 0.00271 | 0.11728 |
| Prizm 5000-Z | 0.00340 | 0.00385 | 0.00274 | 0.11817 |

Power Density Comparison : (Unit: $W/cm^2$)

| Electrode Type | Glove | Sleeve & Knee | Sock | Silicone Pad |
|---|---|---|---|---|
| Well-life WL-2407 | 0.00032 | 0.00036 | 0.00025 | 0.01098 |
| Prizm 5000-Z | 0.00064 | 0.00072 | 0.00051 | 0.02222 |

Based on this comparison result, we made a acknowledge that the model WL-2407 has a lower output power and power density than that of Prizm 5000-Z system while using the same electrode, and that the garment electrode for prescription use will not be packed or sold with WL-2407 model. In case the garment electrode is to be used with WL-2407 model , the effectiveness is to be determined by the physician who prescribes the use of that electrode.

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

8. Conclusions

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of Prizm 5000-Z system (K033122) and Endurance Therapeutics T1040 (K060846). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that



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the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.



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# Indications For Use

510(k) Number (if known):

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (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)



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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

# COVER SHEET MEMORANDUM

**From:** Rahul Ram

**Subject:** 510(k) K091757/S2

**To:** The Record

Please list CTS decision code: **TH**

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc )

✓ **Hold** (Additional Information or **Telephone Hold**).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

| Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.): | | YES | NO |
|---|---|---|---|
| Indications for Use Pages | *Attach IFU* | | No |
| **510(k) Summary** /510(k) Statement | *Attach Summary* | Yes | |
| Truthful and Accurate Statement. | *Must be present for a Final Decision* | Yes | |
| Is the device Class III?<br>If yes, does firm include Class III Summary? | *Must be present for a Final Decision* | | No |
| Does firm reference standards? **FDA Forms 3654 Provided**<br>(If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) | | Yes | |
| Is this a combination product?<br>(Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC | | | No |
| Is this a reprocessed single use device?<br>(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) | | | No |
| Is this device intended for pediatric use only? | | | No |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) **OTC** | | | No |
| Is clinical data necessary to support the review of this 510(k)?<br>Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*?<br>(If not, then applicant must be contacted to obtain completed form.) | | | No |



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| | | |
|---|---|---|
| Does this device include an Animal Tissue Source? | | No |
| All Pediatric Patients age<=21 | | n/a |
| Neonate/Newborn (Birth to 28 days) | | n/a |
| Infant (29 days -< 2 years old) | | n/a |
| Child (2 years -< 12 years old) | | n/a |
| Adolescent (12 years -< 18 years old) | | n/a |
| 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.) | | n/a |
| Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) | | n/a |
| Nanotechnology | | No |

| | | | |
|---|---|---|---|
| Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html) | *Contact OSB.* | | No |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) | *Contact OC.* | | No |

| **Regulation Number** | **Class*** | **Product Code** |
|---|---|---|
| **21 CFR 882.5890** | **II** | **NUH** |

(*If unclassified, see 510(k) Staff)

**Additional Product Codes: GXY**

**Review:** _____ OUDB _____
(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

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Center for Devices & Radiological Health

Division of Ophthalmic, Ear, Nose, and Throat Devices
Diagnostic and Surgical Devices Branch
9200 Corporate Boulevard HFZ-460
Rockville, MD 20850
(240) 276-1498

## Premarket Notification [510(k)] Review

**Date:** 11/18/2009
**To:** RECORD
**From:** Rahul Ram
**Subject:** K091757/S2

| | |
|---|---|
| **Company:** Well Life Healthcare, Ltd.<br>1 Fl., No. 16, Lane 454, Jungjeng Rd<br>Yunghe City, Taipei County, Taiwan, R.O.C | **Contact:** Jenny Hsieh<br>Official Correspondent, Well Life Healthcare, Ltd. |
| **Device Trade Name:** OTC TENS for Arm and Leg Pain Relief, Model WL-2407 | **Email:** jenny@welllifehealthcare.com.tw |
| **Description:** OTC TENS Device / Garment Electrodes | **Phone:** 886-2-29282112 |
| **510(k) Received Date:** August 28, 2009 | **Fax:** 886-2-29281880 |

**Sponsor-Identified Predicate Devices:**

| 510K # | Pro Code | Device Name | Company |
|---|---|---|---|
| K063660 | NUH | OTC TENS FOR LOW BACK PAIN RELIEF, MODEL WL-2407 | Well-Life Healthcare |
| K060846 | NUH, GZX | Therapeutic Massage Companion | Endurance Therapeutics |
| K033122 | NUH | 5000Z System | Prism Medical |

**Recommendation**
The EMSI Garment Electrode requires additional information in order to proceed with the review.

Therefore, I recommend that the file be put on **telephone hold (TH).**

Regulation Number: **21 CFR 882.5890**
Regulation Name: **Transcutaneous electrical nerve stimulator for pain relief.**
Regulatory Class: **Class II**
Product Code: **NUH**

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Additional Product Codes: **GXY**

**IFU as specified in the submission:** ☐ **Pediatric** ☐ **Rx** ☒ **OTC**

"The OTC TENS for Arm and Leg Pain Relief /Model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities."





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

## I Purpose and Background

The applicant would like to introduce **OTC TENS for Arm and Leg Pain Relief (Model WL-2407)** into interstate commerce. The original submission (K091757) was submitted as a Special 510(k), however due to the change in the Indications for Use it was determined (by the lead reviewer at the time, Dexiu Shi) that this submission did not qualify for being a Special 510(k). Dexiu requested additional information to meet the requirements of a Traditional 510(k), which the applicant provided in the previous submission (K091757 / S001). In the current submission (K091757 / S002), the applicant has attempted to address deficiencies related to electrical performance of their device, and the marketing of their device with a prescription device. The scope of this review is limited to how the applicant addresses these deficiencies and furthermore whether resolution of these deficiencies mitigates all safety and effectiveness concerns required for being found substantially equivalent (SE).

## II i) Deficiencies Sent In Response to S1 ii) Responses to Those Deficiencies in S2 & Reviewer Comments to Responses

### i) Deficiency 1 (A & B):

You state that garment electrodes have been cleared under K053214 (TheraKnit Garment Electrodes). You further state that the adhesive electrodes have been cleared under K082065 (Well Life Self Adhesive Electrode), and the conductive gel has been cleared under K983964 (Batch #6060 Conductive Gel). Please address the following:

a. You have not placed any of the above information in the 510(k) summary or labeling. Please provide a revised 510(k) summary and labeling that informs the user of the following third party components.

b. Some of these third party components are indicated for prescription use. However, you have not conducted any performance testing that shows they would be safe and effective for over-the-counter use, which is the case when used as part of your device. Please provide performance testing that shows that these components are suitable for over-the-counter use.

### ii) Response to Deficiency 1 & Reviewer Comments

***In response to Deficiency 1, Part a***, the applicant states that the 510(k) summary has been updated reflecting the third party components.

***REVIEW COMMENT:*** **The applicant has provided the revised 510(k) summary in Attachment 1-a of the submission. This is ADEQUATE.**

Furthermore, the applicant states that the conductive gel has been changed to K022494 (Home Care Jelly) and that this is also reflected in the 510(k) summary.





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***REVIEW COMMENT:*** **Use of the new conductive gel is acceptable for this use. This is ADEQUATE.**

***In response to Deficiency 1, Part b***, the applicant has identified another garment electrode / TENS device combination predicate (K033122, "5000Z System") and provided a comparison of overall impedance between the TheraKnit electrodes and the electrodes of the 5000Z system. Based upon this comparison, reasons the applicant, the TheraKnit garment electrode could be used with the WL-2407 stimulator.

***REVIEW COMMENT:*** **This is NOT ADEQUATE. This comparison does not justify packaging a prescription garment electrode with an OTC device.**

**However, it has still not been clearly established that the TheraKnit electrode will be packaged and sold together with the WL-2407 stimulator; in discussion with the ONDB branch chief, it is clear that an acceptable scenario is where the devices are not packaged together (though the WL-2407 labeling indicates that they should be used together) and the WL-2407 labeling clearly states that the TheraKnit electrode is a prescription device and can only be used with a medical practitioner's consent. An "SE with Limitations" may also be warranted. DEFICIENCY S1 WILL BE CONVEYED TO THE APPLICANT.**

**i) Deficiency 2 (A & B):**

You provide a comparison of output characteristics between your device and your predicate devices. In this comparison, it is clear that the current density for your device is significantly lower than that of your predicate devices. This may affect the device's ability to reduce pain. Please provide the following:

a. Calculations for how you determined current and power density;

b. A revised comparison including a predicate with more similar output characteristics (may be of the product code "NUH" or "GZJ"), or performance data demonstrating that this low current density does not affect the device's ability to reduce pain.

**ii) Response to Deficiency 2 & Reviewer Comments**

***In response to Deficiency 2, Part a and b***, the applicant has provided calculations in Attachment 2. These calculations are based on comparison testing done between the WL-2407 device and the 5000Z device; in both cases, these devices are connected to their respective garment electrodes.

***REVIEW COMMENT:*** **Upon review of this testing, the following is noted:**

- **Calculations were done adequately**
- **Testing shows that due to a lower voltage output for the WL-2407 than**

**the 5000Z, output power and power density for the WL-2407 are about 50% of that for the 5000Z. The applicant claims that this is due to the following: "the 5000Z is a high voltage stimulator, whilst WL-2407 is a typically asymmetrical biphasic TENS device." This rationale is not clear and it is NOT ADEQUATE. The applicant should clarify this and state these parameters and this rationale in the 510(k) summary. DEFICIENCY S2 WILL BE CONVEYED TO THE APPLICANT.**

- **The applicant should conduct dispersion testing to ensure that no "hot spots" are evident in each garment electrode. DEFICIENCY S3 WILL BE CONVEYED TO THE APPLICANT.**

### i) Deficiency 3:

You include a cuff of neoprene and conductive silicone pads, which is new to this device (not cleared under any other 510(k) submissions). However, you have not demonstrated these electrodes' ability to conduct current. Please provide impedance testing that demonstrates the ability to conduct current. This information will ensure that your new electrodes are effective.

### ii) Response to Deficiency 3 & Reviewer Comments

In response to Deficiency 3, the applicant has provided impedance testing that shows that impedance is approximately 18 ohms for the silicon pad electrode.

***REVIEW COMMENT:*** **The information provided is ADEQUATE, however the applicant should additionally provide dispersion testing. DEFICIENCY S3 WILL BE CONVEYED TO THE APPLICANT.**

## III Substantial Equivalence Discussion

Needed only for SE decision

| | YES | NO | |
|---|---|---|---|
| 1. Is the product a device? | ✓ | | If **NO**, See 510(k) staff |
| 2. Is the device subject to 510(k)? | ✓ | | If **NO**, See 510(k) staff |
| 3. Same indications for use? | ✓ | | If **YES**, Go To 5 |
| 4. Do the differences alter the effect or raise new questions of safety and/or effectiveness? | | | If **YES**, Stop **NSE** |
| 5. Same technological characteristics? | | ✓ | If **YES**, Go To 7 |
| 6. Could the new characteristics affect safety and/or effectiveness? | ✓ | | If **YES**, Go To 8 |
| 7. Are the descriptive characteristics precise enough? | | ✓ | If **NO**, Go To 10<br>If **YES**, Stop **SE** |
| 8. Are there **new types** of safety or effectiveness questions? | | | If **YES**, Stop **NSE** |
| 9. Do accepted scientific methods exist for assessing the effects of the new characteristics? | | | If **NO**, Stop **NSE** |
| 10. Are performance data available to allow for assessment of equivalence? | | ✓ | If **NO**, Request Data |
| 11. Do the data demonstrate equivalence? | | | |



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

Final decision:

"Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device: **IT IS A DEVICE**

2. Explain why not subject to 510(k): **IT IS SUBJECT TO A 510(K)**

3. Explain how the new indication differs from the predicate device's indication:

   **THE NEW INDICATION DOES NOT DIFFER FROM THE PREDICATE'S INDICATION.**

4. Explain why there is or is not a new effect or safety or effectiveness issue:

   **NOT APPLICABLE, SINCE THE INDICATIONS FOR USE ARE THE SAME.**

5. Describe the new technological characteristics:

   **NEW ELECTRODES (SOME PREVIOUSLY CLEARED UNDER OTHER 510(K)S)**

6. Explain how new characteristics could or could not affect safety or effectiveness:

   **ELECTRICAL PERFORMANCE OF THE STIMULATOR WITH THESE ELECTRODES MAY BE DIFFERENT (AND THUS RAISE POTENTIAL SAFETY / EFFECTIVENESS CONCERNS)**

7. Explain how descriptive characteristics are not precise enough:

   **ELECTRICAL PERFORMANCE OF THE STIMULATOR / ELECTRODES NEEDS CLARIFICATION**

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

   **THESE CONCERNS ARE TYPICAL OF THIS DEVICE TYPE.**

9. Explain why existing scientific methods can not be used:

   **NOT APPLICABLE**

10. Explain what performance data are needed:

    **IMPEDANCE TESTING AND CLARIFICATION OF PERFORMANCE TESTING IS REQUESTED.**

11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

    **PERFORMANCE DATA PROVIDED IS NOT COMPLETE.**



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## IV Deficiencies

S1. In response to deficiency 1, you identify another garment electrode / TENS device combination predicate (K033122, "5000Z System") and provided a comparison of overall impedance between the TheraKnit electrodes and the electrodes of the 5000Z system. Based upon this comparison, you reason that the TheraKnit garment electrode can be used with the WL-2407 stimulator. Because the TheraKnit device intended is for prescription use only, it is inappropriate for your device to be packaged or sold with the TheraKnit device. Please confirm that your device is not packaged or sold with the TheraKnit device (instead, it is only indicated to be used with the TheraKnit device). Furthermore, please revise your "Operation Manual" to include the following warning:

> "The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."

Alternatively, please remove all references to the TheraKnit Garment Electrodes from your submission and labeling.

S2. In response to deficiency 2, you provide testing and calculations in Attachment 2 of the submission. The testing shows that the output power and power density is roughly half of the corresponding values for your predicate device. You claim that this is due to the fact that "the 5000Z is a high voltage stimulator, whilst WL-2407 is a typically asymmetrical biphasic TENS device." However, you have not stated why this does not significantly diminish the effectiveness of your device. Therefore, please revise your 510(k) summary to include the following:

a. The results of all comparison testing noted in Attachment 2, and;

b. An acknowledgement of the lower output power and power density of your device and a scientific rationale for how effectiveness is equivalent.

This information is important to ensure that your device is equivalent to your predicate devices.

S3. In response to deficiencies 2 and 3, you have provided electrical performance testing. However, you have not provided dispersion testing for any of the electrodes. Please provide dispersion testing to ensure that current traveling through the electrodes does not congregate in "hot spots." This is important to ensure that your device is reasonably safe for its indicated use.

## V Recommendation

The OTC TENS for Arm and Leg Pain Relief, Model WL-2407 requires additional information in order to proceed with the review.

Therefore, I recommend that the file be put on **telephone hold (TH).**



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

**Lead Reviewer Signoff:**

11/14/09

Rahul Ram (ODE/DONED/ONDB)

**Branch Signoff:**

Brad Cunningham (ODE/DONED/ONDB)

Date 11/18/09. Concur: Yes ☑ No ☐

**Division Signoff:**

Kesia Alexander, Ph.D. (ODE/DONED)

Date_____. Concur: Yes ☐ No ☐



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

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## Ram, Rahul

**From:** Ram, Rahul
**ent:** Wednesday, November 18, 2009 5:14 PM
**.o:** 'jenny@welllifehealthcare.com.tw'
**Cc:** Cunningham, Bradley
**Subject:** K091757/S2

**Attachments:** Telephone Hold Memorandum.pdf

Jenny:

Thank you for your latest supplement regarding WL-2407. The submission is being placed on **hold** pending receipt of responses to deficiencies in the attached file.

Telephone Hold Memorandum.pdf ...

Thanks,

Rahul

**Rahul K. Ram**
LTJG, USPHS
*FDA \ CDRH \ ODE*
*(NEW) Division of Ophthalmic, Neurologic & ENT Devices (DONED),*
*(NEW) Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch (ONDB)*
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**Public Health Service**
**DEPARTMENT OF HEALTH & HUMAN SERVICES**
**Food and Drug Administration**

**Memorandum**

**Date:** November 17, 2009

**From:** Rahul K. Ram.
Lead Reviewer, K091757 / S2
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch
Division of Ophthalmic, Neurologic and ENT Devices
Center for Devices and Radiological Health

**To:** Jenny Hsieh
Official Correspondent, Well Life Healthcare, Ltd.
1 Fl., No. 16, Lane 454, Jungjeng Rd.
Yunghe City, Taipei County, Taiwan, R.O.C.
jenny@welllifehealthcare.com.wtw

**Subject:** 510(k): K091757 / S2
Trade Name: OTC TENS for Arm and Leg Pain Relief, Model WL-2407
Dated: November 13, 2009
Received: November 16, 2009

We have reviewed the supplement to your Section 510(k) premarket notification responding to our October 13, 2009 letter. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This 510(k) submission is being placed on HOLD pending the submission of responses to the following deficiencies:

1. In response to deficiency 1, you identify another garment electrode / TENS device combination predicate (K033122, "5000Z System") and provide a comparison of overall impedance between the TheraKnit electrodes and the electrodes of the 5000Z system. Based upon this comparison, you reason that the TheraKnit garment electrode can be used with the WL-2407 stimulator. Because the TheraKnit device intended is for prescription use only, it is inappropriate to package or sell the TheraKnit with your device, as your device is for over-the-counter use. Therefore, please confirm that your device is not packaged or sold with the TheraKnit device (instead, it is only indicated to be used with the TheraKnit device). Furthermore, please revise your "Operation Manual" to include the following warning:

   "The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."



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

Alternatively, please remove all references to the TheraKnit Garment Electrodes from your submission and labeling.

2. In response to deficiency 2, you provide testing and calculations in Attachment 2 of the submission. The testing shows that the output power and power density is roughly half of the corresponding values for your predicate device. You claim that this is due to the fact that "the 5000Z is a high voltage stimulator, whilst WL-2407 is a typically asymmetrical biphasic TENS device." However, you have not stated why this does not significantly diminish the effectiveness of your device. Therefore, please revise your 510(k) summary to include the following:

    a. The results of all comparison testing noted in Attachment 2, and;

    b. An acknowledgement of the lower output power and power density of your device and a scientific rationale for how effectiveness is equivalent.

    This information is important to ensure that your device is equivalent to your predicate devices.

3. In response to deficiencies 2 and 3, you have provided electrical performance testing. However, you have not provided dispersion testing for any of the electrodes. Please provide dispersion testing to ensure that current traveling through the electrodes does not congregate in "hot spots." This is important to ensure that your device is reasonably safe for its indicated use.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm

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

equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm

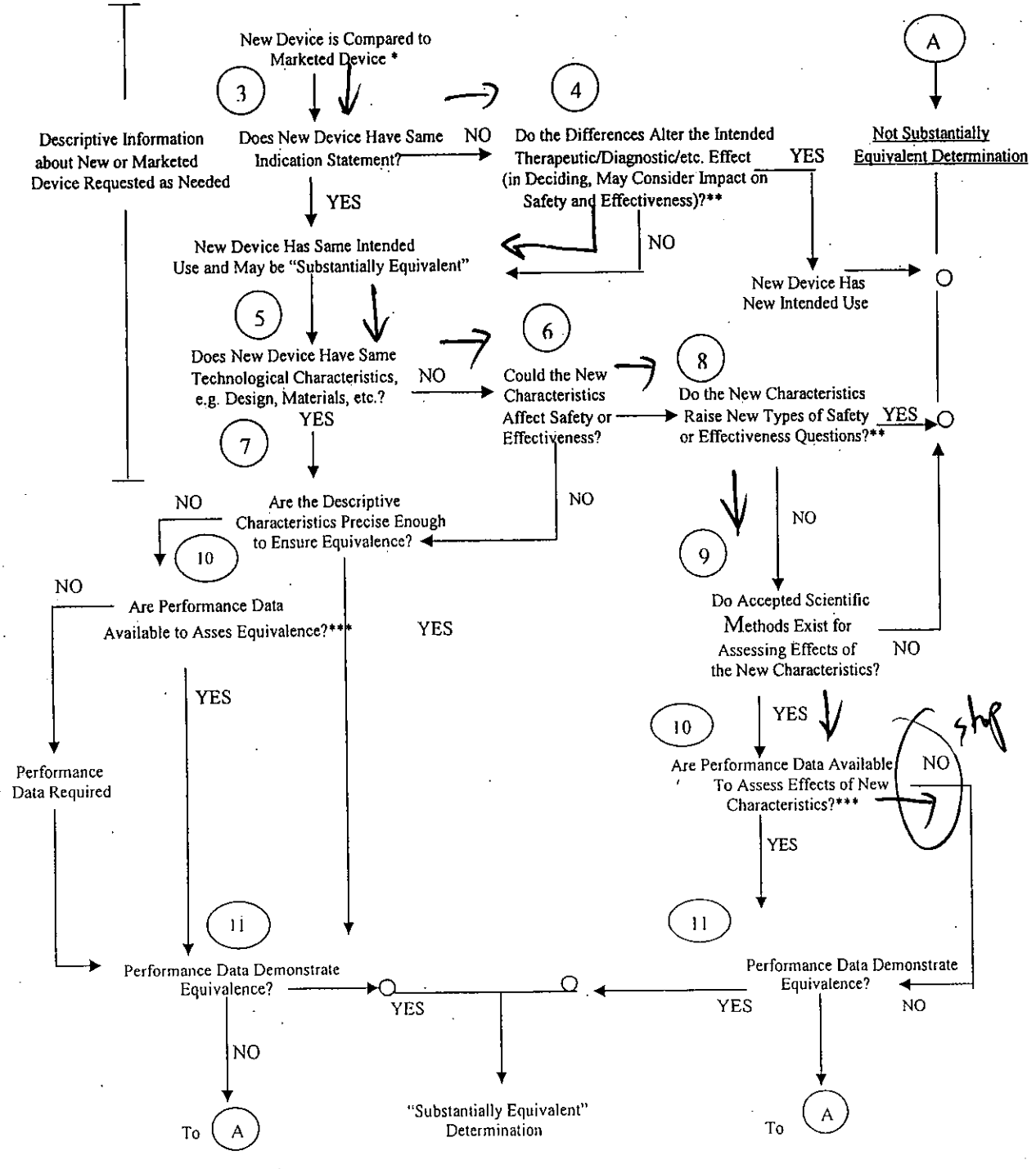
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center at the Center for Devices and Radiological Health (CDRH):

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

If you have any questions concerning the contents of this memorandum, please contact Rahul Ram at (301) 796-6620.

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS




- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**Public Health Service**
**DEPARTMENT OF HEALTH & HUMAN SERVICES**
**Food and Drug Administration**

**Memorandum**

**Date:** November 17, 2009

**From:** Rahul K. Ram
Lead Reviewer, K091757 / S2
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch
Division of Ophthalmic, Neurologic and ENT Devices
Center for Devices and Radiological Health

**To:** Jenny Hsieh
Official Correspondent, Well Life Healthcare, Ltd.
1 Fl., No. 16, Lane 454, Jungjeng Rd.
Yunghe City, Taipei County, Taiwan, R.O.C.
jenny@welllifehealthcare.com.wtw

**Subject:** 510(k): K091757 / S2
Trade Name: OTC TENS for Arm and Leg Pain Relief, Model WL-2407
Dated: November 13, 2009
Received: November 16, 2009

We have reviewed the supplement to your Section 510(k) premarket notification responding to our October 13, 2009 letter. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This 510(k) submission is being placed on HOLD pending the submission of responses to the following deficiencies:

1. In response to deficiency 1, you identify another garment electrode / TENS device combination predicate (K033122, "5000Z System") and provide a comparison of overall impedance between the TheraKnit electrodes and the electrodes of the 5000Z system. Based upon this comparison, you reason that the TheraKnit garment electrode can be used with the WL-2407 stimulator. Because the TheraKnit device intended is for prescription use only, it is inappropriate ~~for your device to be packaged or sold with the TheraKnit device.~~ to package the TheraKnit with your device as your device is intended for OTC use. Please confirm that your device is not packaged or sold with the TheraKnit device (instead, it is only indicated to be used with the TheraKnit device). Furthermore, please revise your "Operation Manual" to include the following warning:

   Therefore "The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."

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

Alternatively, please remove all references to the TheraKnit Garment Electrodes from your submission and labeling.

2. In response to deficiency 2, you provide testing and calculations in Attachment 2 of the submission. The testing shows that the output power and power density is roughly half of the corresponding values for your predicate device. You claim that this is due to the fact that "the 5000Z is a high voltage stimulator, whilst WL-2407 is a typically asymmetrical biphasic TENS device." However, you have not stated why this does not significantly diminish the effectiveness of your device. Therefore, please revise your 510(k) summary to include the following:

    a. The results of all comparison testing noted in Attachment 2, and;

    b. An acknowledgement of the lower output power and power density of your device and a scientific rationale for how effectiveness is equivalent.

    This information is important to ensure that your device is equivalent to your predicate devices.

3. In response to deficiencies 2 and 3, you have provided electrical performance testing. However, you have not provided dispersion testing for any of the electrodes. Please provide dispersion testing to ensure that current traveling through the electrodes does not congregate in "hot spots." This is important to ensure that your device is reasonably safe for its indicated use.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm

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

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investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center at the Center for Devices and Radiological Health (CDRH):

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

If you have any questions concerning the contents of this memorandum, please contact Rahul Ram at (301) 796-6620.



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

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

# COVER SHEET MEMORANDUM

**From:** Rahul Ram, B.S.

**Subject:** 510(k) (Special-to-Traditional) K091757/S1

**To:** The Record

Please list CTS decision code: **TH**.

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc )

✓ **Hold** (Additional Information or **Telephone Hold**).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

| Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.): | | YES | NO |
|---|---|---|---|
| Indications for Use Pages | *Attach IFU* | | No |
| **510(k) Summary** /510(k) Statement | *Attach Summary* | Yes | |
| Truthful and Accurate Statement. | *Must be present for a Final Decision* | Yes | |
| Is the device Class III?<br>If yes, does firm include Class III Summary? | *Must be present for a Final Decision* | | No |
| Does firm reference standards? **FDA Forms 3654 Provided**<br>(If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) | | Yes | |
| Is this a combination product?<br>(Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC | | | No |
| Is this a reprocessed single use device?<br>(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) | | | No |
| Is this device intended for pediatric use only? | | | No |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) **OTC** | | | No |
| Is clinical data necessary to support the review of this 510(k)?<br>Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*?<br>(If not, then applicant must be contacted to obtain completed form.) | | | No |

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

| | | |
|---|---|---|
| Does this device include an Animal Tissue Source? | | No |
| All Pediatric Patients age<=21 | | n/a |
| Neonate/Newborn (Birth to 28 days) | | n/a |
| Infant (29 days -< 2 years old) | | n/a |
| Child (2 years -< 12 years old) | | n/a |
| Adolescent (12 years -< 18 years old) | | n/a |
| 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.) | | n/a |
| Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) | | n/a |
| Nanotechnology | | No |

| | | | |
|---|---|---|---|
| Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html) | *Contact OSB.* | | No |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) | *Contact OC.* | | No |

| Regulation Number | Class* | Product Code |
|---|---|---|
| 21 CFR 882.5890 | II | NUH |

(*If unclassified, see 510(k) Staff)

**Additional Product Codes:** GXY

**Review:** _____ OWDB
(Branch Chief) (Branch Code)

(Date) 10/13/09

**Final Review:** _____
(Division Director)

(Date)

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Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

| **If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):** | | **YES** | **NO** |
|---|---|---|---|
| 1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC) | | Not Aware | |
| 2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)? | | | No |
| 3. Does this device type require a PMA by regulation? (Please see management.) | | | No |
| **Questions 4-8 are intended to help you start your review:** | | **YES** | **NO** |
| 1. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRH PremarketNotification 510kProgram/ Screening Checklist) | | | No |
| 2. a. Did the firm request expedited review? (See management.) | | | No |
| b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html) | | N/A | |
| 3. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device? | Please list document number and/or date, here: | | No |
| 4. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)? | Please list document number, here: | | No |
| 5. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html) | | | No |

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# Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

***Guidance for Industry and FDA Staff***
***Format for Traditional and Abbreviated 510(k)s***
http://www.fda.gov/cdrh/ode/guidance/1567.html

| Title | Related Information | Present | Inadequate | n/a |
|---|---|---|---|---|
| MDUFMA Cover Sheet | Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html | Yes | | |
| CDRH Premarket Review Submission Cover Sheet | CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf | Yes | | |
| 510(k) Cover Letter | Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | Yes | | |
| Indications for Use Statement | Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6 | Yes | | |
| 510(k) Summary or 510(k) Statement | Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7 | Yes (510(k) Summary) | Inadequate | |
| Truthful and Accuracy Statement | Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9 | Yes | | |
| Class III Summary and Certification | Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html | n/a | n/a | n/a |

Rev. 5/30/07



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

| Title | Related Information | Present | Inadequate | n/a |
|---|---|---|---|---|
| Financial Certification or Disclosure Statement | FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf<br>Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html. | n/a | n/a | n/a |
| Declarations of Conformity and Summary Reports (Abbreviated 510(k)s) | Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html.<br>FDA Standards program www.fda.gov/cdrh/stdsprog.html.<br>Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9<br>Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html | n/a | n/a | n/a |
| Executive Summary | See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | Yes | | |
| Device Description | See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | Yes | | |
| Substantial Equivalence Discussion | Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html | Yes | Inadequate | |
| Proposed Labeling | Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10 | Yes | Inadequate | |

| Title | Related Information | Present | Inadequate | n/a |
|---|---|---|---|---|
| Sterilization/Shelf Life | Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html<br>For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html | | | n/a |
| Biocompatibility | FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html | Yes | | |
| Software | Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html | | | n/a |
| Electromagnetic Compatibility/Electrical Safety | CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc<br>See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) | Yes | Inadequate | |
| Performance Testing – Bench | See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | n/a | | |
| Performance Testing – Animal | See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | n/a | n/a | n/a |

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| Title | Related Information | Present | Inadequate | n/a |
|---|---|---|---|---|
| Performance Testing – Clinical | See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005<br>Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf | n/a | n/a | n/a |
| Kit Certification | See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance | n/a | n/a | n/a |



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

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Food and Drug Administration**
**Center for Devices & Radiological Health**

**Division of Ophthalmic, Ear, Nose, and Throat Devices**
**Diagnostic and Surgical Devices Branch**
**9200 Corporate Boulevard HFZ-460**
**Rockville, MD 20850**
**(240) 276-1498**

## Premarket Notification [510(k)] Review

**Date:** 10/13/09
**To:** RECORD
**From:** Rahul Ram
**Subject:** Special-to-Traditional, K091757/S1

| | |
|---|---|
| **Company:** Well Life Healthcare, Ltd.<br>1 Fl., No. 16, Lane 454, Jungjeng Rd<br>Yunghe City, Taipei County, Taiwan, R.O.C | **Contact:** Jenny Hsieh<br>Official Correspondent, Well Life Healthcare, Ltd. |
| **Device Trade Name:** OTC TENS for Arm and Leg Pain Relief, Model WL-2407 | **Email:** jenny@welllifehealthcare.com.tw |
| **Description:** OTC TENS Device / Garment Electrodes | **Phone:** 886-2-29282112 |
| **510(k) Received Date:** September 1, 2009 | **Fax:** 886-2-29281880 |

**Sponsor-Identified Predicate Devices:**

| 510K # | Pro Code | Device Name | Company |
|---|---|---|---|
| K063660 | NUH | OTC TENS FOR LOW BACK PAIN RELIEF, MODEL WL-2407 | Well-Life Healthcare |
| K060846 | NUH, GZX | Therapeutic Massage Companion | Endurance Therapeutics |
| K033122 | NUH | 5000Z System | Prism Medical |

**Recommendation**
The EMSI Garment Electrode requires additional information in order to proceed with the review.

Therefore, I recommend that the file be put on **telephone hold (TH).**

Regulation Number: **21 CFR 882.5890**
Regulation Name: **Transcutaneous electrical nerve stimulator for pain relief.**
Regulatory Class: **Class II**
Product Code: **NUH**



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Additional Product Codes: **GXY**

**IFU as specified in the submission:** ☐ **Pediatric** ☐ **Rx** ☒ **OTC**

"The OTC TENS for Arm and Leg Pain Relief /Model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities."



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

## I Purpose and Background

The applicant would like to introduce **OTC TENS for Arm and Leg Pain Relief (Model WL-2407)** into interstate commerce. The original submission (K091757) was submitted as a Special 510(k), however due to the change in the Indications for Use it was determined (by the lead reviewer at the time, Dexiu Shi) not to qualify for this type of submission. Dexiu requested additional information to meet the requirements of a Traditional 510(k), which the applicant has provided in the current submission (K091757 / S001).

## II Administrative Requirements

| | Yes | No | N/A |
|---|---|---|---|
| Sponsor is on Integrity List | | | |
| MDUFMA Cover Sheet | **Yes** | | |
| CDRH Premarket Review Submission Cover Sheet | **Yes** | | |
| 510(k) Cover Letter | **Yes** | | |
| Indications for Use page must not be confidential | **Yes** | | |
| Truthful and Accuracy Statement | **Yes** | | |
| 510(k) Summary or 510(k) Statement must not be confidential | **Yes** | | |
| Class III Summary and Certification[A] | | | **n/a** |
| Financial Certification or Disclosure Statement (Clinical) | | | **n/a** |
| Certification Statement/Information Form 3674 (Clinical)[B] | | | **n/a** |
| Standards Data Report for 510(k)s | **Yes** | | |
| Executive Summary | **Yes** | | |

Table 1: Summary of administrative documents provided in the submission.

[A] CFR 807.87(j) and 807.94

[B] If box 9C is checked, record the National Clinical Trial (NCT) number(s) and make a copy of the Certification Form and forward to the IDE Staff (HFZ-402).
http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf

**Review Team**
Lead Reviewer Dexiu Shi, Rahul Ram (ONDB)

***REVIEW COMMENT:*** **Administrative requirements for the device submission have been ADEQUATELY met.**

## III Comparison of Indications for Use to Predicate Devices

Current Submission, K090416 (OTC TENS for Arm and Leg Pain Relief (Model WL-2407):

*"The OTC TENS for Arm and Leg Pain Relief / Model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/ or leg) due to strain from exercise or normal household and work activities."* (OTC)



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

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Predicate Submission, K060846 (Therapeutic Massage Companion):

*"To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4*

*To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3*
*To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto l or Auto 4*

*Used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2"*

Predicate Submission, K033122 (5000Z System):

*"The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs)"*

***REVIEW COMMENT:*** **The applicant's own predicate device (whose IFU is not listed above) does not have a similar IFU to the current device. However, the IFU of the current device is equivalent to the above IFU statements. Furthermore, the IFU statement for the current device, as listed above, has been reproduced identically in the labeling. THE INDICATIONS FOR USE ARE ADEQUATE.**

## IV Device Description - Overall

OTC TENS for Arm and Leg Pain Relief, Model WL-2407 (hereinafter "the current device") is a TENS device intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities. The applicant states that the "hardware and software design of the device is completely identical to that of K063660 (the applicant's own device), "except for… …the electrode."

***REVIEW COMMENT:*** **The applicant provides no conflicting information that disputes the claim that the current device is identical to the predicate K063360 (WL-2407 for lower back), except for the new electrodes. Therefore, this review will focus on device performance for the new IFU and safety and effectiveness of the new electrodes.**

## V Device Description - Electrodes

The applicant has included six types of electrodes as part of this device:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 136

- 1) Glove garment electrode
- 2) Elbow Sleeve garment electrode
- 3) Knee Sleeve garment electrode
- 4) Sock garment electrode

The applicant stated in the original submission that the above garment electrodes have been cleared under K053214 (TheraKnit Garment Electrodes).

***REVIEW COMMENT:*** **The above information is acceptable for this use. However, the applicant has not placed this information in the labeling or 510(k) summary. DEFICIENCY 1 SHOULD BE CONVEYED TO THE APPLICANT.**

- 5) Snap-type adhesive electrodes

The applicant stated in the original submission that the adhesive electrodes have been cleared under K082065 (Well Life Self Adhesive Electrode).

***REVIEW COMMENT:*** **As noted above with the garment electrodes, the above information is acceptable for this use. However, the applicant has not placed this information in the labeling or 510(k) summary. DEFICIENCY 1 SHOULD BE CONVEYED TO THE APPLICANT.**

- 6) Neoprene + conductive silicone pad

In the original submission, the applicant stated that the conductive gel was cleared under K983964 (Batch #6060 Conductive Gel).

***REVIEW COMMENT:*** **The applicant has not placed information regarding the conductive gel in the 510(k) summary or labeling. DEFICIENCY 1 SHOULD BE CONVEYED TO THE APPLICANT. Furthermore, the applicant has provided biocompatibility testing for the neoprene + silicone pad. See the "biocompatibility" section for more information.**

| | Yes | No | N/A |
|---|---|---|---|
| Is the device life-supporting or life sustaining? | | **No** | |
| Is the device an implant (implanted longer than 30 days)? | | **No** | |
| Does the device design use software? | | **No** | |
| Is the device sterile? | | **No** | |
| Is the device for single person use? | | **No** | |
| Is the device reusable (not reprocessed single use)? | **Yes** | | |



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

| | Yes | No | N/A |
|---|---|---|---|
| Are "cleaning" instructions included for the end user? | **Yes** | | |
| Table 2: Summary of important device characteristics<br>1. If implanted, see ISO 10933-3, 6, 11, as well as the usual electrode tests. | | | |

*Third Party Components / Accessories*

The device contains 3 third party components (mentioned in detail above):

- K082065 (Well Life Self Adhesive Electrode).
- K983964 (Batch #6060 Conductive Gel).
- K053214 (TheraKnit Garment Electrodes)

*Cleaning Instructions*

The applicant provides cleaning instructions for each component of the device in the labeling.

***REVIEW COMMENT*: Upon review of the labeling, it is noted that the cleaning instructions are ADEQUATE.**

## VI Comparison of Performance to Predicate Devices

The applicant, in the current submission, has provided output characteristics for the current device and two devices which have the same indications for use, with corresponding waveforms. Information for the output characteristics of the predicate devices have been taken from those respective 510(k) summaries.

***REVIEW COMMENT*: The output characteristics are reasonably similar to the T1040 (Therapeutic Massage Companion), however current density is an order of magnitude lower than the T1040. The following is not clear: a) how this current density was calculated, and b) whether this low current density affects the device's ability to treat pain. DEFICIENCY 2 SHOULD BE CONVEYED TO THE APPLICANT.**

## VII Labeling

For all "No" answers see explanation in Reviewer Comments below table.

| | Yes | No | N/A |
|---|---|---|---|
| Has the prescription statement been provided in | | | n/a |



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

| | Yes | No | N/A |
|---|---|---|---|
| accordance with 21 CFR 801.109(b)(1)) or "Rx only". | | | |
| Adequate instructions for OTC use? | Yes | | |
| Appropriate indications for use provided? | Yes | | |
| Appropriate contraindications provided? | Yes | | |
| Appropriate warnings provided? | Yes | | |
| Appropriate cautions provided? | Yes | | |
| Appropriate precautions provided? | Yes | | |
| Appropriate labeling inside device? (e.g. color codes, PS label) | Yes | | |
| Appropriate labeling/alarm outside device? (e.g. name, BF, class) | | | n/a |
| Appropriate labeling in Manual? (e.g. font, contact #, print date) | Yes | | |

Table 4: Summary of the appropriateness of several aspects of the labeling. These were checked in accordance with appropriate guidance documents and/or standards.

***REVIEW COMMENT:*** **The labeling is equivalent – in some cases verbatim – to that provided in the two predicate devices. However, some necessary information is missing from the labeling, related to the electrodes change. SEE DEFICIENCY 1.**

## VIII Sterilization, Shelf Life and/or Reuse

The device is not labeled as a sterile or single use device.

| **1. Sterilant:** | **n/a** |
|---|---|
| a. **Sterilization method** description (e.g., Steam, EtO, Radiation): | **n/a** |
| b. **Dose**, for radiation (e.g., 25 – 50 kGy): | **n/a** |
| c. **Sterilant residuals** remaining on the device: | **n/a** |
| **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)) | **n/a** |
| **3. Sterility assurance level (SAL):** (e.g., $10^{-6}$ for all devices (except $10^{-3}$ for devices that contact intact skin)) | **n/a** |



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| | |
|---|---|
| **4. Is it labeled "Pyrogen Free" (≤0.06 EU/mL neural; 0.5 everywhere else)?** | n/a |
| **5. A description of the packaging** (not including package integrity test data): | n/a |

***REVIEW COMMENT*: The device is not-sterile, not implanted, and only makes contact with the skin for a limited amount of time; therefore this section is NOT APPLICABLE.**

## IX Biocompatibility

The applicant has provided an "intracutaneous reactivity test" and "maximization test for delayed hypersensitivity" for the neoprene belt with silicone pad.

***REVIEW COMMENT*: The information provided demonstrates that the new electrode and belt are BIOCOMPATIBLE.**

## X Software

***REVIEW COMMENT*: The device does not include software; therefore this section is NOT APPLICABLE.**

## XI Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

*Impedance Testing*

The applicant has not provided impedance testing for the new silicone pad.

***REVIEW COMMENT*: This is NOT ADEQUATE. The applicant should provide impedance testing to demonstrate effectiveness of the new electrode. DEFICIENCY X SHALL BE CONVEYED TO THE APPLICANT.**

## XII Performance Testing

***REVIEW COMMENT*: No testing was conducted aside from the biocompatibility and electrical performance testing; no more testing is necessary. Performance testing is NOT ADEQUATE. See deficiencies related to electrical performance testing above.**

## XIII Kit Certification

***REVIEW COMMENT*: The device is not a kit; therefore this section is NOT APPLICABLE.**



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## XIV Substantial Equivalence Discussion

Needed only for SE decision

| | YES | NO | |
|---|---|---|---|
| 1. Is the product a device? | ✓ | | If **NO,** See 510(k) staff |
| 2. Is the device subject to 510(k)? | ✓ | | If **NO,** See 510(k) staff |
| 3. Same indications for use? | ✓ | | If **YES**, Go To 5 |
| 4. Do the differences alter the effect or raise new questions of safety and/or effectiveness? | | | If **YES,** Stop **NSE** |
| 5. Same technological characteristics? | | ✓ | If **YES,** Go To 7 |
| 6. Could the new characteristics affect safety and/or effectiveness? | ✓ | | If **YES,** Go To 8 |
| 7. Are the descriptive characteristics precise enough? | | ✓ | If **NO,** Go To 10<br>If **YES,** Stop **SE** |
| 8. Are there **new types** of safety or effectiveness questions? | | | If **YES,** Stop **NSE** |
| 9. Do accepted scientific methods exist for assessing the effects of the new characteristics? | | | If **NO,** Stop **NSE** |
| 10. Are performance data available to allow for assessment of equivalence? | | ✓ | If **NO,** Request Data |
| 11. Do the data demonstrate equivalence? | | | |

Final decision:

"Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device: **IT IS A DEVICE**

2. Explain why not subject to 510(k): **IT IS SUBJECT TO A 510(K)**

3. Explain how the new indication differs from the predicate device's indication:

   **THE NEW INDICATION DOES NOT DIFFER FROM THE PREDICATE'S INDICATION.**

4. Explain why there is or is not a new effect or safety or effectiveness issue:

   **NOT APPLICABLE, SINCE THE INDICATIONS FOR USE ARE THE SAME.**

5. Describe the new technological characteristics:

   **NEW ELECTRODES (SOME PREVIOUSLY CLEARED UNDER OTHER 510(K)S)**

6. Explain how new characteristics could or could not affect safety or effectiveness:

   **ELECTRICAL PERFORMANCE OF THE STIMULATOR WITH THESE ELECTRODES MAY BE DIFFERENT (AND THUS RAISE POTENTIAL SAFETY / EFFECTIVENESS CONCERNS)**

7. Explain how descriptive characteristics are not precise enough:

   **ELECTRICAL PERFORMANCE OF THE STIMULATOR / ELECTRODES NEEDS CLARIFICATION**



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

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

   **THESE CONCERNS ARE TYPICAL OF THIS DEVICE TYPE.**

9. Explain why existing scientific methods can not be used:

   **NOT APPLICABLE**

10. Explain what performance data are needed:

    **IMPEDANCE TESTING AND CLARIFICATION OF PERFORMANCE TESTING IS REQUESTED.**

11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

    **NOT APPLICABLE AT THIS TIME**

## XV Deficiencies (slightly modified in letter; see attached)

1. You state that garment electrodes have been cleared under K053214 (TheraKnit Garment Electrodes). You further state that the adhesive electrodes have been cleared under K082065 (Well Life Self Adhesive Electrode), and the conductive gel has been cleared under K983964 (Batch #6060 Conductive Gel). Please address the following:

   a. You have not placed any of the above information in the 510(k) summary or labeling. Please provide a revised 510(k) summary and labeling that informs the user of the following third party components.

   b. You have not indicated whether these third party components are packaged with the device. Please be aware that some of these components are for prescription use only, and it is inappropriate to package a prescription use device with an over-the-counter device. Please clarify which components are packaged with your device, if any. A

2. You have provided a comparison of output characteristics between your device and your predicate devices. In this comparison, it is clear that the current density for your device is significantly lower than that of your predicate devices. This may affect the device's ability to reduce pain. Please provide the following:

   a. Calculations for how you determined current and power density;

   b. A revised comparison including a predicate with more similar output or clinical performance data characteristics (may be of the product code "NUH" or "GZJ"), or a narrative justification of why this low current density does not affect the device's ability to reduce pain.

This information will aid in demonstrating the effectiveness of your device



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3. You have included a cuff of neoprene and conductive silicone pads, which is new to this device (not cleared under any other 510(k) submissions). However, you have not demonstrated these electrodes' ability to conduct current. Please provide impedance testing that demonstrates the ability to conduct current.

## XVI Recommendation

The OTC TENS for Arm and Leg Pain Relief, Model WL-2407 requires additional information in order to proceed with the review.

Therefore, I recommend that the file be put on **telephone hold (TH).**

**Lead Reviewer Signoff:**

Rahul Ram, B.S. (ODE/DONED/ONDB)

**Branch Signoff:**

Dexiu Shi, Ph.D. (ODE/DONED/ONDB)

Date 10/13/09. Concur: Yes ☑ No ☐

**Division Signoff:**

Kesia Alexander, Ph.D. (ODE/DONED)

Date_____. Concur: Yes ☐ No ☐



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

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**Public Health Service**
**DEPARTMENT OF HEALTH & HUMAN SERVICES**
**Food and Drug Administration**

**Memorandum**

**Date:** October 13, 2009

**From:** Rahul K. Ram.
Lead Reviewer, K091757 / S1
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch
Division of Ophthalmic, Neurologic and ENT Devices
Center for Devices and Radiological Health

**To:** Jenny Hsieh
Official Correspondent, Well Life Healthcare, Ltd.
1 Fl., No. 16, Lane 454, Jungjeng Rd.
Yunghe City, Taipei County, Taiwan, R.O.C.
jenny@welllifehealthcare.com.wtw

**Subject:** 510(k): K091757 / S1
Trade Name: OTC TENS for Arm and Leg Pain Relief, Model WL-2407
Dated: August 20, 2009
Received: August 28, 2009

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This 510(k) submission is being placed on HOLD pending the submission of responses to the following deficiencies:

1. You state that garment electrodes have been cleared under K053214 (TheraKnit Garment Electrodes). You further state that the adhesive electrodes have been cleared under K082065 (Well Life Self Adhesive Electrode), and the conductive gel has been cleared under K983964 (Batch #6060 Conductive Gel). Please address the following:

    a. You have not placed any of the above information in the 510(k) summary or labeling. Please provide a revised 510(k) summary and labeling that informs the user of the following third party components.

    b. Some of these third party components are indicated for prescription use. However, you have not conducted any performance testing that shows they would be safe and effective for over-the-counter use, which is the case when

used as part of your device. Please provide performance testing that shows that these components are suitable for over-the-counter use.

2. You provide a comparison of output characteristics between your device and your predicate devices. In this comparison, it is clear that the current density for your device is significantly lower than that of your predicate devices. This may affect the device's ability to reduce pain. Please provide the following:

    a. Calculations for how you determined current and power density;

    b. A revised comparison including a predicate with more similar output characteristics (may be of the product code "NUH" or "GZJ"), or performance data demonstrating that this low current density does not affect the device's ability to reduce pain.

    This information will aid in demonstrating the effectiveness of your device.

3. You include a cuff of neoprene and conductive silicone pads, which is new to this device (not cleared under any other 510(k) submissions). However, you have not demonstrated these electrodes' ability to conduct current. Please provide impedance testing that demonstrates the ability to conduct current. This information will ensure that your new electrodes are effective.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center at the Center for Devices and Radiological Health (CDRH):

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

If you have any questions concerning the contents of this memorandum, please contact Rahul Ram at (301) 796-6620.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

# COVER SHEET MEMORANDUM

**From:** Reviewer Name Dexiu Shi

**Subject:** 510(k) Number K091757

**To:** The Record

Please list CTS decision code : **TH**

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc )

■ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, 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* | ✓ | |
| 510(k) Summary /510(k) Statement | *Attach Summary* (Appendix G) | ✓ | |
| Truthful and Accurate Statement. | *Must be present for a Final Decision* | ✓ | |
| Is the device Class III?<br>If yes, does firm include Class III Summary? | *Must be present for a Final Decision* | | ✓ |
| Does firm reference standards?<br>(If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) | | | ✓ |
| Is this a combination product?<br>(Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC | | | ✓ |
| Is this a reprocessed single use device?<br>(Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html) | | | ✓ |
| Is this device intended for pediatric use only? | | | ✓ |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | | ✓ | |
| Is clinical data necessary to support the review of this 510(k)?<br>Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*?<br>(If not, then applicant must be contacted to obtain completed form.) | | | ✓ |
| Does this device include an Animal Tissue Source? | | | ✓ |
| Is this device subject to Section 522 Postmarket Surveillance?<br>(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: 882.5890** **Class*: II** **Product Code: NUH**

**Review:** _____ (Branch Chief) ONDB (Branch Code) 7/28/2009 (Date)

**Final Review:** _____ (Division Director) DONED (Branch Code) 7/28/2009 (Date)

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# PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

| **If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):** | | **YES** | **NO** |
|---|---|---|---|
| 1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC) | | | ✓ |
| 2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)? | | | ✓ |
| 3. Does this device type require a PMA by regulation? (Please see management.) | | | ✓ |
| **Questions 4-8 are intended to help you start your review:** | | **YES** | **NO** |
| 4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc) | | | ✓ |
| 5. a. Did the firm request expedited review? (See management.) | | | ✓ |
| b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html) | | | |
| 6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device? | Please list document number and/or date, here: | | ✓ |
| 7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)? | Please list document number, here: | | ✓ |
| 8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html) | | | ✓ |

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# Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

***Guidance for Industry and FDA Staff***
***Format for Traditional and Abbreviated 510(k)s***
http://www.fda.gov/cdrh/ode/guidance/1567.html

| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| MDUFMA Cover Sheet | Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html | ✓ | | |
| CDRH Premarket Review Submission Cover Sheet | CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf | ✓ | | |
| 510(k) Cover Letter | Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html | ✓ | | |
| Indications for Use Statement | Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6 | ✓ | | |
| 510(k) Summary or 510(k) Statement | Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7 | | X Inadequate | |
| Truthful and Accuracy Statement | Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9 | ✓ | | |
| Class III Summary and Certification | Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html | | | ✓ |
| Financial Certification or Disclosure Statement | FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf<br>Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html. | | | ✓ |
| Declarations of Conformity and Summary Reports (Abbreviated 510(k)s) | Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html.<br>FDA Standards program www.fda.gov/cdrh/stdsprog.html.<br>Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9<br>Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html | | | ✓ |



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

| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| Executive Summary | See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Not provide | |
| Device Description | See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Inadequate | |
| Substantial Equivalence Discussion | Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm | | X<br>Inadequate | |
| Proposed Labeling | Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10 | | X<br>Inadequate | |
| Sterilization/Shelf Life | Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm<br>For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071441.pdf | | X<br>Not provide | |
| Biocompatibility | FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm | | X<br>Not provide | |
| Software | Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm | | X | |
| Electromagnetic Compatibility/Electrical Safety | CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm116566.htm<br>See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) | | X<br>Not provide | |
| Performance Testing – Bench | See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Not provide | |
| Performance Testing – Animal | See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | | ✓ |

| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| Performance Testing – Clinical | See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005<br>Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf | | X<br>Not provide | |
| FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf* | **Standards Data Report Form – Form 3654**<br><br>1: No standard used - **No Standards Form Required**<br><br>2: Declaration of Conformity – **Yes Standards Form Required**<br><br>3: Standard but no declaration – **Yes Standards Form Required** | | X<br>Not provide | |
| Kit Certification | Device Advice<br>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm | | | ✓ |

# Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

***Guidance for Industry and FDA Staff***
***Format for Traditional and Abbreviated 510(k)s***
http://www.fda.gov/cdrh/ode/guidance/1567.html

| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| MDUFMA Cover Sheet | Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html | ✓ | | |
| CDRH Premarket Review Submission Cover Sheet | CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf | ✓ | | |
| 510(k) Cover Letter | Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html | ✓ | | |
| Indications for Use Statement | Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6 | ✓ | | |
| 510(k) Summary or 510(k) Statement | Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7 | | X Inadequate | |
| Truthful and Accuracy Statement | Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9 | ✓ | | |
| Class III Summary and Certification | Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html | | | ✓ |
| Financial Certification or Disclosure Statement | FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf<br>Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html. | | | ✓ |
| Declarations of Conformity and Summary Reports (Abbreviated 510(k)s) | Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html.<br>FDA Standards program www.fda.gov/cdrh/stdsprog.html.<br>Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9<br>Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/regrecstand.html | | | ✓ |



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| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| Executive Summary | See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Not provided | |
| Device Description | See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Inadequate | |
| Substantial Equivalence Discussion | Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm | | X<br>Inadequate | |
| Proposed Labeling | Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10 | | X<br>Inadequate | |
| Sterilization/Shelf Life | Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm<br>For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071441.pdf | | X<br>Not provided | |
| Biocompatibility | FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm | | X<br>Not provided | |
| Software | Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm | | X | |
| Electromagnetic Compatibility/Electrical Safety | CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm116566.htm<br>See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) | | X<br>Not provided | |
| Performance Testing – Bench | See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Not provided | |
| Performance Testing – Animal | See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | | ✓ |





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

| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| Performance Testing – Clinical | See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005<br>Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf | | X<br>Not provided | |
| FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf* | **Standards Data Report Form – Form 3654**<br><br>1: No standard used - **No Standards Form Required**<br><br>2: Declaration of Conformity – **Yes Standards Form Required**<br><br>3: Standard but no declaration – **Yes Standards Form Required** | | X<br>Not provided | |
| Kit Certification | Device Advice<br>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm | | | ✓ |

*DA has recently redesigned the FDA website. As a result, some Web links embedded within the above 510(k) Screening Checklist and Guidance documents are no longer valid. If you find a link that does not work, please try searching for the document using the document title. The updated FDA 510(k) Screening Checklist is available at*

*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm071360.htm*



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# SPECIAL 510(k): Device Modification
## ODE Review Memorandum

(Form for converting a special 510(k) to a traditional 510(k) is attached)

**To:** THE FILE **RE:** DOCUMENT NUMBER **K091757**

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

   K063660 – OTC TENs for Low Back Pain Relief, Model Wl-2407

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

   **Change in Indications for Use (IFU)**

   Proposed new IFU for modified device:

   The OTC TENS for Arm & Leg Pain Relief, Model WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

   IFU for predicate device (K063660):

   The model WL-2407 TENs is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the FUNDAMENTAL **SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   **The proposed modifications:**

   1. The change for the use of garment electrodes as standard accessories.
   2. The change for the use of upper arm belt and snap type adhesive electrode as optional accessories.
   3. The change in device labeling to change the description of indication for use based on the change of electrode as mentioned in 1 and 2.

**Reviewer's Comment:**

The proposed Indication for Use and labeling has been changed. FDA guidance "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance" clearly states that:

> Modifications to the indications for use of the device or any labeling change that affects the intended use of the device should not be submitted as a Special 510(k)...
>
> In addition, it should be clearly stated in the Special 510(k) that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s).

Therefore, I believe this premarket application is not qualified for a special and it has been converted to a traditional 510(k) based on the above reasons.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics.

   The cited predicate device is for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) however, the modified device is for muscles in the lower back. The sponsor should identify an appropriate predicate device which has been cleared for temporary relief of pain associated with sore and aching muscles in the lower back.

5. **A Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

**Reviewer's Comment:** Since this special 510(k) has been converted to a traditional 510(k). The sponsor needs to submit all appropriate documents required for traditional 510(k). (See attached deficiencies.)

6. **A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices)**. Provided and acceptable.



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**Recommendation: TH**

The proposed Indication for Use and labeling has been changed. Therefore, this premarket application is not qualified for a special and it has been converted to a traditional 510(k). The sponsor needs to submit all appropriate documents required for traditional 510(k).

Dexiu Shi 7/24/2008
(Reviewer's Signature) (Date)

Daryl Kaufman 7/24/2008
(Concurrence by Review Branch) (Date)

**Memo of Converting this Special 510(k) to a Traditional 510(k) (see attached form)**

Division Director Concurrence:

July 7, 2009: Concurrence by Jan Callaway, Acting Deputy Director of DONED, July 7, 2009.

Date of POS Concurrence:

July 8, 2009: Concurrence by Marjorie Shulman, Premarket Notification (510(k)) Staff

Date of Phone Conversation with Sponsor:

July 8, 2009: Lead reviewer sent email to inform the sponsor that we believe this premarket application is not qualified for a special and it has been converted to a traditional 510(k) based on the above reasons.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service
Food and Drug Administration

# Memorandum

**Date:** July 28, 2009

**From:** Dexiu Shi, Ph.D.
Lead Reviewer
Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Center for Devices and Radiological Health

**To:** Well Life Healthcare Ltd.
c/o Ms. Jenny Hsieh
1 FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
China (Taiwan) 234

Re: K091757
Trade Name: OTC TENs for arm and leg pain relief, model WL-2407
Dated: June 10, 2009
Received: June 17, 2009

Dear Ms. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. As we informed you in our email of July 8, 2009, your proposed Indication for Use and labeling for your modified device has been changed in comparison to your previously cleared device. FDA guidance "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance" clearly states that:

   "Modifications to the indications for use of the device or any labeling change that affects the intended use of the device should not be submitted as a Special 510(k)..."

   "In addition, it should be clearly stated in the Special 510(k) that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s)."

   We believe this premarket application is not qualified for a special 510(k), and it has been



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



converted to a traditional 510(k) based on the above reasons. Our review indicates that your 510(k) is administratively incomplete for a traditional 510(k) and requires additional information listed in the enclosure. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act).

Please submit the required additional information in duplicate along with a CD copy. Please see FDA "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s", available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

2. Please be advised that your cited predicate device is for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg). However, your modified device is for temporary relief of pain associated with sore and aching muscles in the lower back. Please identify an appropriate predicate device which has been cleared for temporary relief of pain associated with sore and aching muscles in the lower back. Please provide side-be-side comparison information (similarities and differences) to the predicate device including, labeling, intended use, physical characteristics.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

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 document titled "A Suggested Approach to Resolving Least Burdensome Issues" located at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The 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.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center at the Center for Devices and Radiological Health (CDRH).

CDRH will be relocated to the Food and Drug (FDA) White Oak Campus during the summer of 2009. The move will be complete by August 3, 2009. The Document Mail Center will continue to accept regulatory documents at the following address until 4:30 on July 31, 2009:

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

Documents that are to be received August 3, 2009 and after should be sent to the following address:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

If you have any questions concerning the contents of this memorandum, please contact Dexiu Shi, Ph.D. at (301) 796-6470.

Enclosure: Screening Checklist for All Premarket Notification [510(k)] Submissions



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

***Guidance for Industry and FDA Staff***
***Format for Traditional and Abbreviated 510(k)s***
http://www.fda.gov/cdrh/ode/guidance/1567.html

| Title | Related Information | Present | Inadequate | N/A |
|---|---|---|---|---|
| MDUFMA Cover Sheet | Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html | ✓ | | |
| CDRH Premarket Review Submission Cover Sheet | CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf | ✓ | | |
| 510(k) Cover Letter | Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html | ✓ | | |
| Indications for Use Statement | Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6 | ✓ | | |
| 510(k) Summary or 510(k) Statement | Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7 | | X Inadequate | |
| Truthful and Accuracy Statement | Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9 | ✓ | | |
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| Financial Certification or Disclosure Statement | FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf<br>Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html. | | | ✓ |
| Declarations of Conformity and Summary Reports (Abbreviated 510(k)s) | Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html.<br>FDA Standards program www.fda.gov/cdrh/stdsprog.html.<br>Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9<br>Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html | | | ✓ |





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| Executive Summary | See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 | | X<br>Not provided | |
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| Software | Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm | | X | |
| Electromagnetic Compatibility/Electrical Safety | CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm116566.htm<br>See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) | | X<br>Not provided | |
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| Performance Testing – Clinical | See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005<br>Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf<br>www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf | | X<br>Not provided | |
| FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf* | **Standards Data Report Form – Form 3654**<br><br>1: No standard used - **No Standards Form Required**<br><br>2: Declaration of Conformity – **Yes Standards Form Required**<br><br>3: Standard but no declaration – **Yes Standards Form Required** | | X<br>Not provided | |
| Kit Certification | Device Advice<br>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm | | | ✓ |

*FDA has recently redesigned the FDA website. As a result, some Web links embedded within the above 510(k) Screening Checklist and Guidance documents are no longer valid. If you find a link that does not work, please try searching for the document using the document title. The updated FDA 510(k) Screening Checklist is available at*

*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm071360.htm*





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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)**

Note: Please send this to the 510k Staff in Word. You do not need anyone to sign this in person.

**Date:** July 7, 2009

**Reviewer:** Dexiu Shi, ODE/DONED/ONDB

**510(k) Number:** K091757

**Device Name:** OTC TENs for arm and leg pain relief, model WL-2407

**Reason for Conversion: (If change in indications for use please list old and new indications.)**

**1. Change in Indications for Use (IFU)**

Proposed new IFU for modified device:

The OTC TENS for Arm & Leg Pain Relief, Model WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Old IFU for K063660

The model WL-2407 TENs is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

**2. Change in Labeling**

The proposed modifications:

1. The change for the use of garment electrodes as standard accessories.
2. The change for the use of upper arm belt and snap type adhesive electrode as optional accessories.
3. The change in device labeling to change the description of indication for use based on the change of electrode as mentioned in 1 and 2.

**Division Director Concurrence/Name: (Please obtain before calling or e-mailing POS.)**

July 7, 2009: Concurrence by Jan Callaway, Acting Deputy Director of DONED, July 7, 2009.

**Date of POS Concurrence: (Please document POS contact (email or memo)):**

July 8, 2009: Concurrence by Marjorie Shulman, Premarket Notification (510(k)) Staff

**Date of Phone Conversation with Sponsor:**

July 8, 2009: Lead reviewer sent email to inform the sponsor that we believe this premarket application is not qualified for a special and it has been converted to a traditional 510(k) based on the above reasons.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Proposed new IFU for modified device:

The OTC TENS for Arm & Leg Pain Relief, Model WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Old IFU for K063660

The model WL-2407 TENs is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

**2. Change in Labeling**

The proposed modifications:

1. The change for the use of garment electrodes as standard accessories.
2. The change for the use of upper arm belt and snap type adhesive electrode as optional accessories.
3. The change in device labeling to change the description of indication for use based on the change of electrode as mentioned in 1 and 2.

**I need BC and Division's Concurrence before e-mailing POS.**

**Thanks/Dexiu**

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**Shi, Dexiu**

**From:** Shulman, Marjorie G.
**Sent:** Tuesday, July 07, 2009 5:22 PM
**To:** Shi, Dexiu
**Subject:** RE: K091757 - Form for Converting a Special 510(k) to a Traditional

Hi Dexiu,

I have converted this file to a traditional. The new (90th day) due date is September 15, 2009. Please let me know if you need anything else.

Thanks,

Marjorie

*Marjorie Shulman*
Premarket Notification (510(k)) Staff
(240) 276-4040
email: Marjorie.Shulman@FDA.HHS.GOV (please note new email address and new telephone number)

**********
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

**From:** Shi, Dexiu
**Sent:** Tuesday, July 07, 2009 2:44 PM
**To:** Shulman, Marjorie G.
**Cc:** Shi, Dexiu
**Subject:** K091757 - Form for Converting a Special 510(k) to a Traditional

Hi Marjorie:

I am sending you the form for converting above Special 510(k) to a Traditional. The reason for conversion is th there are changes in Indication for Use and Labeling.

**1. Change in Indications for Use (IFU)**

Proposed new IFU for modified device:

The OTC TENS for Arm & Leg Pain Relief, Model WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Old IFU for K063660

The model WL-2407 TENs is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

**2. Change in Labeling**

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

The proposed modifications:

1. The change for the use of garment electrodes as standard accessories.
   The change for the use of upper arm belt and snap type adhesive electrode as optional accessories.
   The change in device labeling to change the description of indication for use based on the change of electrode as mentioned in 1 and 2.

**Thanks,**

Dexiu Shi, Ph.D., Physicist and Biomedical Engineer
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
FDA/CDRH/ODE, HFZ460
9200 Corporate Blvd
Rockville, MD 20850
phone: 240-276-4216
fax: 240-276-4111
dexiu.shi@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e- mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (240) 276-4216.

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**Shi, Dexiu**

**From:** Callaway, Jan C.
**Sent:** Tuesday, July 07, 2009 2:31 PM
**To:** Shi, Dexiu
**Cc:** Ulmer, Kwame; Mann, Eric A
**Subject:** FW: K091757 - Form for Converting a Special 510(k) to a Traditional
**Attachments:** Ulmer, Kwame.vcf

Dexiu,

I concur as well.

Jan Callaway
Acting Deputy Director

---

**From:** Ulmer, Kwame
**Sent:** Tuesday, July 07, 2009 2:14 PM
**To:** Shi, Dexiu; Callaway, Jan C.; Mann, Eric A
**Subject:** RE: K091757 - Form for Converting a Special 510(k) to a Traditional

Dexiu,
I concur that this should be converted because of the change in IFU. When a Division manager concurs, please continue, processing.

Kwame

Kwame Ulmer
Chief
Ophthalmic lasers
Neurostimulators
& Diagnostic devices Branch

Food & Drug Administration
9200 Corporate Blvd
HFZ-460
Rockville, MD 20850
240.276.4262 (v) 240.276.4234 (f)

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

---

**From:** Shi, Dexiu
**Sent:** Tuesday, July 07, 2009 2:11 PM
**To:** Ulmer, Kwame; Callaway, Jan C.; Mann, Eric A
**Subject:** K091757 - Form for Converting a Special 510(k) to a Traditional

Hi,

I am sending you the form for converting above Special 510(k) to a Traditional. The reason for conversio that there are changes in Indication for Use and Labeling.

1. **Change in Indications for Use (IFU)**

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**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 01, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757

Product: OTC TENS FOR ARM AND LEG PAIN

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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

K091757/S1

# Response Report for K091757

Device Name: OTC TENS For Arm & Leg Pain Relief

Model Number: WL - 2407

*Presented by*

**Well Life Healthcare Limited**

Taiwan Branch: 1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# K091757 Response Report

To: Dexiu Shi, Ph.D.
Lead Reviewer
Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Center for Devices and Radiological Health

Date : Aug. 20,2009

FDA CDRH DMC
AUG 28 2009
Received

From: Well Life Healthcare Ltd.
c/o Ms. Jenny Hsieh
1 FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
China (Taiwan) 234

K.35

Re: K091757
Trade Name: OTC TENS for arm and leg pain relief, model WL-2407
Dated: June 10,2009
Received: June 17,2009

Dear Dr. Shi :

First of all, we appreciate your work to review our 510(K) submission and give us the review comments with a very clear screening checklist. We believe it is a good way to instruct us to convert our "Special 510(K)" application into "Traditional 510(K)" via providing missing or inadequate information as mentioned on the checklist.

Enclosed hereafter are our response reports made against your review screening checklist via using the same table of the checklist. In our response reports, we raised some justification for some questions on which we have some different consideration, and provided some additional or revised information to support our response. Please check if our response, justification, and attached information are adequate to address the problems of your review comments.



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

| Title | Review Results | | | Response ID No. | Brief Description of the response | Identification of attached information |
|---|---|---|---|---|---|---|
| | Present | Inadequate | N/A | | | |
| MDUFMA Cover Sheet | √ | | | | | |
| CDRH Premarket Review Submission Cover Sheet | √ | | | | | |
| 510(K) cover Letter | √ | | | | | |
| Indications for Use Statement | √ | | | | | |
| 510(K) Summary or 510(K) Statement | | X Inadequate | | 1 | We provide revised 510(K) Summary | Attachment 1 |
| Truthful and Accuracy Statement | | | √ | | | |
| Class III Summary and Certification | | | √ | | | |
| Financial Certification or Disclosure Statement | | | √ | | | |
| Declarations of conformity and Summary Reports (Abbreviated 510(K)s) | | | √ | | | |
| Executive Summary | | X Inadequate | | 2 | We provide additional Executive Summary | Attachment 2 |
| Device Description | | X Inadequate | | 3 | We provide revised Device Description | Attachment 3 |
| Substantial Equivalence Discussion | | X Inadequate | | 4 | We provide additional SE Discussion Reports | Attachment 4 |
| Proposed Labeling | | X Inadequate | | 5 | We provide revised labeling Information | Attachment 5 |
| Sterilization/Shelf Life | | X Inadequate | | 6 | Since our device does neither need sterilization nor specify shelf life for product specification, we believe it is not necessary to provide any sterilization/shelf life evaluation report for our device. | |
| Biocompatibility | | X Inadequate | | 7 | We provide bio-Compatibility reports for every skin contact material of our device. | Attachment 6 |



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

| Title | Review Results | | | Response ID No. | Brief Description of the response | Identification of attached information |
|---|---|---|---|---|---|---|
| | Present | Inadequate | N/A | | | |
| Software | | X Inadequate | | 8 | We provide software validation report for WL-2407 model | Attachment 7 |
| Electromagnetic Compatibility Electrical Safety | | X Inadequate | | 9 | We provide EMC test report according to EN60601-1-2. | Attachment 8 |
| | | | | | and electrical safety test report according to EN60601-1. | Attachment 9 |
| Performance Testing-Bench | | X Inadequate | | 10 | We provide performance test report according to ANSI/AAMI-NS4 | Attachment 10 |
| Performance Testing-Animal | | | √ | | | |
| Performance Testing-Clinical | | X Inadequate | | 11 | As per the predicate devices, FDA approved the similar devices with the same indication for use. We, therefore, believe it is not necessary to provide additional clinical test report for our device. For the cleared evidence and justification, please see information of attachment 4. | |
| FORM FDA3654, Standards Data Report for 510(k)s | | X Inadequate | | 12 | We provide revised information on FDA Form 3514 & Form 3654 | Attachment 11 |
| Kit Certification | | | √ | | | |

Based upon the "Brief description of the response" as indicated on the table, we include 11 Attachments to address the questions as mentioned on your review comment. Hopefully our response and additional information help to complete your review work. Any question about our response, please keep us informed via e-mail and/or any convenient way. We will keep providing our response as well as missing or inadequate information sooner after receiving your information.

Yours faithfully,

Jenny Hsieh
Official Correspondent
Well-Life Healthcare Ltd.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Attachment 1.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091757 .

1. Submitter's Identifications:
   Well Life Healthcare Limited
   1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 234, Taiwan, ROC

   Contact: Jenny Hsieh

   Date of Summary Preparation: August 20, 2009

2. Name of the Device:

   OTC TENS for Arm & Leg Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):
   1> The Prizm 5000-Z system (K033122)
   2> Endurance Therapeutics T1040 (K060846).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. Basically the stimulation model WL-2407 is completely identical to that of model as mentioned in the Well-Life K063660- 510(K) cleared device. To change the indication for use for the treatment location as the chosen predicate devices, Well-Life change the design of electrode.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:

   <1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).
   <2> For the stimulation electrode, Well-Life uses garment electrodes as standard accessories, and upper arm belt as well as snap type adhesive electrode as optional accessories.
   <3> The output waveform is selectable pre-programming change among P1~P8.
   <4> The output strength is adjustable at 0~80mA, with variable setting time 1~60 minutes counting from switching ON.
   <5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

5. Intended Use:

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of Prizm 5000-Z system (K033122) and Endurance Therapeutics T1040 (K060846). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

**In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.**



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Indications For Use

510(k) Number (if known): K091757

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (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)



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

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# Attachment 2.



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

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# Executive Summary For K091757

## 1> Device Name

Trade name : OTC TENS For Arm & Leg Pain Relief / Model : WL- 2407.

Common name : OTC TENS For Arm & Leg Pain Relief / Model : WL- 2407.

Classification name : Stimulator, Nerve, Transcutaneous For Pain Relief.

## 2> Classification

Trade/Device Name: OTC TENS For Arm & Leg Pain Relief/ Model : WL -2407.
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve, Transcutaneous For Pain Relief.
Regulatory Class: II
Product Code: NUH

## 3> Indication for use

The OTC TENS For Arm & Leg Pain Relief; Model : WL -2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

For the statement of indication for use, please see attachments.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## 4> Technology of Device

The Well Life OTC TENS For Arm & Leg Pain Relief; Model : WL -2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkailne battery) operated TENS device with the following features:

<1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).

<2> The stimulation electrodes are by garment electrodes as standard accessories and upper arm support belt and snap type adhesive electrodes as optional accessories.

<3> The output waveform is selectable pre-programming change among P1~P8.

<4> The output strength is adjustable at 0~80mA, with variable setting time 1~60 minutes counting from switching ON.

<5> The LCD display is provided for the indication of operation status, including operation mode, output program mode, output intensity,time to cut-off, and battery low warning.

Basically the hardware and software design of device is completely identical to that of previous 510(k) cleared models OTC TENS for Low Back Pain Relief / Model WL-2407(K063660) except for the use of electrode. Due to the reason that we are intended to change the indication for use, we made some new design on the electrodes.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## 5> 510(K) Predicate devices

For Well Life OTC TENS For Arm & Leg Pain Relief; Model : WL -2407, Well-Life chose the following two 510(K) cleared devices in which the garment electrode, and snap type adhesive electrodes were used on the arm & leg treatment location :

1. Re: K033122.

   Classification Name: Transcutaneous Nerve Stimulator.

   Trade/Proprietary Name: Prizm Medical, Inc. 5000-Z System.

   Classification: Class II (21 CFR 882.5890)

   Product Code: NUH

   Dated : February 10, 2005.

2. Re: K060846.

   Classification Name: Transcutaneous Nerve Stimulator.

   Trade/Proprietary Name: Endurance Therapeutics T1040.

   Classification: Class II (21 CFR 882.5890)

   Product Code: NUH, NGX, GZJ

   Dated : December 03, 2007.

The comparison table among the three compared models was presented hereafter .



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## 6> Comparison table between new models and cleared model

The main reason for choosing these two predicate 510(K) clear model are because that all of them bear the same intended use as well as almost the same accessories.

For the comparison concerning these features, please see the following comparison table:

| Comparison Features | Models to be Compared | | |
|---|---|---|---|
| | WL-2407 (Well-life) | 5000Z (Prizm) | T1040 (Endurance) |
| Prescription or OTC | OTC | OTC | OTC |
| Indication for use | Pain relief for Arm and leg | Pain relief for Arm and leg | Pain relief for Arm and leg |
| FDA product code | NUH | NUH | NUH & NGX |
| Electrode Used | 1. Garment electrodes<br>2. Adhesive electrode<br>3. Arm belt electrode with conductive gel | Garment electrode | adhesive electrode |

In addition to the significant comparison feature, we also provided the comparison for the output characteristics as the following table :

| Quantity | WL-2407 (Well-life) | 5000Z (Prizm) | T1040 (Endurance) |
|---|---|---|---|
| Max. voltage over 10kΩ, V | 94 | 226 | 154.1 |
| Max. Current over 10kΩ, mA | 9.4 | 22.6 | 15.4 |
| Max. Voltage over 2.2kΩ, V | 56 | 218 | 105.1 |
| Max. Current over 2.2kΩ, mA | 18.18 | 99 | 47.8 |
| Max. Voltage over 500Ω, V | 40 | 208 | 40.7 |
| Max. Current over 500Ω, mA | 80 | 416 | 81.4 |
| Pulse Width, $\mu$seconds | 260 | 100 | 210 |
| Pulse Period, msec | No specified | 10 | 4.1-500 |
| Max. Pulse Frequency, Hz | 120 | 120 | 245 |
| Max. Charge per Phase over 500Ω, $\mu$c | 20.8 | 3.4 | 16.916.9 |
| Max. Current density over 500Ω, mA/cm$^2$ | 0.1 | 16.64 | 2.71 |
| Max. Average Power Density over 500Ω, mW/cm$^2$ | 4 | | 5.35 |

Note: 1. The technical information for WL-2407 is based on the testing waveform and calculation of real sampling model.

2. According to the information in the comparison table, the technical specification for all of three models are within the acceptable limit as specified by FDA guidance for TENS devices.

3. The information of 5000z(Prizm) and T1040(Endurance)comes from the 510(K) summary of T1040(Endurance/K060846) released on FDA web-site.



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

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## 7> Summary for performance testing required for this submission.

According to the device features, the testing for the following standards were considered required for the device:

- The American Standard ANSI/AAMI NS4: 1985 – American National Standard for Transcutaneous Electrical Nerve Stimulators.
- The European Standard EN 60601-1: 1990, Amendment A13: 1996 – Safety of medical device; Electrical equipment - General safety.
- The European Standard EN 60601-1-2: 2001 ; Medical – Electrical equipment – Safety – Electromagnetic Compatibility.
- International Standard EN/ISO 10993-1: 2003; Biological evaluation of medical devices – Part 1: Guidance on selection of tests.
- International standard EN/ISO 10993-5:1999 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:1999)
- International standard EN/ISO 10993-10:2002 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002)



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Attachment : Standard Format for the statement of indication for use.



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# Indications For Use

510(k) Number (if known):

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (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)



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# Attachment 3.



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# Device Description for K091757/WL-2407

## 1> Device Name:

Trade name : OTC TENS For Arm & Leg Pain Relief / Model : WL- 2407.

Common name : OTC TENS For Arm & Leg Pain Relief / Model : WL- 2407.

Classification name : Stimulator, Nerve, Transcutaneous For Pain Relief.

## 2> General Description of Device

The Well Life OTC TENS For Arm & Leg Pain Relief; Model : WL -2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkailne battery) operated TENS device with the following features:

<1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).

<2> The stimulation electrodes are by garment electrodes as standard accessories and upper arm support belt and snap type adhesive electrodes as optional accessories.

<3> The output waveform is selectable pre-programming change among P1~P8.

<4> The output strength is adjustable at 0~80 mA, with variable setting time 0~60 minutes counting from switching ON.

<5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.

Basically the hardware and software design of device is completely identical to that of previous 510(k) cleared models OTC TENS for Low Back Pain Relief / Model WL-2407(K063660) except for the use of electrode. Due to the reason that we are intended to change the indication for use, we made some new design on the electrodes.

The photos for the WL-2407 were provided in section 3, the wave form diagram was provided in section 4, the new design of electrodes was provided in section 5, the device specification was described in section 6, and the relevant drawing was provided in section 7.



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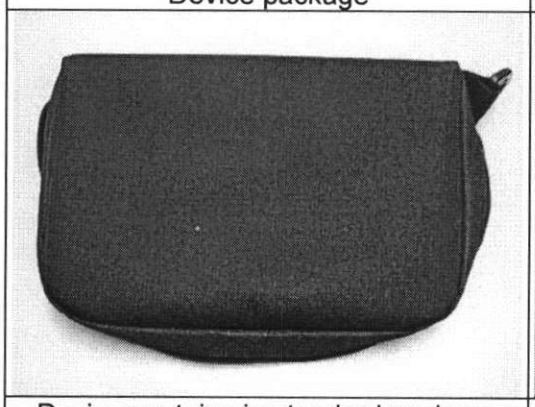
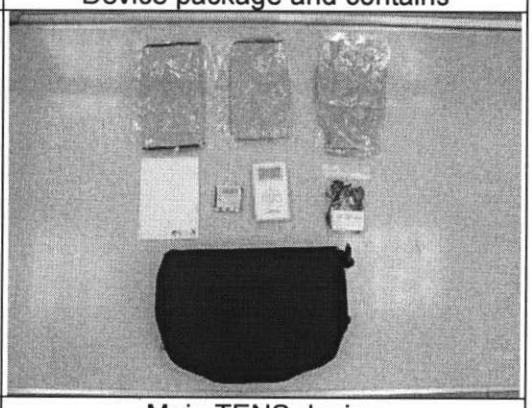
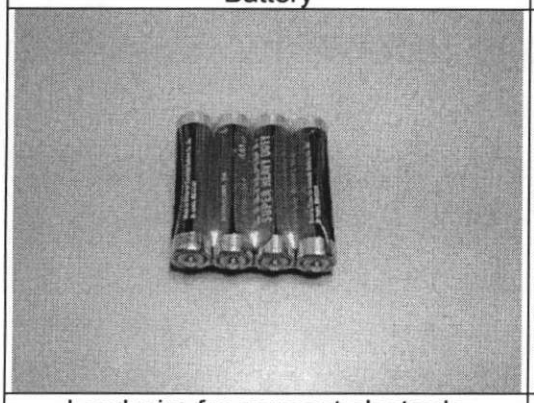
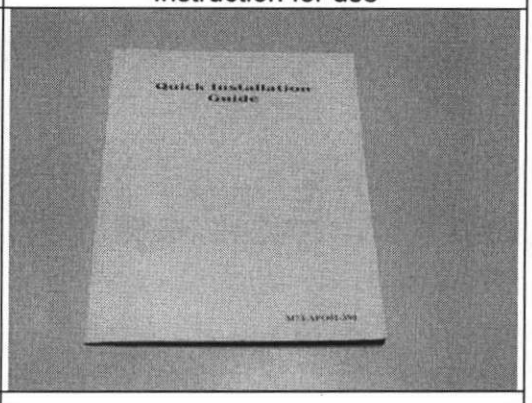
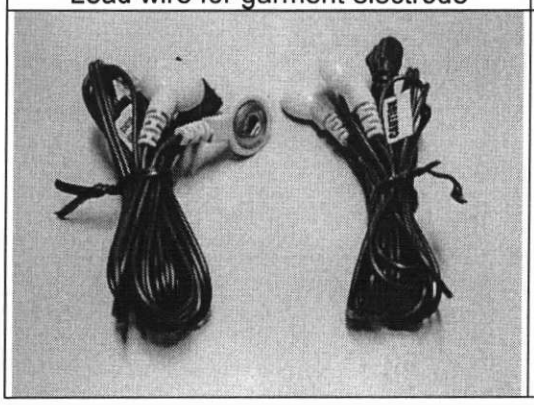
3> Device Photos.

| Device package | Device package and contains |
|---|---|
|  |  |
| Device contains in standard package | Main TENS device |
| | |
| Battery | Instruction for use |
|  |   |
| Lead wire for garment electrode | |
|  | |



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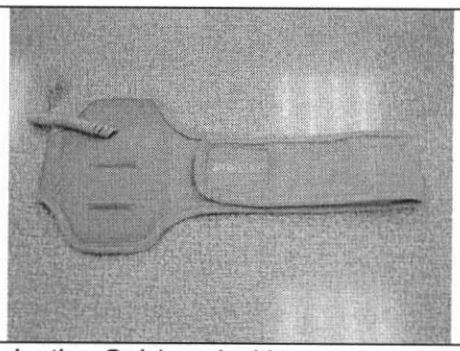
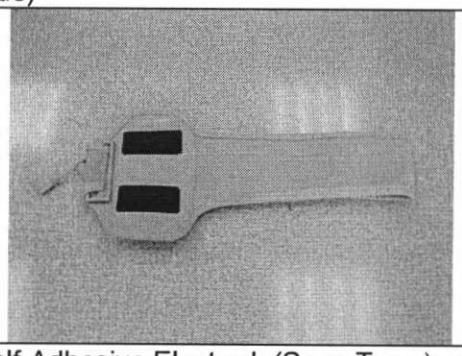
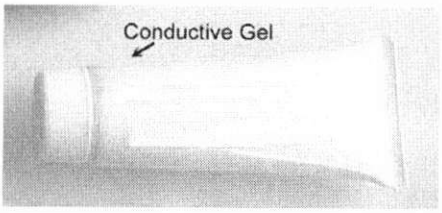
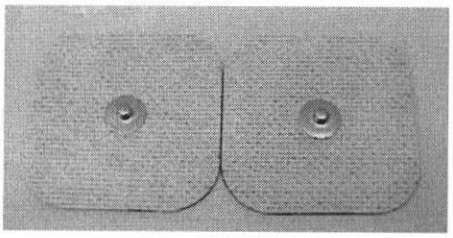
**Accessories**

| Upper Arm support Belt (front side) | Upper Arm support Belt (Back side; Skin side) |
|---|---|
|  |  |
| Conductive Gel (used with upper arm belt) | Self-Adhesive Electrode(Snap Type ) |
|   |  |

4> Waveform Diagram

For the device specification & waveform diagram, please see the following details.



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Well-Life Healthcare Ltd.
Product Waveform Record

| Model | WL-2407 | File No. | |
|---|---|---|---|

Test Conditions：

| No. | Item | SPEC |
|---|---|---|
| 1 | Power Source | 4.5V |
| 2 | Load | 500Ω ±10% |
| 3 | | |
| 4 | | |
| 5 | | |

Test Instrument：

| No. | Instrument | Company | Model |
|---|---|---|---|
| 1 | Power supply | ABM | 8602D |
| 2 | Oscilloscope | Tektronix | TDS1012 |
| 3 | | | |
| 4 | | | |
| 5 | | | |

Function Mode SPEC：

| Function Mode | Pulse width (uS / Vp) | Pulse rate (Hz / Vp) | Waveform Type |
|---|---|---|---|
| P1 | 260 | 15 | Constant |
| P2 | 260 | 60 | Burst |
| P3 | 260 | 60 | Constant |
| P4 | 260~156 | 2~60 | Dense-Disperese |
| P5 | 260~156 | 60 | Modulation Pulse Width |
| P6 | 260 | 7~60 | SD Pulse Rate |
| P7 | 260~156 | 60 | SD Pulse Width |
| P8 | Recycle (P1~P7) | | |

※Function Mode SPEC：±20%。

Date：
2007.05.21

Test：
David Wu



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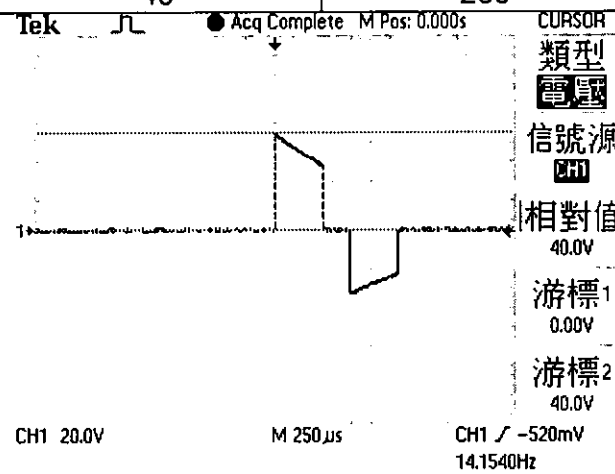
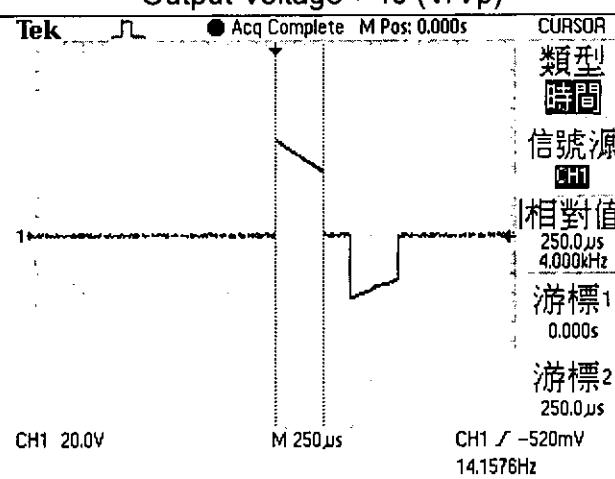
Well-Life Healthcare Ltd.

Product Waveform Record

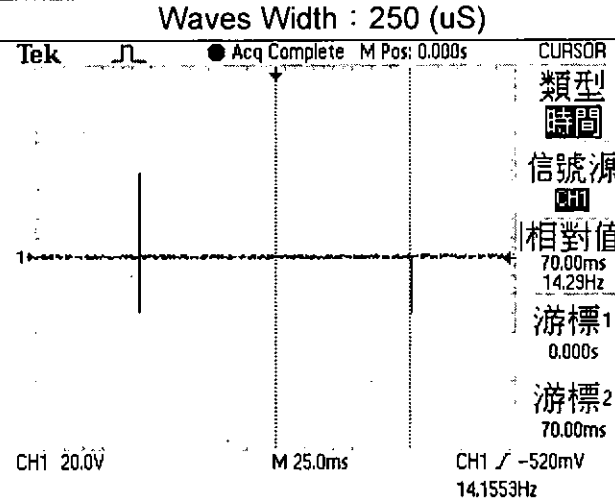
| Model：WL-2407 | | | |
|---|---|---|---|
| Test Channel：CH1 | Function mode：P1 (Continuous) | | Load：500Ω |
| Standard SPEC | | | |
| Tolerance | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
| ±20% | 40 | 260 | 15 |




Output Voltage：40 (V/Vp)




Waves Width：250 (uS)




Frequency：14.29 (Hz/Vp)

Date：
2007.05.21

Test：
David Wu



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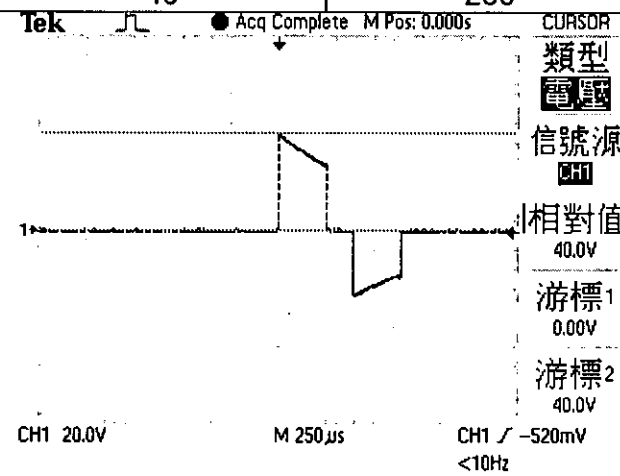
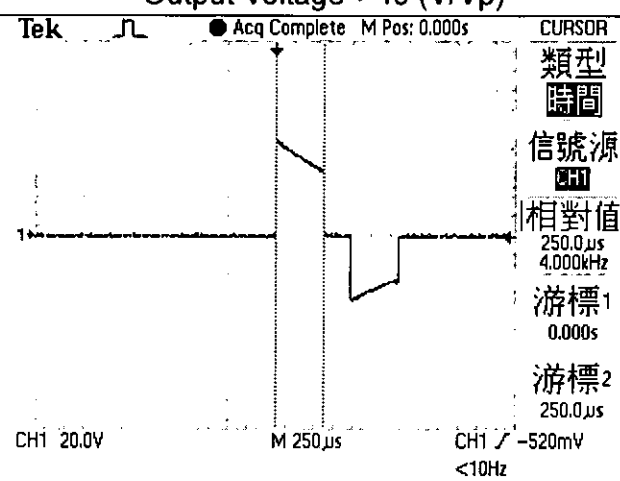
Product Waveform Record

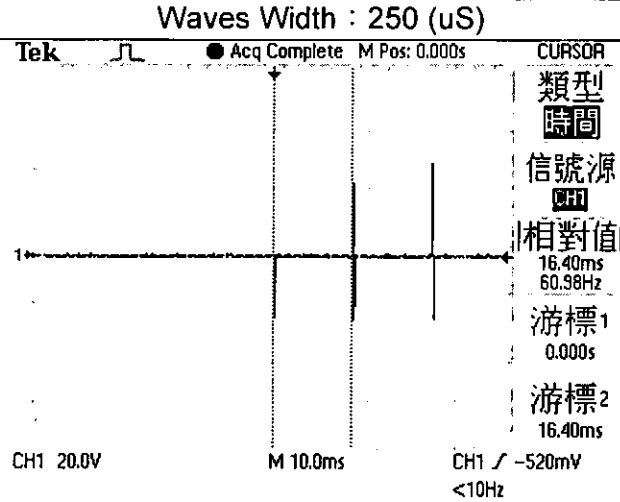
| Model：WL-2407 | | | |
|---|---|---|---|
| Test Channel：CH1 | Function mode：P2 (Burst) | | Load：500Ω |
| Standard SPEC | | | |
| Tolerance | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
| ±20% | 40 | 260 | 60 |




Output Voltage：40 (V/Vp)




Waves Width：250 (uS)




Frequency：60.98 (Hz/Vp)

Date：
2007.05.21

Test：
David Wu



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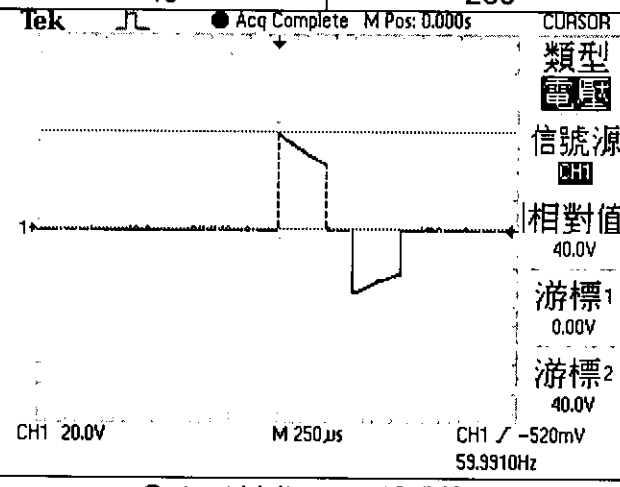
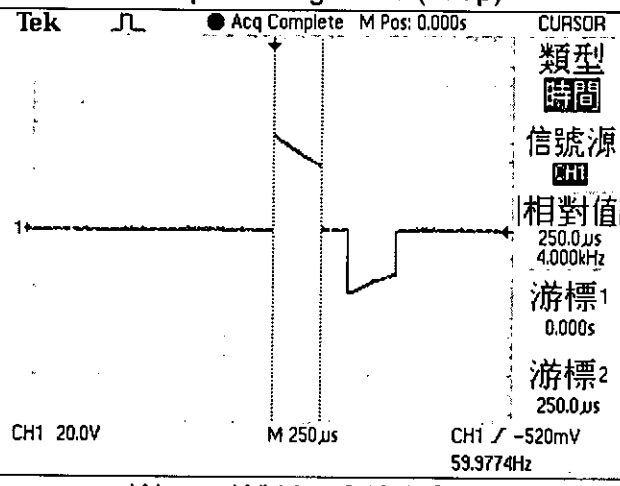
Well-Life Healthcare Ltd.

Product Waveform Record

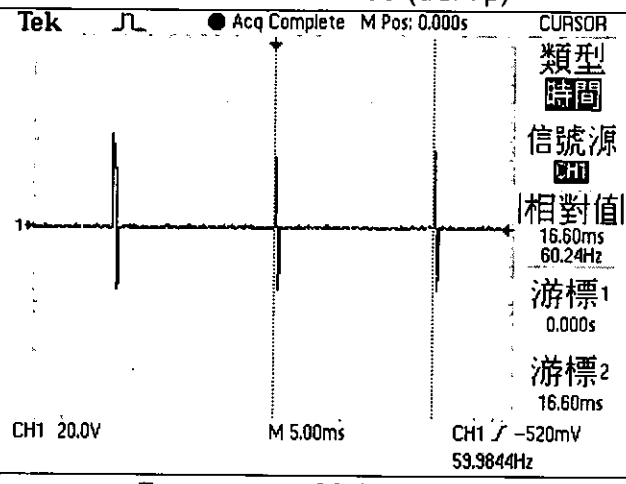
| Model：WL-2407 | | | |
|---|---|---|---|
| Test Channel：CH1 | Function mode：P3 (Continuous) | | Load：500Ω |
| Standard SPEC | | | |
| Tolerance | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
| ±20% | 40 | 260 | 60 |




Output Voltage：40 (V/Vp)




Waves Width：250 (uS/Vp)




Frequency：60.24 (Hz/Vp)

Date：
2007.05.21

Test：
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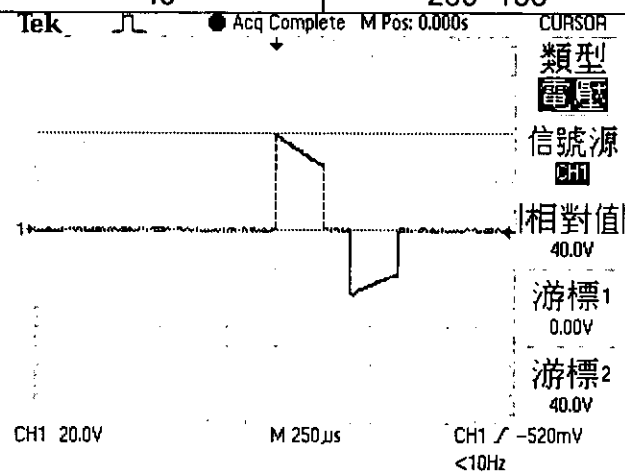
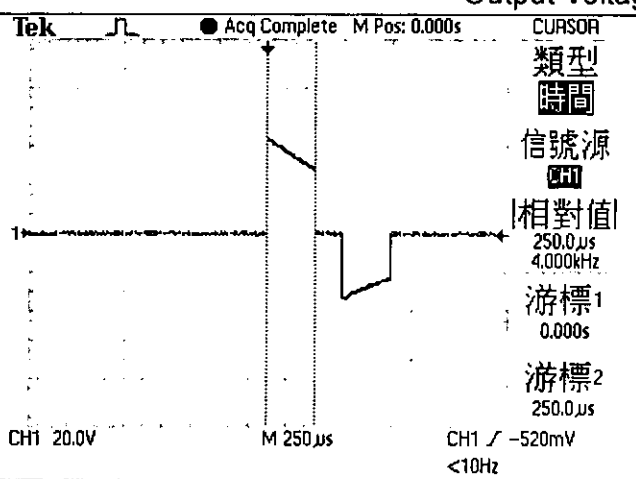
Product Waveform Record

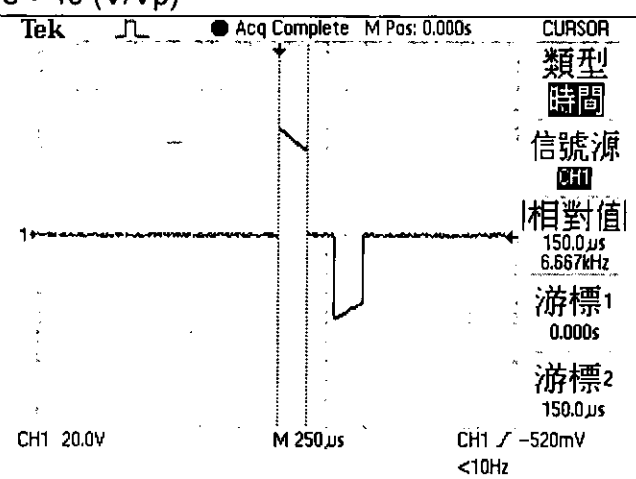
| Model：WL-2407 | | | |
|---|---|---|---|
| Test Channel：CH1 | Function mode：P4 (Dense-Disperese) | | Load：500Ω |
| Standard SPEC | | | |
| Tolerance | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
| ±20% | 40 | 260~156 | 2~60 |



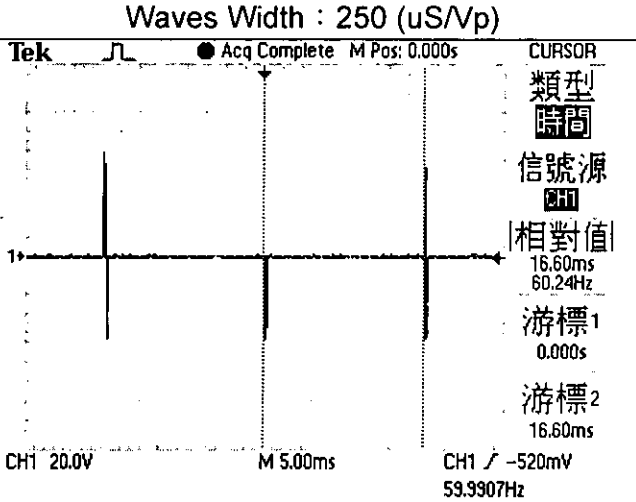

Output Voltage：40 (V/Vp)



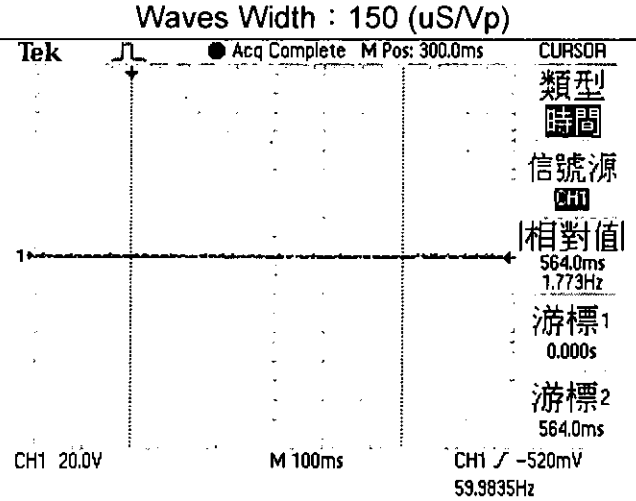

Waves Width：250 (uS/Vp)




Waves Width：150 (uS/Vp)




Frequency：60.24 (Hz/Vp)




Frequency：1.77 (Hz/Vp)

Date：
2007.05.21

Test：
David Wu



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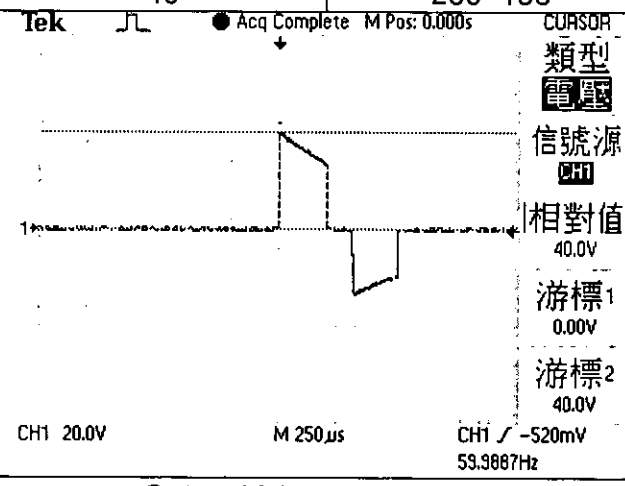
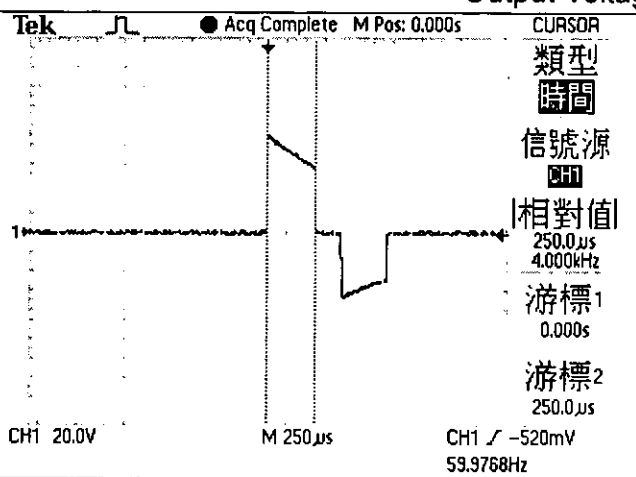
Well-Life Healthcare Ltd.

Product Waveform Record

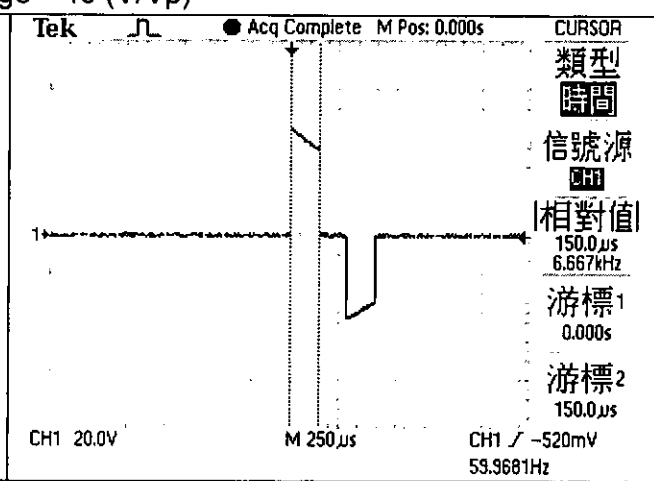
| Model：WL-2407 | | | |
|---|---|---|---|
| Test Channel：CH1 | Function mode：P5 (Modulation Pulse Width) | | Load：500Ω |
| Standard SPEC | | | |
| Tolerance | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
| ±20% | 40 | 260~156 | 60 |



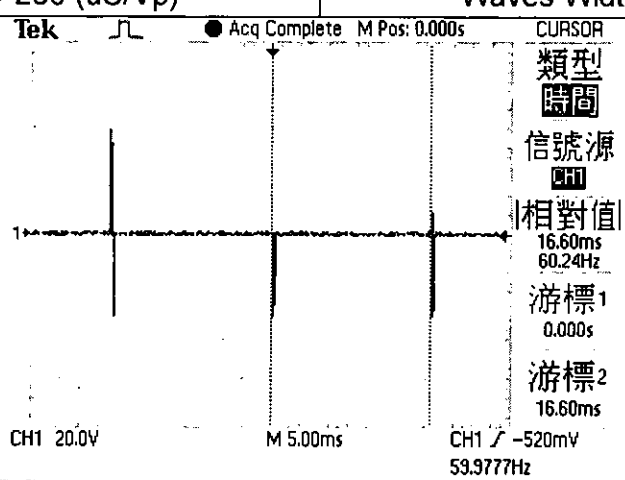

Output Voltage：40 (V/Vp)




Waves Width：250 (uS/Vp)




Waves Width：150 (uS/Vp)




Frequency：60.24 (Hz/Vp)

Date：
2007.05.21

Test：
David Wu



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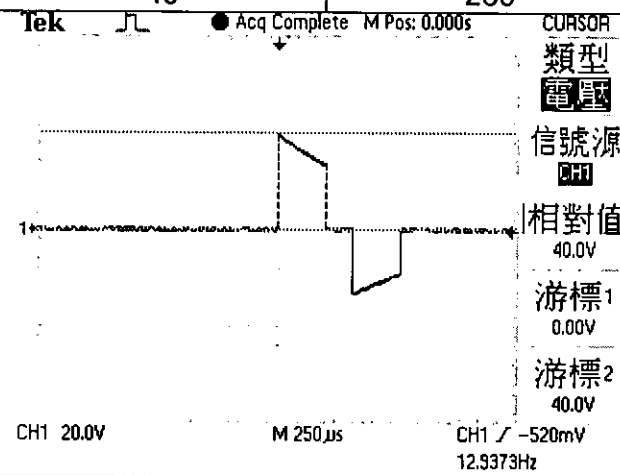
Well-Life Healthcare Ltd.

Product Waveform Record

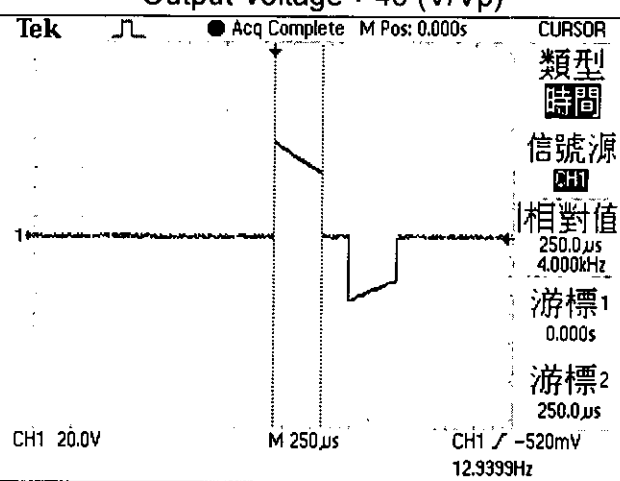
| Model：WL-2407 | | |
|---|---|---|
| Test Channel：CH1 | Function mode：P6 (SD Pulse Rate) | Load：500Ω |

Standard SPEC

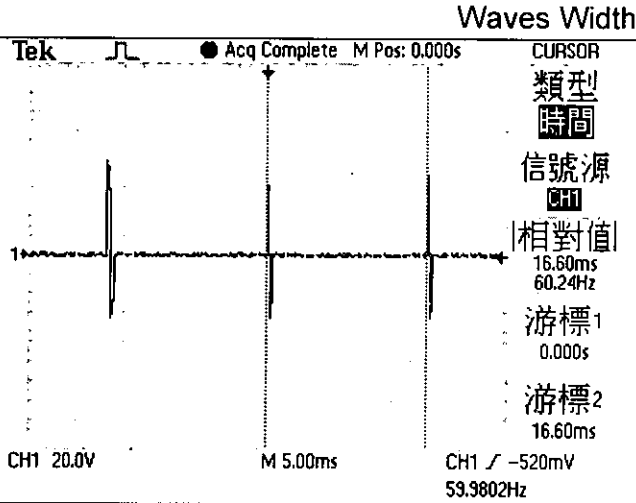
| Standard SPEC | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
|---|---|---|---|
| ±20% | 40 | 260 | 7~60 |



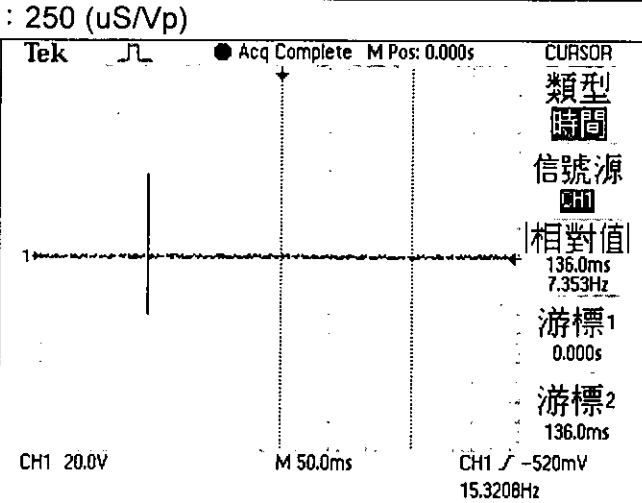

Output Voltage：40 (V/Vp)




Waves Width：250 (uS/Vp)




Frequency：60.24 (Hz/Vp)




Frequency：7.35 (Hz/Vp)

Date：
2007.05.21

Test：
David Wu



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威立德有限公司

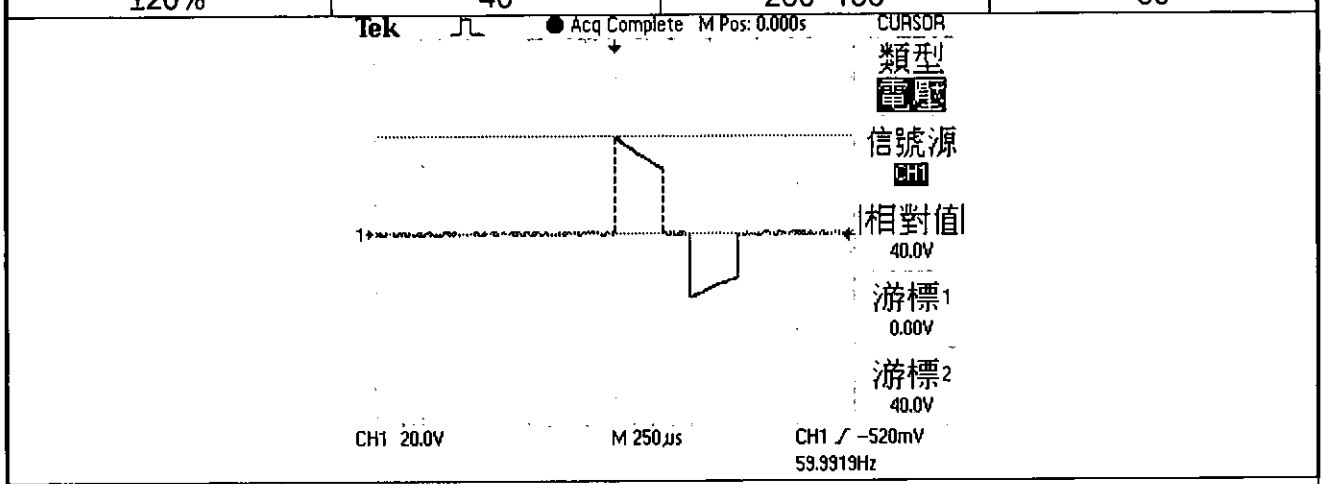
Well-Life Healthcare Ltd.

Product Waveform Record

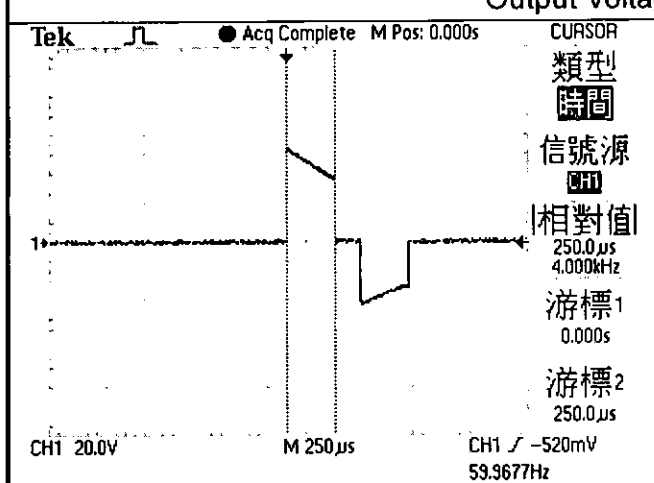
| Model：WL-2407 | | |
|---|---|---|
| Test Channel：CH1 | Function mode：P7 (SD Pulse Width) | Load：500Ω |

Standard SPEC

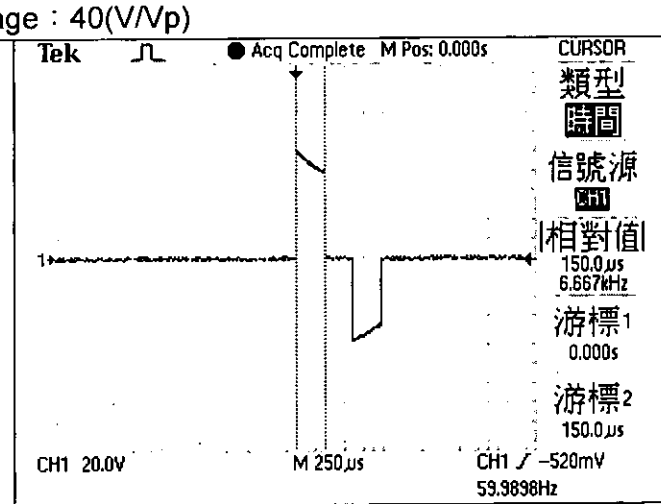
| Standard SPEC | Output Voltage (V/Vp) | Waves Width (uS/Vp) | Frequency (Hz/Vp) |
|---|---|---|---|
| ±20% | 40 | 260~156 | 60 |



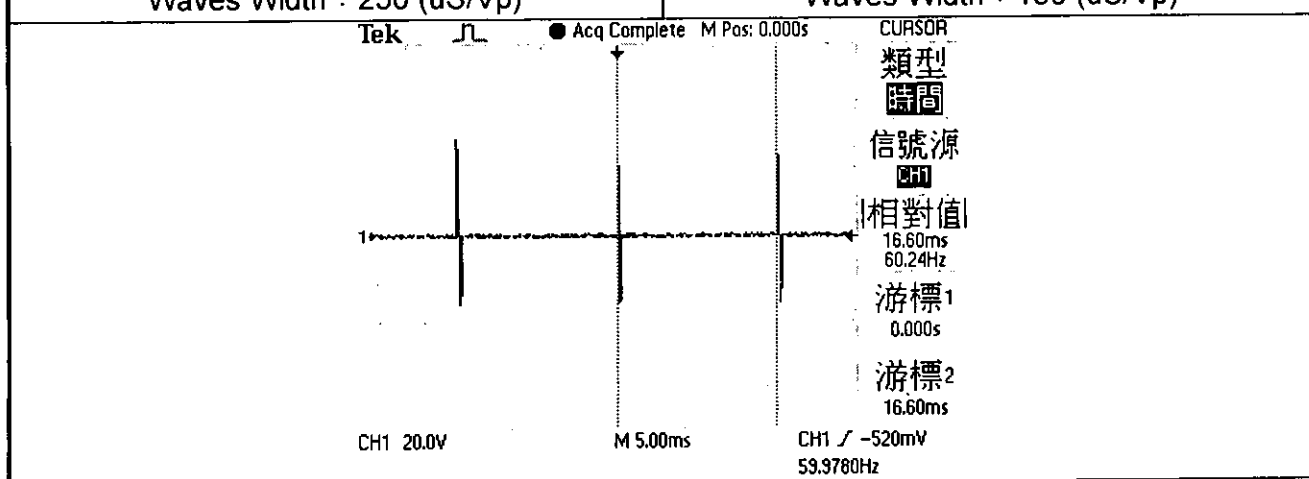

Output Voltage：40(V/Vp)




Waves Width：250 (uS/Vp)




Waves Width：150 (uS/Vp)




Frequency：60.24 (Hz/Vp)

Date：
2007.05.21

Test：
David Wu



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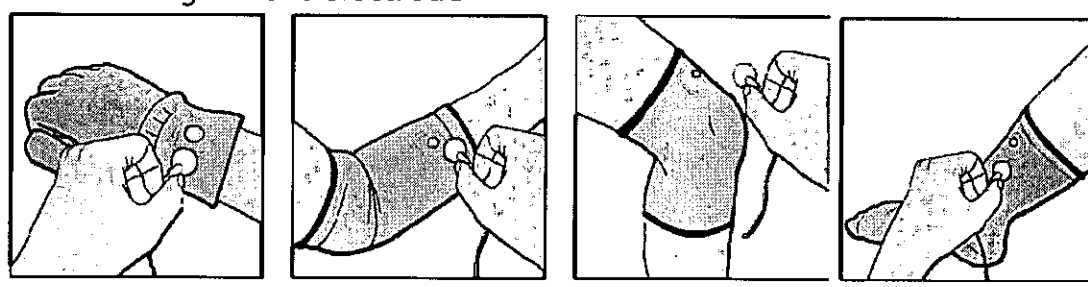
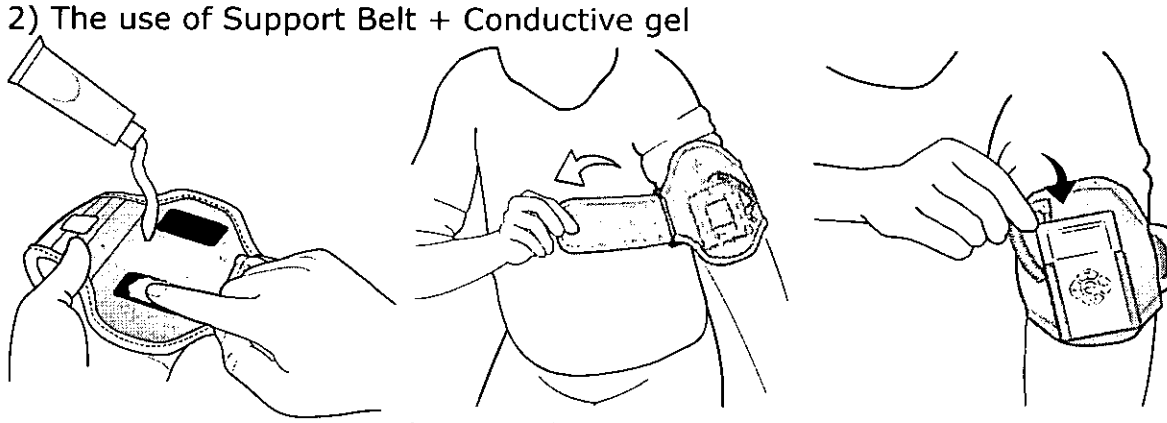
## 5> Explanation of electrodes

### 1) The use of garment electrode



Glove | Elbow Sleeve | Knee Sleeve | sock

### 2) The use of Support Belt + Conductive gel

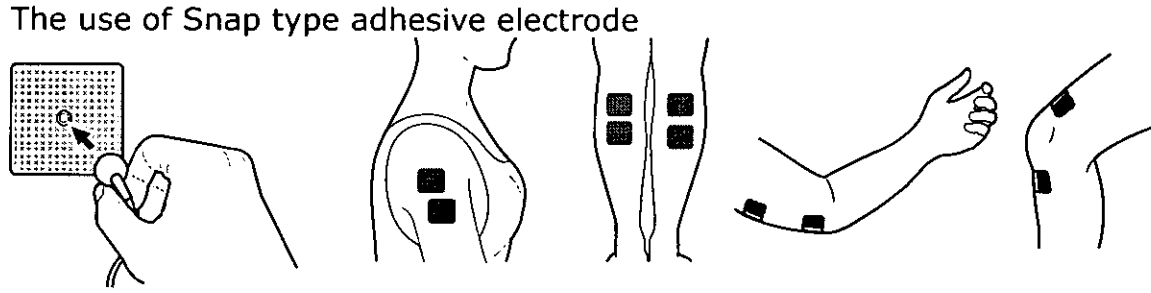


Before use, dampen the integrated silicon electrodes with water or a conductive gel.

Insert the belt through the square ring, stretch the ends of the cuff, and press the electrodes firmly against your skin

Connecting the cable to the device.

### 3) The use of Snap type adhesive electrode



Preparing treatment site and accessories connect the lead wires to the electrodes before applying the electrodes to the skin.

(a) (b) (c) (d)

Place the electrodes *(a) shoulder (b) leg (c) elbow (d) Knee*

As mentioned on the description of "Intended Use", u ser could choose from System arm /Leg accessories pack , optional choices by individual from the followings :



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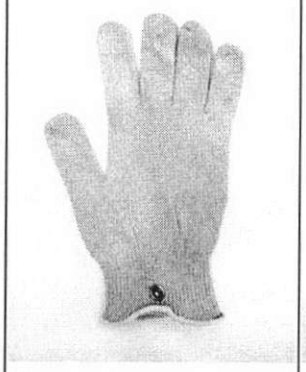
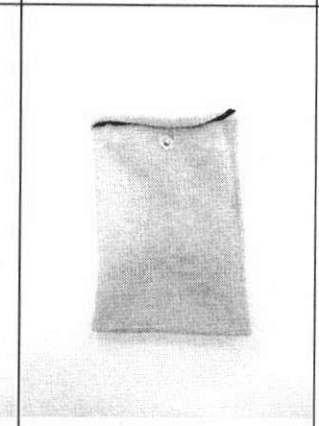
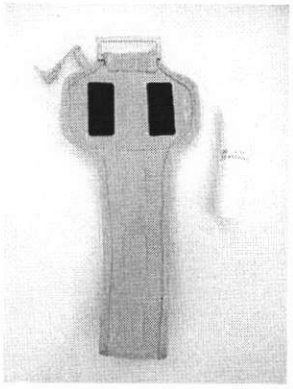
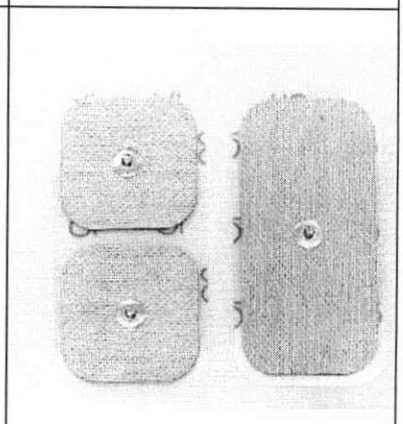
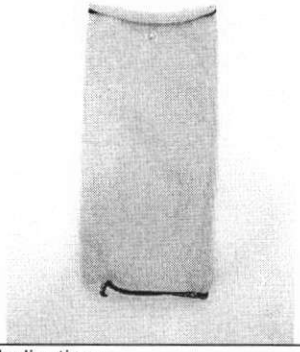
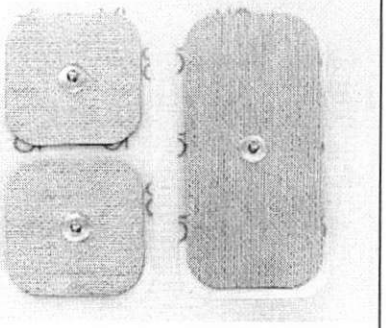
| Indication for Arm use | | | |
|---|---|---|---|
| Conductive Mesh Garment Electrode Glove | Conductive Mesh Garment Electrode Elbow Sleeve | Support belt + Conductive Silicone pad with gel tube | Self Adhesive Electrodes |
|  |  |  |  |
| Size indication:<br><br>Theraknit Part no, measured by Palm Width .<br><br>Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm | Size indication:<br><br>Theraknit Part no, measured by elbow circumference<br><br>Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 301 0: over 30 cm | One size fit all neoprene belt (adjust by Velco according to arm circumference 24~3 6 cm ) , W ell-Life p art no. TB-0040<br><br>Size of conductive silicone pad is - 25x50mm, 2 pcs ; Well-Life part no. SP2550 , or bigger size 50x50mm available | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |

| Indication for Leg use | | |
|---|---|---|
| Conductive Mesh Garment Electrode Socks | Conductive Mesh Garment El ectrode Knee Sleeve | Self Adhesive Electrodes |
| |  |  |
| Size indication:<br><br>Theraknit Part no, measured by shoe size.<br><br>Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size | Size Indication :<br><br>Theraknit Part no, measured by Knee circumference .<br><br>Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |



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6> Device Specification : As the following specification table.

| *Model* | *WL-2407* |
|---|---|
| Manufacturer W | ell-Life |
| Classification | Class II |
| Waveform | Asymmetrical<br>Monophasic<br>Square |
| Channels | Dual |
| Power supply | 4.5 volt (3xAAA/Alkaline battery) |
| Circuit designed | Digital & Pre-program |
| Software | Yes |
| Amplitude (mA) | 0-80 (Adjustable) |
| Pulse rate (Hz) | 120 max |
| Width (μs) | 260 fixed |
| Power ON indicator | LCD |
| Timer (min) | 0~ 60 |
| Weight (grams) (batt. not include) | 100 |
| Size (mm) | 90×5.08×12.7 |
| Prescription or OTC | OTC |
| Maximum Output Voltage (V) (±10%)<br>@ 500Ω<br>@ 1kΩ<br>@ 2kΩ | <br>40<br>68<br>92 |
| Maximum Output Current (mA) (±10%)<br>@ 500Ω<br>@ 1kΩ<br>@ 2kΩ | <br>80<br>68<br>46 |
| Pulse Width (μS) | 30-260 |
| Frequency (Hz) | 1-150 |
| Maximum Phase charge (μC) @500Ω | 20.8 |
| Maximum Current Density ($mA/cm^2$) @500Ω | 0.1 |
| Maximum Power Density ($W/cm^2$) @500Ω | 0.004 |



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7> Device Drawing : As the following specification table.

See the following details.



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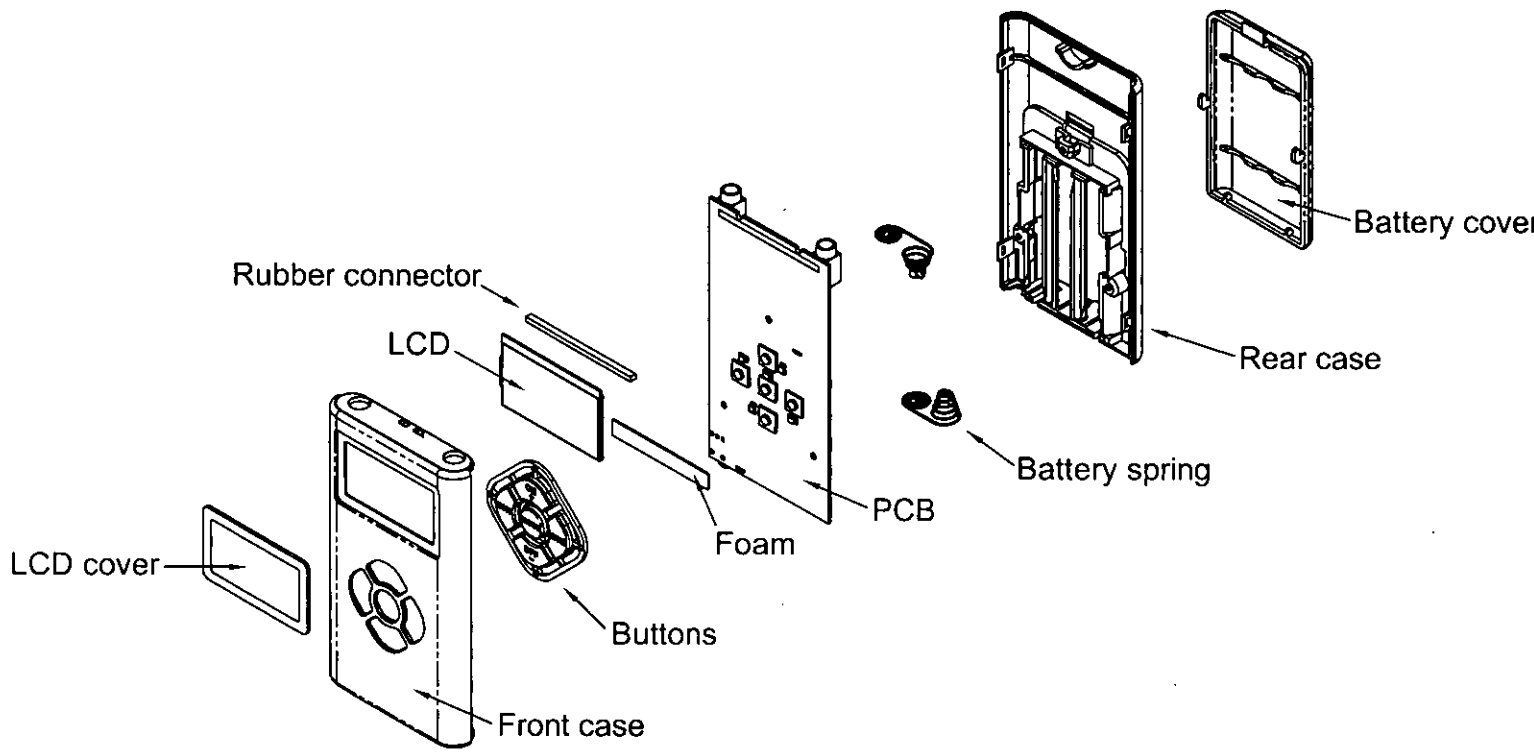


| 變更紀錄 | | | | | | | | | | 圖面編號 | | 公司名稱 | Well-Life Healthcare Ltd. | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 欄位 | 變更位置 | 變更日期 | 經辦 | 核准 | 欄位 | 變更位置 | 變更日期 | 經辦 | 核准 | 繪圖 | Sam | 機種名稱 | WL-2407 | |
| 1 | | | | | 4 | | | | | 檢查 | | 圖檔名稱 | | |
| 2 | | | | | 5 | | | | | 核准 | | 版本 | | 材料編號 |
| 3 | | | | | 6 | | | | | 製圖日期 | | 頁數 | 1/1 | |

(b) (4) Engineering Diagrams

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# Attachment 4.

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# Substantial Equivalence Discussion for K091757

## 1> General

Basically this report is aimed at providing the substantial equivalence evidence for the comparison among Well-Life new device of K091757 and the chosen predicate 510(K) cleared devices. For this report, the information for the chosen predicate 510(K) cleared devices was provided in section 2, the comparison table was presented in section 3, and the results as well as the conclusions of Substantial Equivalence Comparison was provided in section 4.

## 2> Information of chosen predicate 510(K) cleared model.

As mentioned in our previous submission, the new model was modified from our Well-Life's K063660-510(K) cleared model and compared to the following two predicate devices with the same operation method and indication for use:

1. Re: K033122.

   Classification Name: Transcutaneous Nerve Stimulator.
   Trade/Proprietary Name: Prizm Medical, Inc. 5000-Z System.
   Classification: Class II (21 CFR 882.5890)
   Product Code: NUH
   Dated: February 10, 2005.

2. Re: K060846.

   Classification Name: Transcutaneous Nerve Stimulator.
   Trade/Proprietary Name: Endurance Therapeutics T1040.
   Classification: Class II (21 CFR 882.5890)
   Product Code: NUH, NGX, GZJ
   Dated: December 03, 2007.

For substantial equivalence comparison, we provided the following two attached information for K033122 & K060846 hereafter:

- Appendix 1. SE information for K033122.
- Appendix 2. SE information for K060846.



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## 3> Specification Comparison between new model and cleared models

For the comparison concerning these features, please see the following comparison table:

| Comparison Features | Models to be Compared | | |
|---|---|---|---|
| | WL-2407 (Well-life) | 5000Z (Prizm) | T1040 (Endurance) |
| Prescription or OTC | OTC | OTC | OTC |
| Indication for use | Pain relief for Arm and leg | Pain relief for Arm and leg | Pain relief for Arm and leg |
| FDA product code | NUH | NUH | NUH & NGX |
| Electrode Used | 1. Garment electrodes<br>2. Adhesive electrode<br>3. Arm belt electrode with conductive gel | Garment electrode | adhesive electrode |

In addition to the significant comparison feature, we also provided the comparison for the output characteristics as the following table:

| Quantity | WL-2407 (Well-life) | 5000Z (Prizm) | T1040 (Endurance) |
|---|---|---|---|
| Max. voltage over 10kΩ, V | 94 | 226 | 154.1 |
| Max. Current over 10kΩ, mA | 9.4 | 22.6 | 15.4 |
| Max. Voltage over 2.2kΩ, V | 56 | 218 | 105.1 |
| Max. Current over 2.2kΩ, mA | 18.18 | 99 | 47.8 |
| Max. Voltage over 500Ω, V | 40 | 208 | 40.7 |
| Max. Current over 500Ω, mA | 80 | 416 | 81.4 |
| Pulse Width, αseconds | 260 | 100 | 210 |
| Pulse Period, msec | No specified | 10 | 4.1-500 |
| Max. Pulse Frequency, Hz | 120 | 120 | 245 |
| Max. Charge per Phase over 500Ω, αc | 20.8 | 3.4 | 16.916.9 |
| Max. Current density over 500Ω, mA/cm$^2$ | 0.1 | 16.64 | 2.71 |
| Max. Average Power Density over 500Ω, mW/cm$^2$ | 4 | | 5.35 |

Note: 1. The technical information for WL-2407 is based on the testing waveform and calculation of real sampling model.

2. According to the information in the comparison table, the technical specification for all of three models are within the acceptable limit as specified by FDA guidance for TENS devices.

3. The information of 5000z (Prizm) and T1040 (Endurance) comes from the 510(K) summary of T1040 (Endurance/K060846) released on FDA web-site.

**For the further substantial equivalence comparison, please see the following section.**



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## 4> Substantial Equivalence Comparison

Based on the detail information and comparison as above mentioned, the following analysis for the possible impact concerning the comparison difference as well as its conclusion is presented:

### 4.1. The Issue of Specification difference and risk assessment

According to the specification comparison described in chapter 3, the main specification difference may be listed hereafter:

| No | Difference | Brief Description of Difference | Evaluation of difference and/or justification |
|---|---|---|---|
| 1 | Treatment time | ⅄ Prizm 5000-z is 15 minutes ~ 24 hours.<br>⅄ Unknown for Endurance T1040.<br>⅄ WL-2407 is 1~ 60 minutes | This difference does not cause any impact on operation function |
| 2 | Intensity amplitude | ⅄ Prizm 5000-z is 0~200 Volts<br>⅄ Endurance T1040 is 0~150 Volts.<br>⅄ WL-2407 is 0~160 Volts | WL-2407 provided higher safety operation level than prizm 5000-z device |
| 3 | Wave form | ⅄ Prizm 5000-z is mono-phase pulse with 100αs fixed pulse duration.<br>⅄ Endurance T1040 provides 210 αs pulse duration.<br>⅄ WL-2407 is monophase pulse with 260 αs fixed pulse duration | For the WL-2407 wave form, Well-life has proven the effectiveness in K063660, so reasonable to claim the same clinical effectiveness, even there exist some differences in wave form between two models. |
| 4 | Power Supply | ⅄ Prizm 5000-z use 3V (2*AAA battery) power<br>⅄ WL-2407 use 4.5V (3*AAA battery)power<br>⅄ Endurance T1040 use 4.5V (3*AAA) battery. | The difference on the use of power specification does not cause any impact on the performance and safety of device. |
| 5 | No. of output channel | ⅄ Prizm 5000-z provides only single output channel.<br>⅄ WL-2407 provide 2 independent output channels<br>⅄ Endurance T1040 provide 2 independent output channels. | The difference in the No. of output channel dose not causes any impact on the performance and safety of device. |



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| | | | |
|---|---|---|---|
| 6 | Weight and dimension | ⅄ For prizm 5000-z, the weight is 2.5 ounce, and the dimension is 2"X2.4"X0.65" mm.<br>⅄ For WL-2407, the weight is 100 g, and the dimension is 90X5.08X12.7 mm<br>⅄ Unknown for Endurance T1040. | The difference in the weight and dimensions of device does not cause any impact on the performance and safety of device |
| 7 | The use of electrodes | ⅄ Prizm 5000-z use only garment electrode.<br>⅄ For WL-2407, not only garment electrode but also arm cuff with gel and adhesive electrode are used for Arm and leg.<br>⅄ Endurance T1040 use only adhesive electrode for Arm & Leg pain relief. | ⅄ WL-2407 provides more operation options on Arm and Leg stimulation.<br>⅄ The safety for the use of electrodes for WL-2407 model was assessed with acceptable result in Clause 7.2. |

As comparison evaluation on the above mentioned table, the only technical issue needs justification is the use of electrode. For this technical issue, we have conducted and completed the assessment for the major output characteristics concerning the use of new electrode on our device WL-2407 in clause 4.2, and get the conclusion of acceptable results. For the details of evaluation, please see clause 4.2.

For the main difference as above mentioned, Well-Life has completed the risk assessment according to ISO 14971 and their quality management system. The assessment result indicated that the new models OTC TENS for Arm & Leg Pain Relief / model WL-2407 have the same safety level as well as the same indication for use, while compared with the cleared model Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846).



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## 4.2. Major output characteristics comparison

As previous discussion, the use of garment electrode is the most significant change for this new 510(k) submission. In order to prove that the safety for the use of garment electrodes is still within the acceptable range of TENS device, we make assessment as this clause.

According to the safety requirement as mentioned in FDA guidance for the TENS device, the current density and power density delivered from the TENS device shall be within the acceptable range as specified in the FDA guidance.

Practically speaking, this issue could be easily ensured by comparing the cross-section area of the electrode use. In section 2.4 of the original 510(K) submission document, we have given very clear information to make comparison for the cross section area for each type of electrode. We would like to repeat it again as the following table.

| Location | Electrode use condition | Possible size | Minimum Size |
|---|---|---|---|
| Arm | The use of glove garment or elbow garment. | Glove : S/M/L<br>Wristlet Sleeve:10*18 | 435 $cm^2$ |
| | Adhesive electrode<br>(Well-Life CM5050 or CM50100) | 50 mm x 100mm, or<br>50mm x 50mm | 50mm * 50mm = 25 $cm^2$ |
| | The Neoprene + Conductive silicone pad with conductive gel. | 25mm x 50mm, or<br>50mm x 50 mm | 25mm * 50mm = 12.5 $cm^2$ |
| Leg | The use of conductive sock (garment electrode) | S/M/L/XL | 540 $cm^2$ |
| | The use of conductive knee sleeve (garment electrode) | 10*27 | 380 $cm^2$ |

From the information of table, it is very clear that the cross section area of adhesive electrode is far smaller than any one of garment electrode. Therefore it is also clear without any additional approval that the maximum output current density and power density happens in the condition of using adhesive.
**(Note: The minimum cross-section of the new well-life electrode is 2.5 cm * 5.0 cm =12.5$cm^2$)**

Therefore, it could be reasonable foreseen that the use of garment electrode is safer than the use of adhesive electrode for the same output specification of TENS device. And the comparison of output characteristics is only required for the condition of using adhesive electrode.



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Based on this conclusion, we would like to provide the comparing calculation for WL-2407 in the condition of using adhesive electrode of the same dimension as the followings.

The major output characteristics are compared hereafter:

1. Maximum charge per pulse.
   Maximum charge per pulse = maximum current x maximum pulse width
   Maximum charge per pulse of WL-2407 = 0.26s X 80mA = 20.8 micro coulomb,

   All the maximum charge per pulse of above devices are smaller than 25 micro coulomb.

2. Maximum average current density.
   Maximum average current density = $I^2$x R / Area
   = (Ix Duty cycle) $^2$ / Area
   In here, R = 500ohm, electrode area = 12.5 $cm^2$; the calculation is as hereafter.
   Maximum average current density of WL-2407 = 0.0998 $mA/cm^2$ $\cong$ 0.1 $mA/cm^2$

3. Maximum peak power density.
   Maximum peak power density = I x V / Area; the calculation is as hereafter.
   Maximum peak power density of WL-2407 = 3.99 $mW/cm^2$ $\cong$ 0.004 $W/cm^2$

For the calculation of the data as above mentioned, please see NS4 test report.

Based on the comparison information as above mentioned, the major output characteristics for the new model and the predicated cleared model are within the acceptable range of ANSI/AAMI NS4.



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## 4.3. Analysis for the other conformity issues

### A. Design control actives

As mentioned in clause 3 and clause 4.1, the different hardware circuit and different power supply voltage was used for the new device and 510(K) cleared device. Basically the new device and Endurance Therapeutics T1040 (K060846) used 4.5V (3xAAA battery) power. Prizm 5000-Z (K033122) used 3V (2xAAA battery) power.

For this difference, we have carried out the following tests to prove that our new devices were still in compliance with the requirement of the following two standards:
- Performance test according to ANSI/AAMI NS-4 1985.
- EMC test according to EN 60601-1-2: 2001
- Electrical Safety Test according to EN 60601-1:1990/A13:1996.

All the design control actives were performed in accordance with the design control procedures of Well Life. Therefore; we believe it is appropriate to address that the new device, OTC TENS for Arm & Leg Pain Relief / model WL-2407 is substantial equivalent to our predicated model Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846).

### B. Materials and Composition

Basically the materials used for the construction of the different mechanical parts are completely identical for the new device and the device being modified.

The garment electrode is the only new material used for our new device OTC TENS for Arm & Leg Pain Relief / model WL-2407. Since the garment electrode used for OTC TENS for Arm & Leg Pain Relief / model WL-2407 is the 510(k) cleared electrodes which has been claimed for the use of TENS device, it may be considered adequate to use this garment electrode for our new device from the material and composition point of view. The 510(K) cleared information for the garment electrode has been provided in clause 2.4 of original submission document.

Therefore, in terms of materials and composition, the OTC TENS for Arm & Leg Pain Relief / model WL-2407 do not involve any changes or modifications which could significantly affect the safety or effectiveness of the modified device, as compared to the cleared models: Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 K060846).



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## 5>. Assessment Conclusions and Signature

Based upon the clear 510(K) predicate model information and substantial equivalence comparison as above mentioned, we can conclude that the Well-Life OTC TENS For Arm & Leg Pain Relief/ Model: WL-2407 could be considered as substantial equivalent to the chosen 510(K) cleared predicate models Prizm 5000-Z (K033122) and Endurance Therapeutics T1040 (K060846).

This evaluation was carried out by David Wu, reviewed and approved by Jenny Hsieh.

| Signature | |
|---|---|
| Comparison conducted by David Wu | Comparison approved by Jenny Hsieh |
| David Wu | Jenny Hsieh |



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Appendix 1. SE Information for K033122



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K033122



## 510(k) SUMMARY of SAFETY and EFFECTIVENESS

### I. GENERAL INFORMATION

| | |
|---|---|
| **Trade or (Proprietary) Name:** | 5000Z System (OTC) |
| **Common or usual name:** | Transcutaneous Electronic Nerve Stimulator (TENS) |
| **Classification Name:** | FDA has classified Transcutaneous Electronic Nerve Stimulator (TENS) as Class II devices. (21 C.F.R. § 882.5890) |
| **Submitter's Name And Address:** | Cathryn N. Cambria<br>for Prizm Medical, Inc.<br>Regulatory Resources Group<br>5536 Trowbridge Drive<br>Dunwoody, GA 30338 |
| **Submission Date:** | September 29, 2003 |

### II. INDICATIONS FOR USE

The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs).

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## III. DEVICE DESCRIPTION

The 5000Z System (OTC) is a compact battery operated transcutaneous electrical stimulator that delivers a micro-current to the surface area of our patented conductive Silver-Thera E.M. garment electrodes to provide electrical stimulation for pain. It is designed not to exceed 100 volts across the garment electrodes. The technical Specifications for the 5000Z Stimulator can be found in Exhibit E. It is microprocessor controlled, allowing for easy setup of the treatment parameters and precise control of each setting, with a garment electrode dedicated to the upper or lower extremities. The system incorporates a proprietary connection from the stimulator to the electrodes that renders the device unusable without the dedicated electrodes. It is designed for ease of patient use with clearly marked intensity buttons.

Please refer to the Operations Manual (Exhibit A) for photographs and a more thorough description of the device.

The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs).

The primary function of the 5000Z System (OTC) is the same as the Micro-Z™ Stimulation System, Axelgaard Mfg. Co. UltraStim Kit and Woodside Biomedical ReliefBand® and raises no new questions of safety and effectiveness.

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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 MD 20850

Prizm Medical, Inc.
c/o Ms. Cathryn N. Cambria
Regulatory Resources Group, Inc.
5536 Trowbridge Drive
Dunwoody, GA 30338

APR 15 2005

Re: K033122
Trade Name: Prizm Medical, Inc. 5000-Z System
Regulatory Name: 21 CFR 882.5890
Regulatory Class: II
Product Code: NUH
Dated: February 10,2005
Received: February 10,2005

Dear Ms. Cambria:

We have reviewed your Section 510(k) preinarket 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Warnings section of the device labeling immediately following the indications for use section:

1. Warning: If you have numbness, tingling or loss of feeling/sensation in your arms, hands, legs or feet. this may represent a more serious problem like diabetic neuropathy. Consult your physician before using the device.

2. Warning: If you have swelling of the arm or leg, it may be more serious than simple muscle pain from overuse. Consult your doctor before using the device.

3. Warning: Use the glove or stocking only on healthy skin. Do not use on open wounds or rashes, or over swollen, red, infected or inflamed skin.

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Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device'and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



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

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# Indications for Use

510(k) Number (if known): K0?3122

Device Name: Prim Medical, Inc. 5000

Indications For Use: "To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities."

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

4/15/05



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

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Appendix 2. SE Information for K060846



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

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K060846



## 510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92(c)

**1.0 Submitter's Name and Address:**

Endurance Therapeutics
122B First Street, NE
Dauphin, Manitoba Canada
R7N 1B5

**Contact Name:**
Brad Brezden
122B First Street, NE
Dauphin, Manitoba
Ph. / Fax 1-877-274-4962

DEC 0 3 2007

**Date Prepared:** August 27, 2007

**2.0 Name of Device and Classifications**

**Trade/Device Name:** T1040:
**Common Name:** TENS
**Regulation Number:** 21 CFR 882.5890
Transcutaneous Electrical Nerve Stimulator for Pain Relief
**Classification Name:** Stimulator, Nerve, Transcutaneous, Over-the-Counter.
**Regulatory Class:** Class II
**Product Code** NUH, NGX, GZJ

**3.0 Predicate Devices**

| | | |
|---|---|---|
| K011880 Compex Sport | Sport Muscle Stimulator | 21CFR890.5850 OTC |
| K033122 Prizm Medical inc. | 5000Z OTC TENS | 21CFR882.5890 OTC |
| K050174 Bio Stim Kit, | Back Pain Relief System | 21CFR882.5890 OTC |

**4.0 Device Description:**

The T1040 is a portable; battery powered (4.5 VDC) multi function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device.

Independent channel (two pads) that effectively transfers your desired choice of pre-programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. A garment belt is used to hold the electrode pads to treat the lower back muscles. There are 10 modes of operation, 6 manual and 4 automatic.



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**Electrical Parameter Comparisons**

**Table 14 – Comparison Table**

| Quantity | T1040 | Bio-Stim | Compex | 5000Z |
|---|---|---|---|---|
| Max. Voltage over 10kΩ, V | 154.1 | 132 | 126.8/103.3 | 226 |
| Max. Current over 10kΩ, mA | 15.4 | 13.2 | 12.7/10.3 | 22.6 |
| Max. Voltage over 2.2kΩ, V | 105.1 | 90 | 167.8/153.5 | 218 |
| Max. Current over 2.2kΩ, mA | 47.8 | 41 | 76.3/69.8 | 99 |
| Max. Voltage over 500Ω, V | 40.7 | 29.5 | 48 | 208 |
| Max. Current over 500Ω, mA | 81.4 | 59 | 96.1 | 416 |
| Pulse Width, μseconds | 210 | 30 - 225 | 270 | 100 |
| Pulse Period, msec | 4.1 - 500 | 9 – 12.5 | 125 | 10 |
| Max. Pulse Frequency, Hz | 245 | 110 | 118 | 120 |
| Max. Charge per Phase over 500Ω, μC | 16.9 | 7.6 | 32.3 | 3.4 |
| Max. Current Density over 500Ω, $mA/cm^2$ | 2.71 | 3.93 | 3.84 | 16.64 |
| Max. Average Power Density over 500Ω, $mW/cm^2$ | 5.35 | 1.1 | 10.2 | |

## 5.0 Intended Use:

To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto1 or Auto 4

Is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2

## 6.0 Substantial Equivalence:

The electrical stimulation provided by the T1040 is substantially equivalent to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling; i.e., for OTC sale. The pulses in the waveform combinations are restricted in amplitude and duration to values consistent with other devices quoted above.(see Appendix 4)

Technological characteristics, features, specifications, materials and intended uses of the T1040 are substantially equivalent to the quoted predicate devices.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness.



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The T1040 has modes that offer substantially equivalent technical specifications, features and effective results as each of the predicates listed.

## 7.0 Non-Clinical Tests Performed:

Compliance to applicable voluntary standards includes AAMI NS-4 1985, as well as EN 60601-1, EN 60601-1-2, ISO 9001;2000 and ISO 13485:2003

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

## 8.0 Conclusion:

The electrical stimulation provided by the T1040 is similar to that commonly employed by muscle stimulators and TENS devices that have been cleared for marketing without prescription labeling.

The T1040 has the same intended uses and the similar technological characteristics as these OTC cleared predicates. Moreover, verification and validation tests contained in this submission demonstrate that the differences in the T1040 still maintain the same safety and effectiveness as that of the cleared devices.

In other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Concerns of safe and proper use of electrodes and electrode pad placements have been fully addressed by making the user conscious of the proper placement of electrodes and proper operations of the device through detail in the User's Instruction Manual.

We believe that there are no new safety or effectiveness issues concerning this device to be introduced.

The safety of the device, to be used for the proposed indications without medical prescription or supervision, is established by the fact that no adverse events have been reported since 2002 with over 300,000 units sold with out a prescription in 20 countries.

Over 300 000 units sold with no adverse effects reported, proves its specific technical, safety measures and features are safe and effective when used without medical supervision. An even greater and more detailed user instruction manual regarding safe operation and adhesive pad placements is proposed for the USA marketplace and consumers.

The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrate that electrical stimulation does improve muscle performance as well as temporary pain reduction.



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

DEC 0 3 2007

Endurance Therapeutics
% Mr. Brad Brezden
CEO
122 B – First Street, NE
Dauphin, Manitoba, Canada
R7N 1B5

Re: K060846
Trade/Device Name: T1040
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH, NGX
Dated: August 27, 2007
Received: September 4, 2007

Dear Mr. Brezden:

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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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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



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## 13.0 Statement of Indication for Use

510(k) Number (if known): K060846

Device Name: T1040

Indications for Use:

To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4

To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3

To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Auto1 or Auto 4

Used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2

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

(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 General, Restorative, and Neurological Devices**

**510(k) Number** K060846



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# Attachment 5.



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

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# Chapter 4. Labeling

Basically the labeling for the new models include the labeling on the product package and user manual. The labeling on the product package is as indication of section 4.1, and the detail labeling of user manual for each new models are as indication of section 4.2.



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

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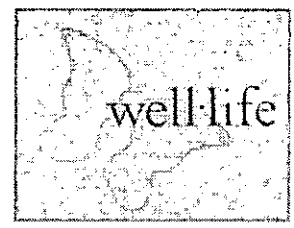
## 4.1. Example for the product Labeling

Brand Name (logo).

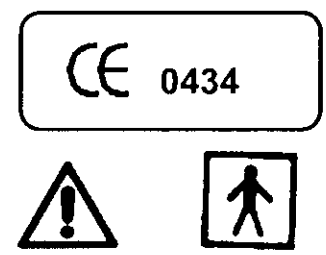



Product label

WL-2407 S/N:

OTC TENS For Arm & Leg Pain Relief.

Made by Well-Life Healthcare Ltd. Taiwan

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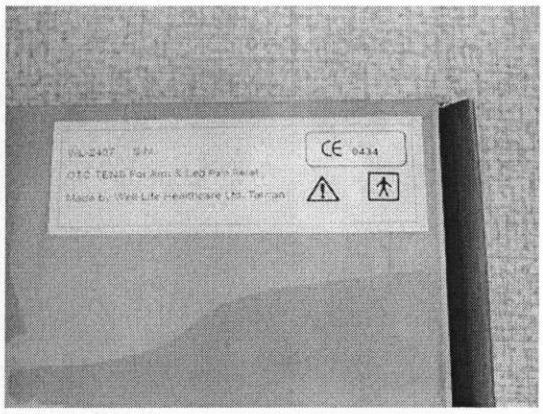
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

## Photos of product labeling

| Package of Device | Package of Device |
|---|---|
| | |

| Well-Life label on package | Package and Device |
|---|---|
|   | |

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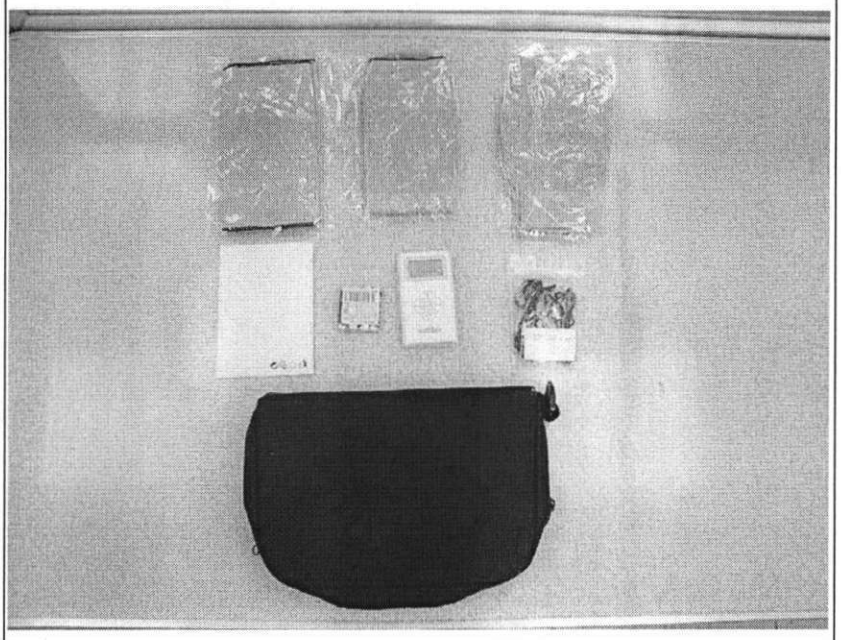
639. WL-2407 interior package & Contents



638. WL-2407 & Standard Accessories.

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## 4.2. WL-2407 OTC TENS for Arm & Leg Pain Relief User Manual

See the following details.



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

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# Operation Manual

Model: WL-2407

WELL LIFE HEALTHCARE LTD.

1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C



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

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# WELL LIFE

# Arm and Leg Pain Management System

## Intended Use

The WELL LIFE Arm & Leg Management System WL-2407 is intended for temporary relief of p ain associated with sore and aching muscles in the upper and lower extremities ( arm and/or leg) due to strainfrom exercise or normal household and work activities.

## Table of Contents


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

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## SAFETY INSTRUCTIONS

Read instruction manual before operation. Be sure to comply with all "CAUTIONS" and "WARNINGS" in the manual. Failure to follow instructions can cause harm to user or device.

Please read the following information carefully before using the **WELL LIFE Arm & Leg Pain Management System.**

**Contraindications: Do not use this System if any of the following conditions are present.**

- Do not use this System if you have a cardiac pacemaker, implanted defibrillators or any other implanted metallic or electronic device.
- Do not use this System if you have undiagnosed chronic pain.

**Warnings for proper use and safety**

**If you have numbness, tingling or loss of feeling/sensation in your arms, hands, legs or feet this may represent a more serous problem like diabetic neuropathy. Consult your physician before using the device.**

**If you have swelling of the arm or leg, it may be more serious than simple muscle pain from overuse. Consult your physician before using the device.**

**Use the glove or stocking only on healthy skin. Do not use on open wounds or rashes, or over swollen, red, infected or inflamed skin.**

- If you are under the care of a Physician, consult with your Physician before using this System.
- The long-term effects of this System are not known.
- Do not place the pads on or close to your heart.
- Do not place the pads around or close to your neck. Do not apply stimulation over the neck. Severe spasm of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck could also have adverse effect hearing or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart.
- Do not place the pads on or around your head. The efects of stimulation of the brain are unknown.
- Do not use the pads over or close to sores.
- Do not use this System while sleeping.
- Do not use if you feel numbness.
- Do not use this System in or close to water.
- Use the pads only on normal, healthy, clean and dry skin. Do not use the pads on open wounds or rashes, or over swollen, red, infected or inflamed skin.
- If you have ever had back surgery, consult your Physician before using this System.



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

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## Precautions for the safe use of this WELL LIFE Arm & Leg Pain Management System

- Read User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- The System is intended for individual person use.
- The System is not effective for pain associated with Central Pain Syndromes, such as headaches.
- The System is for pain caused by muscle soreness, and should be placed only around muscles where pain originates.
- The pain may indicate that you have some other health problem. You should know the reason and source of your pain before using this System. Do not solely rely on the treatment of this System for pain.
- The safety of using the System during pregnancy or birth has not been established.
- The effectiveness of the System depends greatly on a person's individual physical condition. It may not always be effective for every user.
- If you have had medical or physical treatment for your muscle pain, consult with your treatment provider before using this System. You should contact your physician prior to using the System following recent surgical procedures. Stimulation may disrupt the healing process.

⚠ **Use Caution and consult your Physician before using System if any of the following conditions apply to you:**

- If you have suspected or diagnosed heart problem.
- If you have suspected or diagnosed epilepsy.
- If you have a tendency to bleed internally following an injury.
- If you recently had surgery, or have ever had surgery on your back.
- If areas of skin lack normal sensations, such as skin that tingles or is numb.
- During menstruation or during pregnancy.
- Some people may feel skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using your System and consult your Physician.
- If skin under one of more pads feels irritated after using the stimulator for a long period of time, use the stimulator for a shorter period of time.
- Minor redness at stimulation placement is a normal skin reaction. It is not considered as skin irritation, and it will normally disappear within 30 minutes after the electrodes are removed. If the redness does not disappear after 30 minutes from the removal of electrodes, do not use the stimulator again until after the excessive redness has disappeared.
- Turn off the stimulator if the stimulation feels unpleasant or does not provide pain relief.
- Keep your System out of the reach of children.
- Use your stimulator only with the pads, snap cables and accessories recommended by the manufacture.
- Do not use this System when driving, operating machinery or when swimming.
- Before removing the belt and pads, be sure to turn OFF both power knobs to avoid unpleasant stimulation.
- **If your pain does not improve, becomes more than mild or if it continues for four to six days, stop using this System and consult your Physician.**

### Adverse Reactions

- Skin irritation and burns under the pads have been reported by some people who have applied electronic stimulators to their skin.



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

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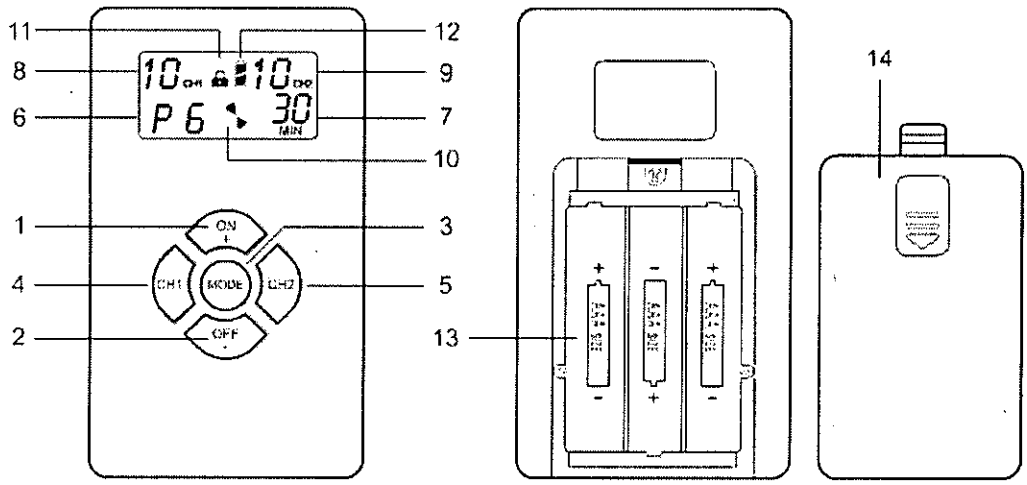
## ABOUT THE DEVICE




Front View

Rear View

1. Power on / adjust / increase setting key
2. Power off / adjust / decrease setting key
3. Program / therapy time selection
4. CH1 key
5. CH2 key
6. Program number
7. Therapy time remaining
8. CH1 intensity level
9. CH2 intensity level
10. Therapy duration status
11. Lock status indicator
12. Battery status indicator
13. Batteries compartment
14. Battery cover



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## How Your WELL LIFE Arm & Leg Pain Management System works

The main function of p ain relief comes fr om the continuous stim ulation pulse generated from the dual channels stimulator. We can not ensure that the pain relief is 100% effective for everyone. However , when used according to our instruction, it can be a safe, non-addictive, non-invasive pain reliever.

## Conditions that may affect your WELL LIFE Arm & Leg Pain Management System

Since the stimulator is a battery-operated electronic System, its output performance and safety may be affected greatly in extreme humidity. Therefore, it is very important to keep the stimulator dry to ensure the safety and performance of the stimulator.



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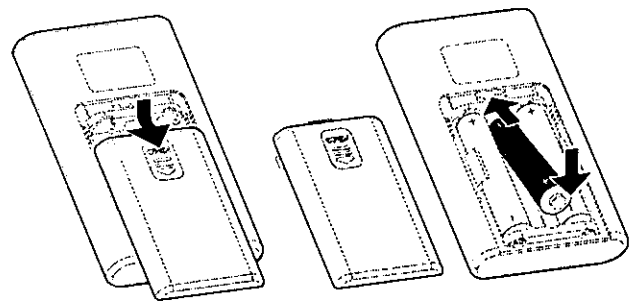
# Operation Instruction

## Inserting/Changing the Batteries

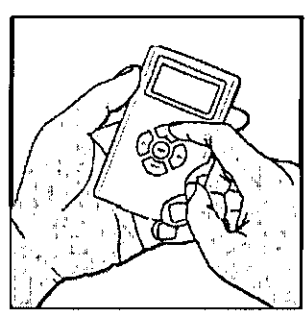


1. Open the battery compartment at the back of the device by pushing the battery cover labelled "Open" downward (this area features raised marks for easy identification).
2. Insert 3 AAA (1.5 V) batteries in the battery compartment; make sure to match up the symbols (+/–).
3. Close the battery cover by carefully placing the stud into the slot in the rear area and sliding it upward, applying slight pressure.
4. Follow the same procedure when replacing the battery at a later date.

**Note** : for important precautions regarding the batteries ,please be informed:

- Always use only 3x1.5V(AAA) batteries.
- Keep away from children.
- Do not recharge.
- Do not short-circuit.
- Do not throw into a fire.
- Please recycle. Do not dispose of old batteries with your household waste; dispose of them safely at your
- recycling centre or business where the batteries were purchased.

## Turning On the Device



1. Press and hold the ON+ buton for two (2) seconds to turn on the device.
2. The most recently selected treatment time and program will flash when the unit is turned on.

## Turning Off the Device

1. The device turns off automatically after the therapy session time has elapsed.
2. To turn the unit off manually, press the OFF- button for three (3) seconds. The display will blank and the device will turn off.
3. In an emergency you may also pull the connector(s) from the device and then remove the cuff or belt.

**Note**: To prevent unpleasant electric shocks, never remove the device while it is still turned on.



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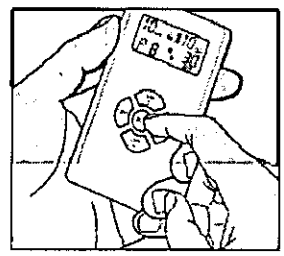
## Selecting the Treatment Time



1. Press MODE. The preset (default) treatment time will flash on the display.
2. To increase or decrease the treatment time, press the button ON + (to increase) or the button OFF – (to decrease) repeatedly until the desired duration appears on the display.
3. Press MODE again to save your selection. The treatment time you selected will appear on the display the next time you turn the device on.

**Note**: If you change programs during the course of a therapy session, the treatment time will not reset unless you manually reset it by performing the steps described above.

## Selecting the Program

The stimulator WL-2407 offers eight different preset treatment programs. The programs differ with respect to varying pulse widths and frequencies. The user may choose suitable stimulation mode depending on hips personal condition, as the following trail and determination steps :

1. Start from P1, change every mode for a couple of seconds, and sense the stimulation of each mode.
2. Choose the suitable mode in which you feel most comfortable, and set the device at that model.
3. In case you feel senseless about the determined mode before the end of stimulation, repeat 1 & 2 steps to change the operation to the other suitable stimulation model.

## Selecting the Therapy Intensity Level

1. Intensity is adjustable according to the channel selected. Select the channel you wish to adjust by pressing CH1 or CH2. "CH1" or "CH2" will flash on the display.
2. To increase or decrease the intensity, press ON +(to increase) or OFF – (to decrease) repeatedly until the desired intensity level flashes on the display.

**Note**: You will feel the intensity increase or decrease as you select the intensity level. You can use this as a guide to select a level that is comfortable for you.

3. Press MODE to save your selection.



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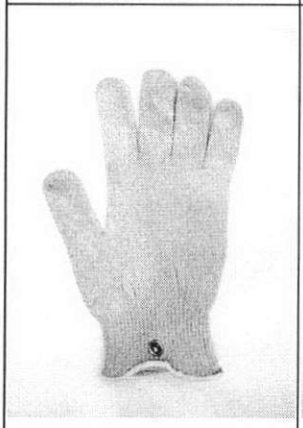
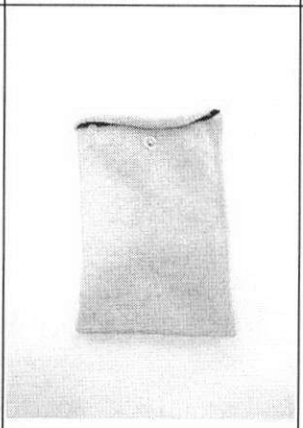
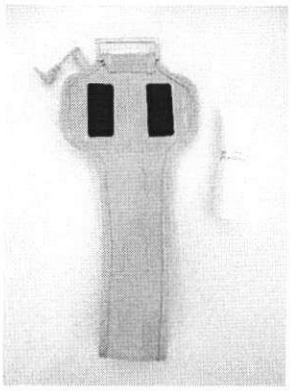
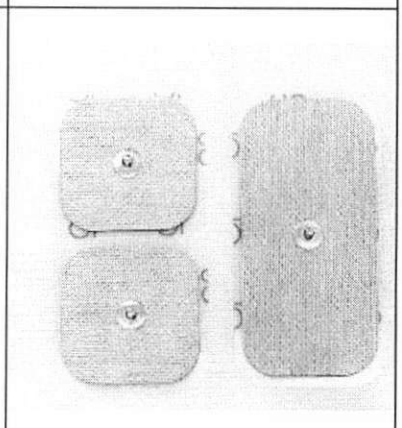
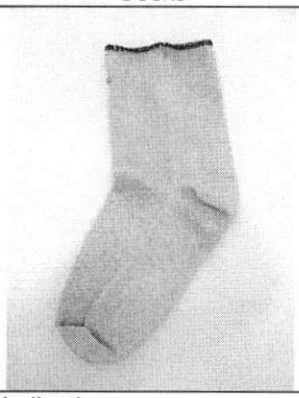
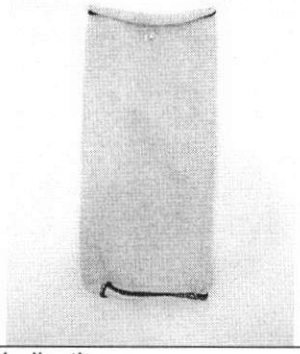
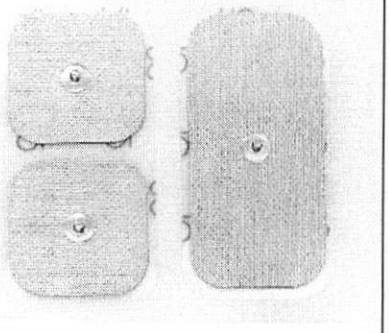
## Putting on Accessories

As mentioned on the description of "Intended Use", user could choose from System arm /Leg accessories pack , optional choices by individual from the followings :

| Indication for Arm use | | | |
|---|---|---|---|
| Conductive Mesh Garment Electrode Glove | Conductive Mesh Garment Electrode Elbow Sleeve | Support belt + Conductive Silicone pad with gel tube | Self Adhesive Electrodes |
|  |  |  |  |
| Size indication:<br><br>Theraknit Part no, measured by Palm Width .<br><br>Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm | Size indication:<br><br>Theraknit Part no, measured by elbow circumference<br><br>Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 3010: over 30 cm | One size fit all neoprene belt (adjust by Velco according to arm circumference 24~36 cm ) , Well-Life part no. TB-0040<br><br>Size of conductive silicone pad is - 25x50mm, 2 pcs ; Well-Life part no. SP2550 , or bigger size 50x50mm available | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |

| Indication for Leg use | | |
|---|---|---|
| Conductive Mesh Garment Electrode Socks | Conductive Mesh Garment Electrode Knee Sleeve | Self Adhesive Electrodes |
|  |  |  |
| Size indication:<br><br>Theraknit Part no, measured by shoe size.<br><br>Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size | Size Indication :<br><br>Theraknit Part no, measured by Knee circumference .<br><br>Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm | A pack of 4 pcs square size ( 5x5 cm) , or rectangular ( 5x10 cm) of self-adhesive electrodes.<br><br>Well-Life part no. CM-5050, CM-5010. |



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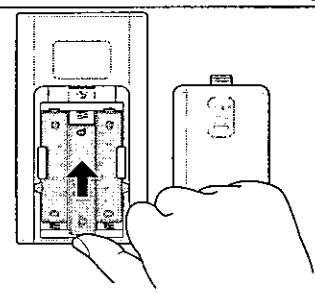
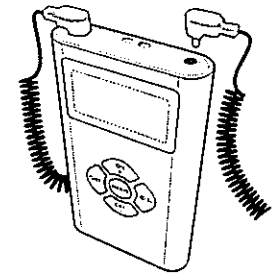
## Quick reference Guide

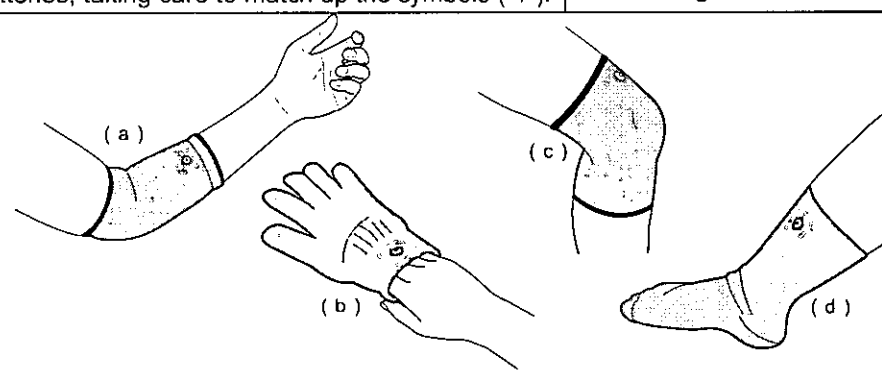
### i. How to attach conductive mesh garment electrode (Glove, Sock, Elbow/Knee )



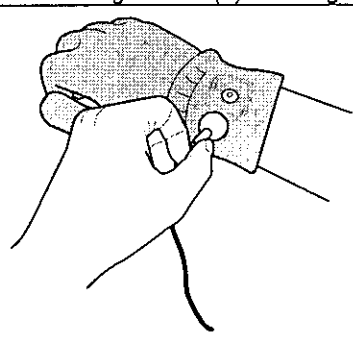
Step 1:
Insert 3AAA batteries, taking care to match up the symbols (+/-).



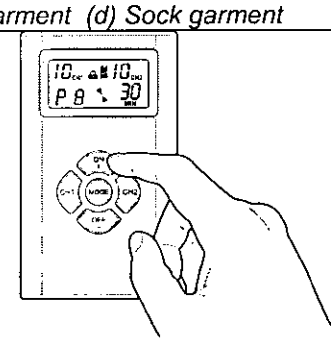
Step 2:
Connecting the cable to the device.




Step 3: Preparing treatment site and accessories
*(a) Elbow Sleeve garment (b) Glove garment (c) Knee Sleeve garment (d) Sock garment*

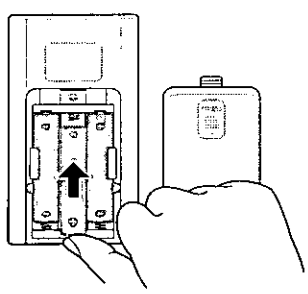


Step 4: Putting cable on the garment

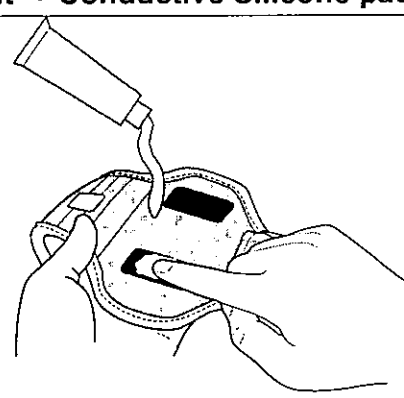


Step 5:
Power On / Select Program / Timer / Intensity Level

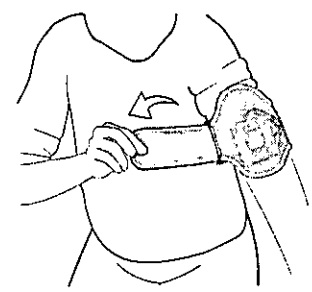
### ii. How to attach Support belt + Conductive Silicone pad with gel tube on the arm



Step 1:
Insert 3AAA batteries, taking care to match up the symbols (+/-).



Step 2:
Before use, dampen the integrated silicon electrodes with water or a conductive gel.



Step 3:
Insert the belt through the square ring, stretch the ends of the cuff, and press the electrodes firmly against your skin



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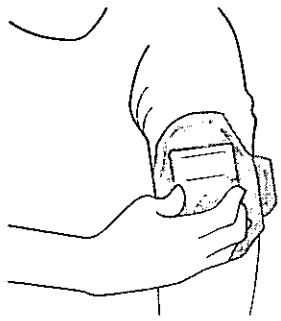
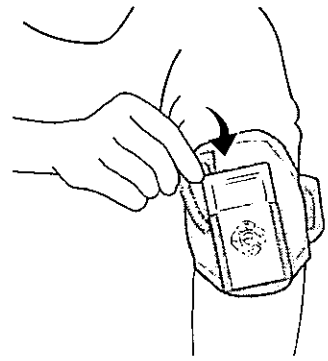


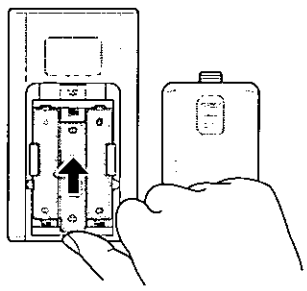
Step 4:
Insert the device into clip holder



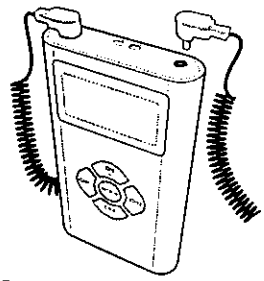
Step 5:
Connecting the cable to the device.

Step 6:
Power On / Select Program / Timer / Intensity Level

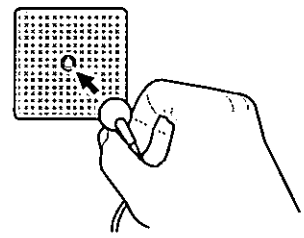
## iii. How to attach self adhesive electrodes



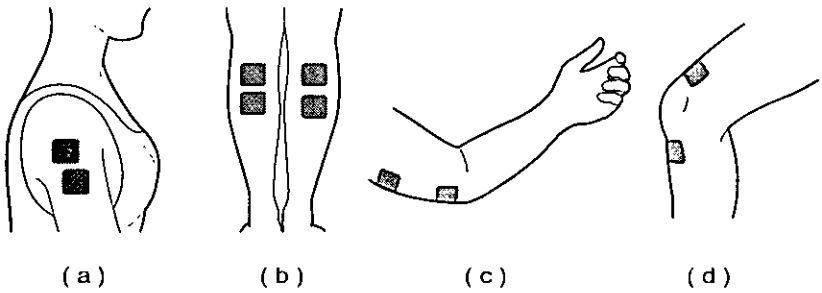
Step 1:
Insert 3AAA batteries, taking care to match up the symbols (+/-).



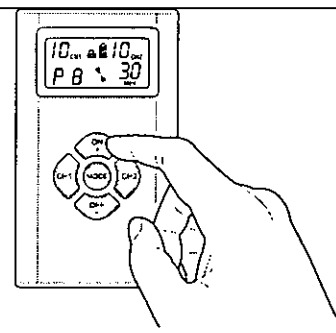
Step 2:
Connecting the cable to the device.



Step 3:
Preparing treatment site and accessories connect the lead wires to the electrodes before applying the electrodes to the skin.




Step 4:
Place the electrodes *(a) shoulder (b) leg (c) elbow (d) Knee*



Step 5:
Power On / Select Program / Timer / Intensity Level



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## How to clean Your WELL LIFE Arm & Leg Pain Management System

**Stimulator**

The stimulator may be wiped clean with a small amount of soapy water on a clean cloth. **Do not submerge the stimulator in liquids or expose it to ANY amounts of water.**

**Snap Cables**

Disconnect the snap cables from the belt and the stimulator. Then snap cables may be wiped with a clean, damp cloth. When re-connecting,take one snap cable, and snap its two connectors onto the metal snaps on one side of the thumbhole. Repeat for other side of thumbhole. Tuck lower snap cable under tension strap toward the top of the belt.

**Conductive Mesh Garment Electrode & Support Belt**

Before washing the belt, remove the pads and put them on the storage liners. Remove the snap cables and the stimulator from the belt. Hand-wash your Support Belt in cool water. Do not wash the belt in the washing machine.

The support belt should be air-dried, lying flat or hanging. **Do not put the belt in clothes dryer.**

## Maintaining Your WELL LIFE Arm & Leg Pain Management System

1. Your Stimulator uses the standard AAA battery. If stimulation seems to be weak, or the stimulator will not turn on, check battery. To replace the battery, make sure both power knobs are turned OFF. Slide the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert the AAA/1.5Volt battery according to the diagram in the battery compartment. To close the cover, slide from the bottom up.

2. Be sure to put the storage liners on the pads when not using your Low Back Pain Management System. You may use the larger storage liners provided. Replace the pads on your support belt if they no longer stick to your skin or to the belt.

3. If your support belt is damp after use, allow it to air-dry before re-applying.

4. When connecting and disconnecting a snap cable, hold it by the molded end and pull. Do not pull on the cable itself. Replace snap cable if worn or broken.



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## How to Store Your WELL LIFE Arm & Leg Pain Management System

1. S tore your Pain Management System at room temperature in a dry place, out of the reach of children.
2. If the stimulator will not be used for more than a week, remove the battery from the stimulator.

## When To Order New Pads

The electrode pads are disposable and use an adhesive that will dry after prolonged usage or storage. Pads should be replaced when they lose their adhesive quality, or you sense a change in stimulation sensation. If you're in doubt about the integrity of the pads, order fresh pads.

To order new pads see Replacement Parts page .

## Check the WELL LIFE Arm & Leg Pain Management System before using

Before using your WELL LIFE Arm & Leg Pain Management System, always check all of the parts to be sure they are in good working order. Make sure of the following:

1. The battery still has power and it is not corroded.
2. All four pads are in the proper place on the support belt, covering the metal snaps.
3. Both snap cables are in good condition.
4. Both snap cables are properly connected to the belt and the stimulator.

## Warranty

This WELL LIFE Arm & Leg Pain Management System carries a one-year warranty from the date of purchase.

The warranty applies to the WELL LIFE Arm & Leg Pain Management System and necessary parts and labor relating thereto. The distributor reserves the right to replace or repair the unit at their discretion.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations or disassembly by unauthorized individuals.



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

## Replacement Parts

Contact WELL LIFE for ordering information for replacement parts, Be sure to use only WELL LIFE Arm & Leg Pain Management System parts.

Conductive Mesh Garment Electrode:

| | |
|---|---|
| **Socks**<br><br>Theraknit Part no, measured by shoe size. | Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size |
| **(Gloves)**<br><br>Theraknit Part no, Measured by Palm Width . | Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm |
| **Elbow Sleeve**<br><br>Theraknit Part no, measured by elbow circumference | Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 3010: over 30 cm |
| **Knee Sleeve**<br><br>Theraknit Part no, measured by Knee circumference. | Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm |

Snap Cable (set of 2): Part # LE-WS-0012
Self -adhesive Pads (set of 4): Part # CM5050 , CM50100
Support belt: Part # TB-0040 + Conductive Silicone pad (set of 2): Part # SP2550

## Conformity to Standards

The Stimulator is in compliance with:

- EN 60601-1: 1990 - Safety of medical device; electrical equipment - General safety.
- ANSI/AAMI NS 4 –1985; Transcutaneous Electrical Nerve Stimulators.



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

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## Troubleshooting Guide

If you have a problem using your Low Back Pain ManagementSystem, review the following table find a solution.

| Problem | Solution |
|---|---|
| The stimulator will not turn on. | Check the battery – be sure it is firmly in place. Change the battery if necessary. |
| The stimulator has new AAA battery, but will not turn on. | Call Customer Service |
| The stimulator turns on and then off quickly | Replace the battery. |
| The stimulator is on, but there is no stimulation | Check the snap cables for breakage. If broken, replace. |
| The stimulator is on, but there is no stimulation | Make sure the snap cables are securely snapped onto the support belt and into the stimulator socket. |



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## WL-2407 Stimulator Technical Specifications

Power Source: 4.5Volt (3xAAA/Alkaline battery)

Dimension: 90 x 5.08 x 12.7mm

Weight: Approx. 100 gram (battery not included)

| Program | Max. | Phase duration | Rate | Function mode | Wave form Type |
|---|---|---|---|---|---|
| P1 | 80mA | 260uS | 15Hz | Constant | A |
| P2 | 80mA | 260uS | 15Hz | Modulated | A |
| P3 | 80mA | 260uS | 120Hz | Constant | A |
| P4 | 80mA | 260~150uS | 2 ~ 100Hz | Modulated | B |
| P5 | 80mA | 260uS | 100Hz | Modulated | A |
| P6 | 80mA | 260uS | 80 <->7 Hz | Modulated | C |
| P7 | 80mA | 260uS | 60Hz | Modulated | A |
| P8 | 80mA | P1 ~P7 | | Cycle | A/B/C |

Time: 1~60 minutes.



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

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# Attachment 6.



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

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## 4.7 Biocompatibility Conformity Evaluation.

### 4.7.1. General.

Basically the only skin contact parts for this series of device is include adhesive electrode. The skin contact category specified according to ISO 10993 may be defined as an externally, tissue communicating, limited duration device.

According to the requirement of ISO 10993 standards, the cytotoxicity, sensitization, irritation/intracutaneous tests may be required for those material.

To ensure the conformity of bio-compatibility, Well-life has submitted the representative skin contact material of electrode to the bio-compatibility texting laboratory for test. The bio-compatibility test report was attached hereafter.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Biocompatibility - Cytotoxicity test report.



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

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FAX : 04-23597862

Contract No. : Q-08041005
Report No. : 9708029-E1

# BIOCOMPATIBILITY STUDY

Test Item :

**CYTOTOXICITY TEST**

Test Artical :

**Well-Life Cutaneous Electrode, Mesh garment, and Neoprene Belt**

Sponsor :

**Well-Life Healthcare., LTD**

Sampling company :

**Well-Life Healthcare., LTD**

Sampling Address :

**1F, NO.16, 454 LANE, CHUNG-CHENG Rd., YOHCHE CITY, TAIPEI HSEIN, TAIWAN, R.O.C.**

Method :

ISO 10993-5

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3. The name of the test article(s) to be tested is supplied by the sponsor; PIDC is responsible for carrying out necessary analyzing procedures only.
4. The Analysis/Test Report is invalid, if it is modified or duplicated without PIDC's permission.
5. PIDC does not guarantee the reported values in the Report when test is done by using other test pieces. The Test Report may not be used as evidence in a court of law.
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Contract No. : Q-08041005
Report No. : 9708029-E1

## INTRODUCTION

The test article identified below was extracted, and the extracts were subjected to an *in vitro* cytotoxicity study for biocompatibility based on the requirements of the International Organization for Standardization, Biological Evaluation of Medical Devices, and Part 5: Tests for in vitro cytotoxicity.

The cells were first exposed to the extract on Jul 29, 2008, and the observations were concluded on Jul 31, 2008.

## MATERIALS

The sample provided by the sponsor was identified and handled as follows :

Test Article : Well-Life Cutaneous Electrode, Mesh garment, and Neoprene Belt

Lot No. : ***

Product No. : ***

Specification of sample : ***

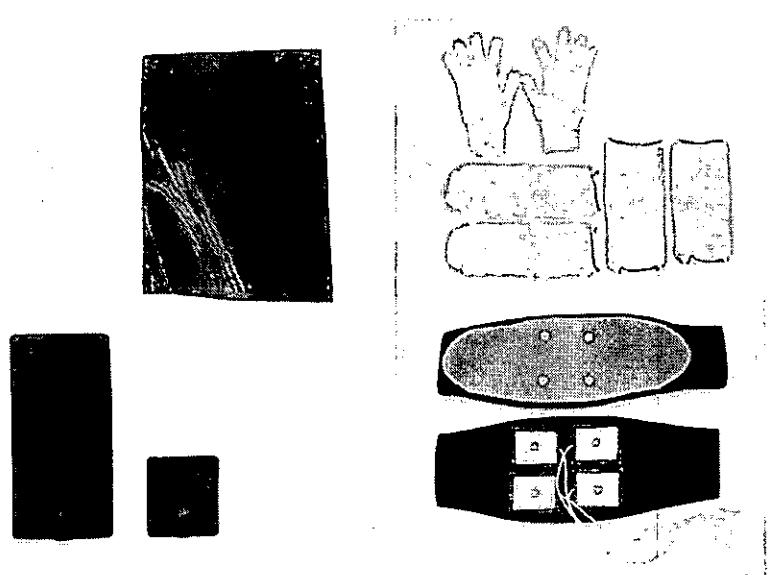
Sample No. : M08051403

Date of receive : 2008.05.14

Date of analysis : 2008.7.29~7.31

Storage Conditions : Room temperature

Sample image :





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Report No. : 9708029-E1

Extraction Vehicle : Minimum Essential Medium (MEM) with 10% horse serum (HS)

Test Article Preparation : Based on the ISO 10993-12, a 1.72 g of the test article was covered with 8.60 mL of MEM with 10% HS. Triplicate preparations were extracted at 37 ℃ for 24 hr. 200 μL of each extract were added to triplicate culture vessels and were incubated at 37 ℃ in 5% $CO_2$ for 48 hr.

Negative Control : The current PIDC negative control material, high density polyethylene, was used as the negative control. Based on the ISO 10993-12, a 2.02 g portion of control material was covered with 10 mL of MEM with 10% HS. Triplicate preparations were subjected to the same extraction conditions as described for the test article.

Positive control : The current PIDC positive control material, tin stabilized polyvinyl chloride, was used to determine a cytotoxicity end-point. Based on the ISO 10993-12, a 2.08 g portion of control material was covered with 10 mL of MEM with 10% HS. Triplicate preparations were subjected to the same extraction conditions as described for the test article.

## METHODS

Test System Management :

L-929 mouse (NCTC Clone 929, derivative of strain L; BCRC 60091) were propagated at 37 ℃ in a gaseous environment of 5% $CO_2$ in an open flask containing MEM supplemented with 10% HS. For this study, wells were seeded, labeled with passage number and date, and incubated at 37 ℃ in 5% $CO_2$ in order to obtain confluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved PIDC Standard Operating Procedures.

Experimental Procedure :

A single culture well with a confluent cell monolayer was selected for each replicate of each preparation (test, negative control, and positive control). Each well was labeled with the lab number (or appropriate control), replicate number (A, B, or C), and dosing date. The growth medium contained in each of three culture wells was replaced with 2 mL of the corresponding replicate of each test extract, negative control, and positive control preparation. All test and control wells were incubated at 37 ℃ in 5% $CO_2$ for 48 hr.

Cell cultures were examine microscopically at 100X magnification to determine cell morphology. Observations for cytotoxicity were evaluated using the United States Pharmacopoeia (USP) guidelines. Scoring for cytotoxicity was based on the following criteria :

| Grade | Reactivity | Condition of Culture |
|---|---|---|
| 0 | None | Discrete intracytoplasmic granules; no cell lysis. |
| 1 | Slight | Not more than 20% of cells are round, loosely attached, and without intracytoplasmic granules; some lysed cells are present. |
| 2 | Mild | Not more than 50% of cells are round and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells. |
| 3 | Moderate | Not more than 70% of cells monolayer contains rounded cells or is lysed. |
| 4 | Severe | Nearly complete destruction of the cell monolayer. |



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

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Report No. : 9708029-E1

For the suitability of the system to be confirmed, the negative controls must have been a grade of 0 (reactivity none) and the positive controls must have been a grade of 3 or 4. The test article passes the test if all three of the monolayers exposed to the test medium showed no greater than a grade of 2 (mild reactivity). The test would have been replaced if the controls did not perform as anticipated and/or if all three test wells did not yield the same conclusion.

## RESULTS

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by PIDC. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice.

The observations and scores obtained were as follow :

| Well | Confluent monolayer | Cell lysis (%) | Score | Reactivity |
|---|---|---|---|---|
| Test article (A) | Present | 0 | 0 | None |
| Test article (B) | Present | 0 | 0 | None |
| Test article (C) | Present | 0 | 0 | None |
| Negative control (A) | Present | 0 | 0 | None |
| Negative control (B) | Present | 0 | 0 | None |
| Negative control (C) | Present | 0 | 0 | None |
| Positive control (A) | Absent | 95 | 4 | Severe |
| Positive control (B) | Absent | 95 | 4 | Severe |
| Positive control (C) | Absent | 95 | 4 | Severe |

## CONCLUSION

Under the conditions of this study, the test extracts showed none evidence of causing cell lysis or toxicity. The test extracts were none cytotoxic and met the requirements of the test. The negative controls, and the positive controls performed as anticipated.



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

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Report No. : 9708029-E1

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated Plastics Industry Development Center (PIDC) archive files.

Experimenter : _____

Study and Supervisory Personnel : _____

R & D Department Medical Device Laboratory

Approved by :



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

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Contract No. : Q-08041005
Report No. : 9708029-E1

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated Plastics Industry Development Center (PIDC) archive files.

Experimenter : I-Wen Tzeng 9/9/2008

Study and Supervisory Personnel : Mei-Jan Chu 9/9/2008

R & D Department Medical Device Laboratory
Approved by :

PLASTICS INDUSTRY DEVELOPMENT CENTER MEDICAL DEVICE LABORATORY R&D Department



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

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# Biocompatibility – Irritation test report.



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Contract No. : Q-08041005
Report No. : 9708030-E1

# BIOCOMPATIBILITY STUDY

Test Item :

**INTRACUTANEOUS REACTIVITY TEST**

Test Artical :

**Well-Life Cutaneous Electrode, Mesh garment, and Neoprene Belt**

Sponsor :

**Well-Life Healthcare., LTD**

Sampling company :

**Well-Life Healthcare., LTD**

Sampling Address :

**1F, NO.16, 454 LANE, CHUNG-CHENG Rd., YOHCHE CITY, TAIPEI HSEIN, TAIWAN, R.O.C.**

Method :

ISO 10993-10

Notice : 1. The Test Report has to be presented, if necessary, as complete copy, not part of it.

2. The contents of this report are for reference only, not for advertising, general public or any other commercial purposes.

3. The name of the test article(s) to be tested is supplied by the sponsor; PIDC is responsible for carrying out necessary analyzing procedures only.

4. The An alysis/Test Rep ort is in valid, i f it is m odified or dup licated without PIDC's permission.

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Contract No. : Q-08041005
Report No. : 9708030-E1

## INTRODUCTION

The test article id entified below was ex tracted and determined for i ntracutaneous reactivity test in accordance with ISO 10993-12 and ISO 10993-10, respectively.

The purpose of this study was to assess the potential for irritation of the test article to the skin of rabbit.

The extracts of test article were prepared on Jul 29, 2008 and applied on Jul 30, 2008, and the observations were concluded on Aug 02, 2008.

## MATERIALS

The sample provided by the sponsor was identified and handled as follows :

Test Article : Well-Life Cutaneous Electrode, Mesh garment, and Neoprene Belt

Lot No. : ***

Product No. : ***

Specification of sample : ***

Sample No. : M08051403

Date of receive : 2008.05.14

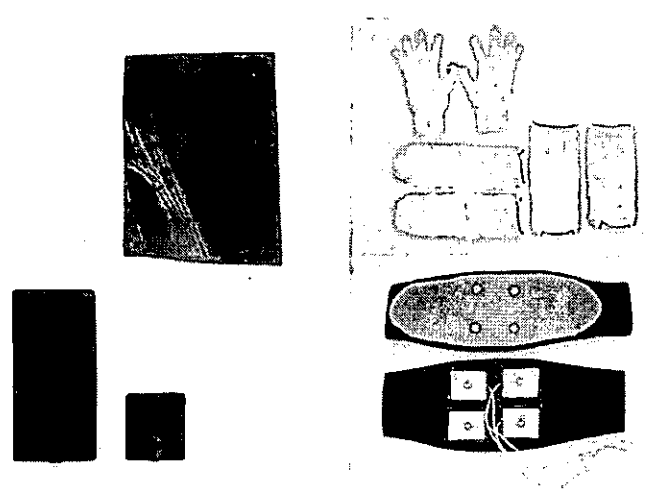
Date of analysis : 2008.7.29~2008.8.2

Storage Conditions : Room temperature

Extraction Vehicle : Saline、Cottonseed oil

Preparation : The ratio based on the ISO 10993-12, 0.2 g sections of test articles were immersed with 1 mL of saline and 0.2 g in 1 mL of cottonseed oil respectively and were extracted at 37 ℃ for 24 hr.

Sample image :





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Report No. : 9708030-E1

## METHODS

Test System Management : Following ISO 10993-2

Species : Rabbit (*Oryctolagus cuniculus*)

Breed : New Zealand white

Source : Animal Health Research Institute (AHRI), Council of Agriculture, Executive Yuan

Sex : Male

Body weight range : 2.1~3.0 kg

Age : Adult

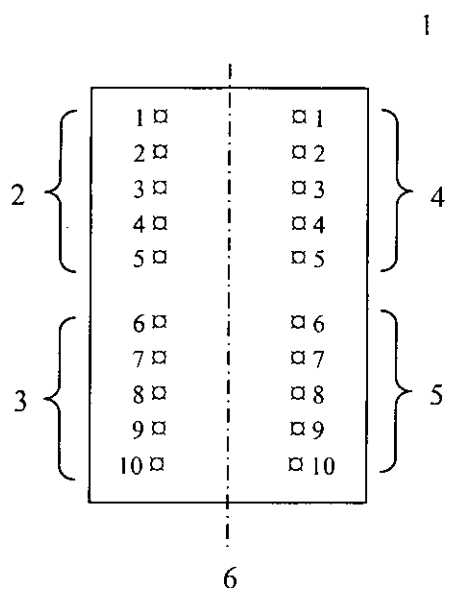
Acclimation period : 7 days

Temperature : 25 ℃

Humidity : 70 % RH

Experimental procedure :

The back of each animal was clipped free of fur at least 4hr but not more than 24hr before test. Injected intracutaneously 0.2 mL of the extract at five on one side of each rabbit (see Figure 1).




**Key**

1 Cranial end

2 0.2 mL injection of polar extract

3 0.2 mL injection of polar solvent control

4 0.2 mL injection of non-polar extract

5 0.2 mL injection of non-polar solvent control

6 Caudal end

Figure 1. Arrangement of injection sites



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Each test sites was observed and recorded the results in accordance with ISO 10993-10 Grading system for intracutaneous (intradermal) reactions (table 1) at 24, 48 & 72 hr after injection.

Table 1. Grading system for intracutaneous (intradermal) reactions

| Reaction | Primary irritation score |
|---|---|
| **Erythema and eschar formation** | |
| No erythema | 0 |
| Very slight erythema (barely perceptible) | 1 |
| Well-defined erythema | 2 |
| Moderate erythema | 3 |
| Severe erythema (beet-redness) to eschar formation preventing grading of erythema | 4 |
| **Oedema formation** | |
| No oedema | 0 |
| Very slight oedema (barely perceptible) | 1 |
| Well-defined oedema (edges of area well-defined by definite raising) | 2 |
| Moderate oedema (raised approximately 1 mm) | 3 |
| Severe oedema (raised more than 1 mm and extending beyond exposure area) | 4 |
| **Total possible score for irritation** | 8 |
| Note – Other adverse change at the skin sites shall be recorded and reported. | |

The primary irritation index of the test article was calculated in accordance with ISO 10993-10 Table 2. Irritation response categories in rabbit.

Table 2. Irritation response categories in rabbit

| Response category | Mean score |
|---|---|
| Negligible | 0 ~ 0.4 |
| Slight | 0.5 ~ 1.9 |
| Moderate | 2 ~ 4.9 |
| Severe | 5 ~ 8 |



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Contract No. : Q-08041005
Report No. : 9708030-E1

## RESULTS

Individual results of skin reaction recorded in Table 3. No irritation was observed on the skin of rabbits so that the primary irritation index (PII) of the test article was calculated to be 0.0.

Table 3. Skin reaction record

| Rabbit No. | Reaction | 24 hr | | | | 48 hr | | | | 72 hr | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Control | | Article | | Control | | Article | | Control | | Article | |
| | | (A) | (B) | (A) | (B) | (A) | (B) | (A) | (B) | (A) | (B) | (A) | (B) |
| 1 | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Notice : (A) Saline ; (B) Cottonseed oil

## CONCLUSION

Under the conditions of this study, the extracts injected into the rabbits' skin for 3 days, no discernible gross reaction or hyperemia was observed. So the test extracts would not be considered an irritation to the skin.

## RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated Plastics Industry Development Center (PIDC) archive files.

Experimenter : _____

Study and Supervisory Personnel : _____

R & D Department Medical Device Laboratory

Approved by :



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

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Contract No. : Q-08041005
Report No. : 9708030-E1

## RESULTS

Individual results of skin reaction recorded in Table 3. No irritation was observed on the skin of rabbits so that the primary irritation index (PII) of the test article was calculated to be 0.0.

Table 3. Skin reaction record

| Rabbit No. | Reaction | 24 hr | | | | 48 hr | | | | 72 hr | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Control | | Article | | Control | | Article | | Control | | Article | |
| | | (A) | (B) | (A) | (B) | (A) | (B) | (A) | (B) | (A) | (B) | (A) | (B) |
| 1 | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | Erythema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Notice : (A) Saline ; (B) Cottonseed oil

## CONCLUSION

Under the conditions of this study, the extracts injected into the rabbits' skin for 3 days, no discernible gross reaction or hyperemia was observed. So the test extracts would not be considered an irritation to the skin.

## RECORD STORAGE

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Experimenter : I- Wen Tzeng 9/9/2008

Study and Supervisory Personnel : Mei-Jan Chu 9/9/2008

R & D Department Medical Device Laboratory

Approved by :

MEDICAL DEVICE LABORATORY R&D Department



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

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# Biocompatibility – Maximization Sensitization test report.



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

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TEL : 04-23595900
FAX : 04-23597862

Contract No. : Q-08041005
Report No. : 9709011-E1

# BIOCOMPATIBILITY STUDY

Test Item :

**MAXIMIZATION TEST FOR DELAYED HYPERSENSITIVITY**

Test Artical :

**Well-Life Cutaneous Electrode, Mesh garment,**

**and Neoprene Belt**

Sponsor :

**Well-Life Healthcare., LTD**

Sampling company :

**Well-Life Healthcare., LTD**

Sampling Address :

**1F, NO.16, 454 LANE, CHUNG-CHENG Rd., YOHCHE**

**CITY, TAIPEI HSEIN, TAIWAN, R.O.C.**

Method :

ISO 10993-10

Notice : 1. The Test Report has to be presented, if necessary, as complete copy, not part of it.

2. The contents of this report are for reference only, not for advertising, general public or any other commercial purposes.

3. The name of the test article(s) to be tested is supplied by the sponsor; PIDC is responsible for carrying out necessary analyzing procedures only.

4. The An alysis/Test Rep ort is in valid, i f it is m odified or dup licated without PIDC's permission.

5. PIDC does not guarantee the reported values in the Report when test is done by using other test pieces. The Test Report may not be used as evidence in a court of law.

6. Only the original copy is considered to be official one.



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

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FAX : 04-23597862

Contract No. : Q-08041005
Report No. : 9709011-E1

## INTRODUCTION

The test article identified below was extracted and determined for sensitization in accordance with ISO 10993-12 and ISO 10993-10, respectively.

The purpose of this study was to assessment of the potential of the material under test to produce skin sensitization in the guinea pig using the technique applied for single chemicals in the guinea pig maximization test.

The extracts of test article were prepared on Aug 05, 2008, and applied on Aug 19, 2008, and the observations were concluded on Sep 15, 2008.

## MATERIALS

The sample provided by the sponsor was identified and handled as follows :

Test Article : Well-Life Cutaneous Electrode, Mesh garment, and Neoprene Belt

Lot No. : ***

Product No. : ***

Specification of sample : ***

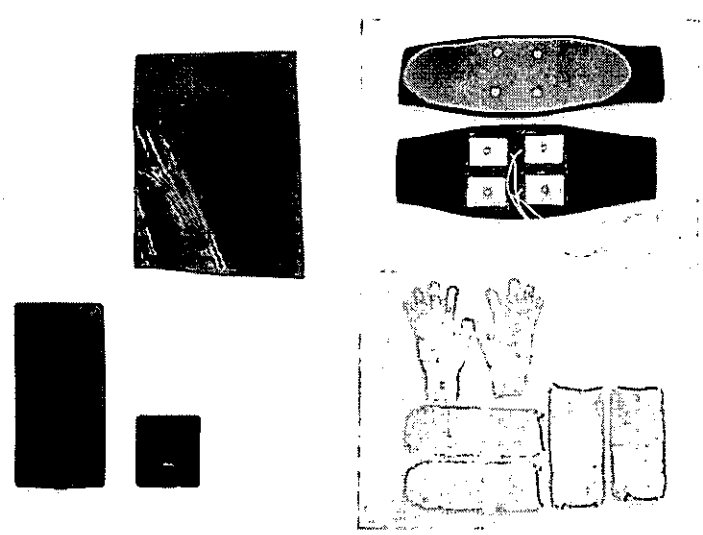
Sample No. : M08051403

Date of receive : 2008/05/14

Date of analysis : 2008/08/05~2008/09/15

Storage Conditions : Room temperature

Sample image :





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Contract No. : Q-08041005
Report No. : 9709011-E1

## METHODS

Test System Management : Following ISO 10993-2

Species : Guinea pig

Breed : Syrian

Source : Animal Health Research Institute Council of Agriculture Executive Yuan

Sex : Male

Body weight range : 300 ~ 500g

Age : Adult

Acclimation period : 7 days

Temperature : 25 ℃

Humidity : 70 % RH

Experimental procedure :

(A) Preparation :

Extraction Vehicle : Saline

Test article extract : The extraction ratio was based on the ISO 10993-12, and was extracted at 37 ℃ for 24 hr.

Animal treatment : Clip and shave the fur on all treatment sites prior to all steps in the test procedure. For intradermal injection, inject 0.1 mL per site. For topical application, saturate an appropriate filter paper (4 $cm^2$) with the test sample and apply the patch to the clipped skin under an occlusive dressing secured by a wrap around the torso of the animal.

(B) Preliminary test :

Topically apply a range of dilutions of the sample to the flanks of at least three animals. Remove the occlusive dressings and patches after 24 hr, and assess the application sites for erythema and oedema using the Magnusson and Kligman grading scale given in Table 1.

The extract, extraction ratio 0.2 g / mL based on the result of preliminary test, is executed for the main test.



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

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**PLASTICS INDUSTRY DEVELOPMENT CENTER**
MEDICAL DEVICE LABORATORY

ADDRESS : No.193, 38th ROAD, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN, ROC

TEL : 04-23595900
FAX : 04-23597862

Contract No. : Q-08041005
Report No. : 9709011-E1

Table 1. Magnusson and Kligman scale

| Patch test reaction | Grading scale |
|---|---|
| No visible change | 0 |
| Discrete or patchy erythema | 1 |
| Moderate and erythema | 2 |
| Intense erythema and swelling | 3 |

(C) Main test :

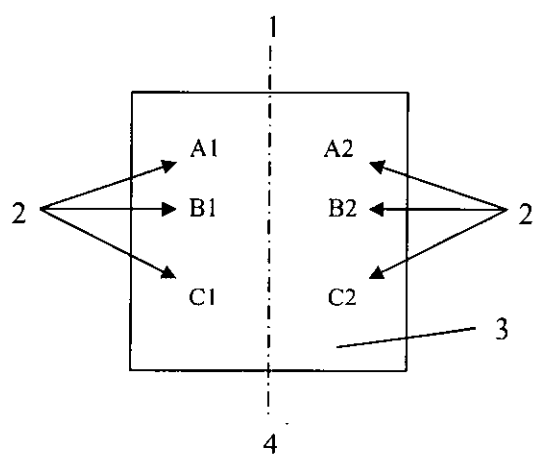
Intradermal induction phase :

Make a pair of 0.1 mL injection of each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A : A 50: 50 (v/v) stable emulsion of Freund's complete adjuvant mixed with saline.

Site B : This extracts which was prepared above; inject the control animal with saline alone.

Site C : This extract, used at site B, emulsified in a 50: 50 (v/v) stable emulsion of Freund's complete adjuvant; inject the control animal with an emulsion of saline




**Key**
1 Cranial end
2 0.1 mL intradermal injection
3 Clipped intrascapular region
4 Caudal end

Figure 1 - Location of intradermal injection sites





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TEL : 04-23595900
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Report No. : 9709011-E1

Topical induction phase :

Seven days after completion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animal, using a 4 $cm^2$ filter paper, so as to cover the intradermal injection sites. Use the concentration selected in intradermal induction phase for site B. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48 hr.

Treat the control animals similarly, using saline alone.

Challenge phase :

At 14 days after completion of the topical induction phase, administer the test sample and the control by topical application to sites that were not treated during the induction stage, using a filter paper of area approximately 4 $cm^2$ soaked in the test sample at the concentration selected in intradermal induction phase for site B. Secure the patches with an occlusive dressing. Remove the dressings and patches after 24 hr.

Observe the appearance of the challenge skin sites of the test and control animals 24 hr and 48 hr after removal of the dressings. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1.

## RESULTS

Individual results of skin reaction recorded in table 2. No sensitivity was observed on the skin of guinea pig. The reaction scale was calculated to be 0.0, so that the test article would not be considered a delayed hypersensitivity to the skin.



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

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TEL : 04-23595900
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Report No. : 9709011-E1

Table 2. Main test result

| Test site / Animal No. | A1 | | A2 | | B1 | | B2 | | C1 | | C2 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Notice : Control animal is No.11~15

## CONCLUSION

Under the conditions of this study, the extracts contacted with the guinea pigs' skin for 2 days, no discernible gross reaction or hyperemia was observed. So the test extracts would not be considered sensitivity to the skin.

## RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated Plastics Industry Development Center (PIDC) archive files.

Experimenter : _____

Study and Supervisory Personnel : _____

R & D Department Medical Device Laboratory

Approved by :





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

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PLASTICS INDUSTRY DEVELOPMENT CENTER
MEDICAL DEVICE LABORATORY

ADDRESS : No.193, 38th ROAD, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN, ROC

TEL : 04-23595900
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Contract No. : Q-08041005
Report No. : 9709011-E1

Table 2. Main test result

| Test site / Animal No. | A1 | | A2 | | B1 | | B2 | | C1 | | C2 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr | 24 hr | 48 hr |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Notice : Control animal is No.11~15

## CONCLUSION

Under the conditions of this study, the extracts contacted with the guinea pigs' skin for 2 days, no discernible gross reaction or hyperemia was observed. So the test extracts would not be considered sensitivity to the skin.

## RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated Plastics Industry Development Center (PIDC) archive files.

Experimenter : I-Wen Tzeng 09-23-2008

Study and Supervisory Personnel : Mei-Jan Chu 09-23-2008

R & D Department Medical Device Laboratory

Approved by :

PLASTICS INDUSTRY DEVELOPMENT CENTER MEDICAL DEVICE LABORATORY R&D Department



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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 7.



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

(b) (4) Software Validation Reports and Results

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# Attachment 8.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# CERTIFICATE

**Issued Date: Dec. 17, 2007**
**Report No.: 079060R-ITCEP02V02**

This is to certify that the following designated product

**Product** : **Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS)**
**Trade name** : **WELL LIFE**
**Model Number** : **WL-2401/OTC TENS, WL-2402/OTC TENS, WL-2403/OTC TENS, WL-2404/OTC TENS, WL-2405/OTC TENS, WL-2406/OTC TENS, WL-2407/OTC TENS, WL-2412 OTC EMS**
**Company Name** : **Well-Life Healthcare Limited**

This product, which has been issued the test report listed as above in QuieTek Laboratory, is based on a single evaluation of one sample and confirmed to comply with the requirements of the following EMC standard.

**EN 55011:1998+A1: 1999+A2: 2002**
**EN 61000-3-2: 2000 + A2: 2005**
**EN 61000-3-3: 1995 + A1: 2001**
**EN 60601-1-2: 2002**
**IEC 61000-4-2 Edition 1.2: 2001-04**
**IEC 61000-4-3: 2002+A1: 2002**
**IEC 61000-4-4: 2004**
**IEC 61000-4-5 Edition 1.1: 2001-04**
**IEC 61000-4-6 Edition 2.1: 2004-11**
**IEC 61000-4-8 Edition 1.1: 2001-03**
**IEC 61000-4-11 Second Edition: 2004-03**

TEST LABORATORY

Vincent Lin / Deputy Manager

QuieTek No.5-22, Ruei-Shu Valley, Ruei-Ping Tsuen Lin Kou Shiang, Taipei 244 Taiwan, R.O.C.
TEL:+886-2-8601-3788 FAX:+886-2-8601-3789 Email:service@quietek.com http://www.quietek.com



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

CE

# Test Report

Product Name : Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS)

Model No. : WL-2401/OTC TENS, WL-2402/OTC TENS, WL-2403/OTC TENS, WL-2404/OTC TENS, WL-2405/OTC TENS, WL-2406/OTC TENS, WL-2407/OTC TENS, WL-2412 OTC EMS

Applicant : Well-Life Healthcare Limited

Address : 1F., No.16, Lane 454 Jungjeng Road, Yunghe City, Taipei County, Taiwan

Date of Receipt : 2007/08/30

Issued Date : 2007/12/17

Report No. : 079060R-ITCEP02V02

The test results relate only to the samples tested.

The test results shown in the test report are traceable to the national/international standard through the calibration of the equipment and evaluated measurement uncertainty herein.

This report must not be used to claim product endorsement by CNLA, NVLAP or any agency of the Government.

The test report shall not be reproduced except in full without the written approval of QuieTek Corporation.



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

CE

# Declaration of Conformity

The following product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Electromagnetic Compatibility Directive (2004/108/EC). The listed standards as below were applied:

The following Equipment:

| | | |
|---|---|---|
| Product | : | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) |
| Model Number | : | WL-2401/OTC TENS, WL-2402/OTC TENS, WL-2403/OTC TENS, WL-2404/OTC TENS, WL-2405/OTC TENS, WL-2406/OTC TENS, WL-2407/OTC TENS, WL-2412 OTC EMS |
| Trade Name | : | WELL LIFE |

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Electromagnetic Compatibility Directive (2004/108/EC). For the evaluation regarding EMC, the following standards were applied:

**RFI Emission:**

| | | |
|---|---|---|
| EN 55011:1998+A1:1999+A2:2002 Class B | : | Product family standard |
| EN 61000-3-2:2000+A2: 2005 | : | Limits for harmonic current emission |
| EN 61000-3-3:1995+A1: 2001 | : | Limitation of voltage fluctuation and flicker in low-voltage supply system |

**Immunity:**

| | | |
|---|---|---|
| EN 60601-1-2: 2002 | : | Product family standard |

The following importer/manufacturer is responsible for this declaration:

Company Name : _____

Company Address : _____

Telephone : _____ Facsimile : _____

Person is responsible for marking this declaration:

| | |
|---|---|
| Name (Full Name) | Position/ Title |
| Date | Legal Signature |

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

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QuieTek Corporation

QTK No.: 079060R-ITCEP02V02

# CE
# Statement of Conformity

This certifies that the following designated product:

Product : Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS)

Model Number : WL-2401/OTC TENS, WL-2402/OTC TENS, WL-2403/OTC TENS, WL-2404/OTC TENS, WL-2405/OTC TENS, WL-2406/OTC TENS, WL-2407/OTC TENS, WL-2412 OTC EMS

Trade Name : WELL LIFE

Company Name : Well-Life Healthcare Limited

This product is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the laws of the Member States relating to Electromagnetic Compatibility Directive (2004/108/EC). For the evaluation regarding EMC, the following standards were applied:

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| EN 55011:1998+A1:1999+A2:2002 Class B | : Product family standard |
| EN 61000-3-2:2000+A2: 2005 | : Limits for harmonic current emission |
| EN 61000-3-3:1995+A1: 2001 | : Limitation of voltage fluctuation and flicker in low-voltage supply system |

**Immunity:**

| | |
|---|---|
| EN 60601-1-2: 2002 | : Product family standard |

TÜV DNV NVLAP NEMKO CNLA 0914

TEST LABORATORY

Vincent Lin / Deputy Manager

The verification is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test lab. Logo.

QuieTek Corporation / No.5-22, Ruei-Shu Valley, Ruei-Ping Tsuen Lin Kou Shiang, Taipei 244 Taiwan, R.O.C.
Tel: 886-2-8601-3788, Fax: 886-2-8601-3789, E-mail: service@quietek.com



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

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# Test Report Certification

Issued Date : 2007/12/17
Report No : 079060R-ITCEP02V02

QuieTek

| | | |
|---|---|---|
| Product Name | : | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) |
| Applicant | : | Well-Life Healthcare Limited |
| Address | : | 1F., No.16, Lane 454 Jungjeng Road, Yunghe City, Taipei County, Taiwan |
| Manufacturer | : | Well-Life Healthcare Limited |
| Model No. | : | WL-2401/OTC TENS, WL-2402/OTC TENS, WL-2403/OTC TENS, WL-2404/OTC TENS, WL-2405/OTC TENS, WL-2406/OTC TENS, WL-2407/OTC TENS, WL-2412 OTC EMS |
| Rated Voltage | : | Mode 1:DC 4.5V (Power by Battery)<br>Mode 2: AC 100~240V / 50/60Hz |
| Trade Name | : | WELL LIFE |
| Applicable Standard | : | EN 55011:1998+A1:1999+A2:2002 Class B(Group 1)<br>EN 60601-1-2: 2002 Class B<br>EN 61000-3-2:2000+A2: 2005<br>EN 61000-3-3:1995+A1: 2001 |
| Test Result | : | Complied |
| Performed Location | : | Linkou EMC laboratory (Linkou Laboratory)<br>No.5-22,Ruei-Shu Valley, Ruei-Ping Tsuen Lin Kuo Shiang, Taipei, 244 Taiwan, R.O.C.<br>TEL:+866-2-8601-3788 / FAX:+886-2-8601-3789 |

Documented By : Jinn Chen
( Engineering Adm. Assistant / Jinn Chen )

Reviewed By : [illegible]
( Assistant Engineer / Harrison Chen )

Approved By : [illegible]
( Deputy Manager / Vincent Lin )



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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



## Laboratory Information

We , **QuieTek Corporation**, are an independent EMC and safety consultancy that was established the whole facility in our laboratories. The test facility has been accredited by the following accreditation Bodies in compliance with ISO 17025, EN 45001 and Guide 25:

| | | |
|---|---|---|
| **Taiwan R.O.C.** | : | **BSMI, DGT, CNLA** |
| **Germany** | : | **TUV Rheinland** |
| **Norway** | : | **Nemko, DNV** |
| **USA** | : | **FCC, NVLAP** |
| **Japan** | : | **VCCI** |

The related certificate for our laboratories about the test site and management system can be downloaded from QuieTek Corporation's Web Site : http://tw.quietek.com/modules/myalbum/
The address and introduction of QuieTek Corporation's laboratories can be founded in our Web site : http://www.quietek.com/
If you have any comments, Please don't hesitate to contact us. Our contact information is as below:

**HsinChu Testing Laboratory :**
No.75-2, 3rd Lin, Wangye Keng, Yonghxing Tsuen, Qionglin Shiang, Hsinchu County 307, Taiwan, R.O.C.
TEL:+886-3-592-8858 / FAX:+886-3-592-8859 E-Mail : service@quietek.com

NVLAP Lab Code : 200347-0

1313

**LinKou Testing Laboratory :**
No. 5-22, Ruei-Shu Valley, Ruei-Ping Tsuen, Lin-Kou Shiang, Taipei, Taiwan, R.O.C.
TEL : 886-2-8601-3788 / FAX : 886-2-8601-3789 E-Mail : service@quietek.com

NVLAP Lab Code: 200533-0

0914



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

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# 1. General Information

## 1.1. EUT Description

| | |
|---|---|
| Product Name | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) |
| Trade Name | WELL LIFE |
| Model No. | WL-2401/OTC TENS, WL-2402/OTC TENS, WL-2403/OTC TENS, WL-2404/OTC TENS, WL-2405/OTC TENS, WL-2406/OTC TENS, WL-2407/OTC TENS, WL-2412 OTC EMS |

| Component | |
|---|---|
| Power Adapter | MFR:ITE, M/N:GFP051U-0965<br>Input:AC 100-240V/50-60Hz, 0.2A<br>Output: DC9V, 0.65A<br>Cable IN:Non-shielded, 1.8m, with one ferrite core bonded. |

| Group ID | Model | Detail specification | | | | |
|---|---|---|---|---|---|---|
| | | Channel no. | Max. amp | Pulse width | Frequency | Operation mode |
| WL-24XX OTC | WL-2401/OTC TENS | 2 | 50mA | 250μs fixed | 30Hz fixed | Modulation |
| | WL-2402/OTC TENS | 2 | 80mA | 260μs fixed | 120Hz Max. | Modulation |
| | WL-2403/OTC TENS | 2 | 80mA | 260μs fixed | 120Hz Max. | Modulation |
| | WL-2404/OTC TENS | 2 | 80mA | 260μs fixed | 150Hz Max. | Modulation |
| | WL-2405/OTC TENS | 2 | 80mA | 260μs fixed | 150Hz Max. | Modulation |
| | WL-2406/OTC TENS | 2 | 80mA | 260μs fixed | 120Hz Max. | Modulation |
| | WL-2407/OTC TENS | 2 | 80mA | 260μs fixed | 60Hz Max. | Modulation |
| | WL-2412 OTC EMS | 2 | 80mA | 250μs fixed | 1~160Hz | Modulation |



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## 1.2. Mode of Operation

QuieTek has verified the construction and function in typical operation. All the test modes were carried out with the EUT in normal operation, which was shown in this test report and defined as:

| | |
|---|---|
| Pre-Test Mode | |
| Mode 1:Normal Operation | |
| Final Test Mode | |
| Emission | Mode 1:Normal Operation |
| Immunity | Mode 1:Normal Operation |



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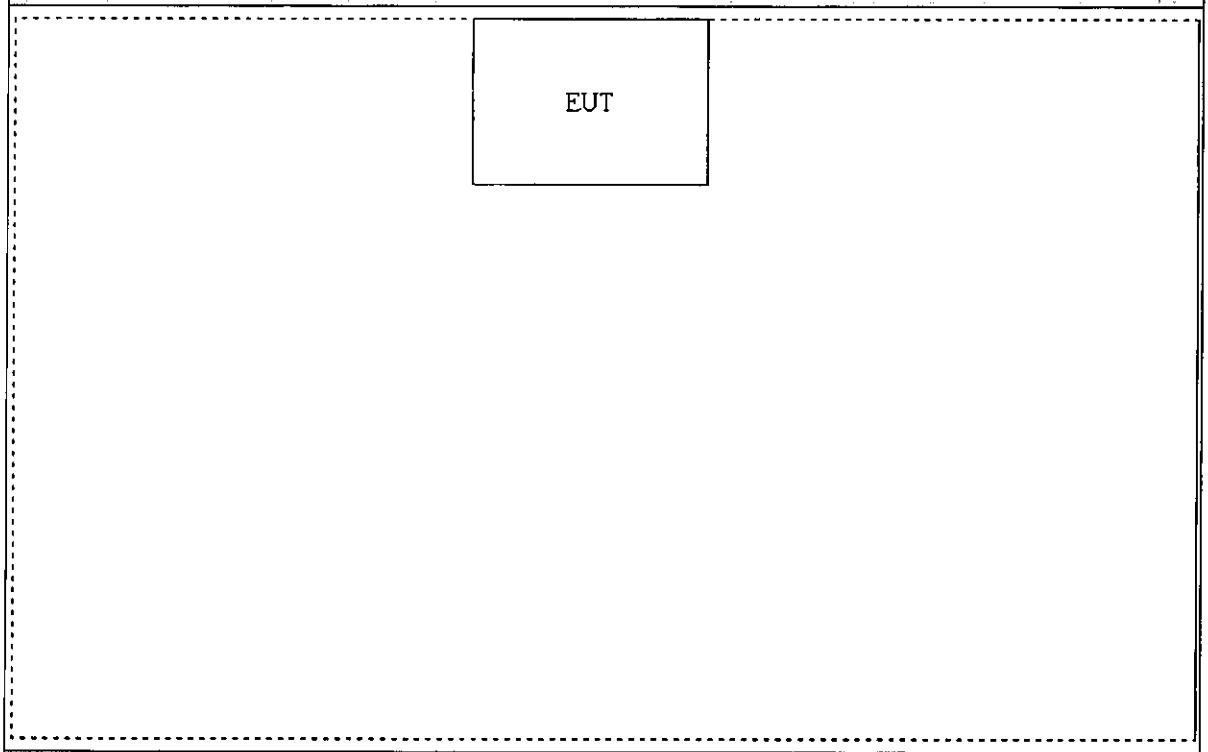
### 1.3. Tested System Details

The types for all equipments, plus descriptions of all cables used in the tested system (including inserted cards) are:

| Product | | Manufacturer | Model No. | Serial No. | Power Cord |
|---|---|---|---|---|---|
| 1 | N/A | N/A | N/A | N/A | N/A |

### 1.4. Configuration of Tested System

Connection Diagram




| Signal Cable Type | | Signal cable Description |
|---|---|---|
| A | N/A | N/A |



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## 1.5. EUT Exercise Software

| | |
|---|---|
| 1 | Setup the EUT and simulators as shown on 1.3. |
| 2 | Turn on the power of all equipment. |
| 3 | Verity the model operation. |
| 4 | Repeat the above procedure 1.4.2 to 1.4.3 |



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## 2. Technical Test

### 2.1. Summary of Test Result

☒ No deviations from the test standards

☐ Deviations from the test standards as below description:

| Emission | | | |
|---|---|---|---|
| Performed Item | Normative References | Test Performed | Deviation |
| Conducted Emission | EN 55011: 1998+A1: 1999+A2: 2002 Class B(Group 1) | Yes | No |
| Radiated Emission | EN 55011: 1998+A1: 1999+A2: 2002 Class B(Group 1) | Yes | No |
| Power Harmonics | EN 61000-3-2:2000+A2:2005 | Yes | No |
| Voltage Fluctuation and Flicker | EN 61000-3-3:1995+A1:2001 | Yes | No |

| Immunity | | | |
|---|---|---|---|
| Performed Item | Normative References | Test Performed | Deviation |
| Electrostatic Discharge | IEC 61000-4-2 Edition 1.2: 2001-04 | Yes | No |
| Radiated susceptibility | IEC 61000-4-3:2002+A1:2002 Class B | Yes | No |
| Electrical fast transient/burst | IEC 61000-4-4:2004 | Yes | No |
| Surge | IEC 61000-4-5 Edition 1.1: 2001-04 | Yes | No |
| Conducted susceptibility | IEC 61000-4-6 Edition 2.1: 2004-11 | Yes | No |
| Power frequency magnetic field | IEC 61000-4-8 Edition 1.1: 2001-03 | Yes | No |
| Voltage dips and interruption | IEC 61000-4-11 2nd Edition: 2004-03 | Yes | No |



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## 2.2. List of Test Equipment

Conducted Emission / SR1

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| EMI Test Receiver | R&S | ESCS 30 | 836858/022 | 2007/07/21 |
| LISN | R&S | ESH3-Z5 | 836679/020 | 2007/02/17 |
| LISN | R&S | ENV4200 | 833209/007 | 2007/07/27 |
| Pulse Limiter | R&S | ESH3-Z2 | 357.88.10.52 | 2007/09/07 |

Radiated Emission / Site5

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| Bilog Antenna | Schaffner Chase | CBL6112B | 2920 | 2007/09/15 |
| Broadband Horn Antenna | Schwarzbeck | BBHA9170 | 208 | 2007/07/25 |
| EMI Test Receiver | R&S | ESCS 30 | 100369 | 2007/08/15 |
| Horn Antenna | Schwarzbeck | BBHA9120D | 305 | 2007/08/10 |
| Pre-Amplifier | QTK | N/A | N/A | 2007/05/01 |
| Spectrum Analyzer | Advantest | R3162 | 100803463 | 2007/01/03 |

Power Harmonics / SR3

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| AC Power Source(Harmonic) | Schaffner | NSG 1007 | HK54148 | 2007/07/11 |
| IEC1000-4-X Analyzer(Flicker) | Schaffner | CCN 1000-1 | X7 1887 | 2007/07/11 |

Voltage Fluctuation and Flicker / SR3

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| AC Power Source(Harmonic) | Schaffner | NSG 1007 | HK54148 | 2007/07/11 |
| IEC1000-4-X Analyzer(Flicker) | Schaffner | CCN 1000-1 | X7 1887 | 2007/07/11 |

Electrostatic Discharge / SR6

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| ESD Simulator System | KeyTek | MZ-15/EC | 0112372 | 2007/08/02 |
| Horizontal Coupling Plane(HCP) | QuieTek | HCP AL50 | N/A | N/A |
| Vertical Coupling Plane(VCP) | QuieTek | VCP AL50 | N/A | N/A |

Radiated susceptibility / CB5

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| AF-BOX | R&S | AF-BOX ACCUST | 100007 | N/A |
| Audio Analyzer | R&S | UPL 16 | 100137 | 2007/03/16 |
| Bilog Antenna | Schaffner Chase | CBL6112B | 2450 | 2007/01/03 |
| Broad-Band Antenna | Schwarzbeck | VULB 9166 | 1085 | 2007/08/02 |
| CMU200 UNIV.RADIOCOMM | R&S | CMU200 | 104846 | 2007/03/16 |
| Directional Coupler | A&R | DC 6180 | 22735 | N/A |
| Dual Microphone Supply | B&K | 5935 | 2426784 | 2007/08/04 |
| Mouth Simulator | B&K | 4227 | 2439692 | 2007/08/04 |
| Power Amplifier | A&R | 100W10000M7 | A285000010 | N/A |
| Power Amplifier | A&R | 30S1G3 | 309453 | N/A |



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| | | | | |
|---|---|---|---|---|
| Power Meter | R&S | NRVD(P.M) | 100219 | 2007/04/21 |
| Pre-Amplifier | A&R | 150A220 | 23067 | N/A |
| Probe Microphone | B&K | 4182 | 2278070 | 2007/08/04 |
| Signal Generator | R&S | SMY02(9K-2080) | 825454/028 | 2007/09/22 |

Electrical fast transient/burst / SR2

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| Schaffner NSG 2050 System Mainframe | N/A | N/A | N/A | 2006/12/28 |

Surge / SR2

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| Schaffner NSG 2050 System Mainframe | N/A | N/A | N/A | 2006/12/28 |

Conducted susceptibility / SR6

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| Schaffner NSG 2070 RF-Generator | N/A | N/A | N/A | 2007/04/21 |

Power frequency magnetic field / SR3

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| Induction Coil Interface | Schaffner | INA 2141 | 6002 | N/A |
| Magnetic Loop Coil | Schaffner | INA 702 | 199749-020IN | N/A |
| Magnetic/Electric field measuring system | Lackmann Phymetric | MV3 | N/A | N/A |
| Triaxial ELF Magnetic Field Meter | F.B.BELL | 4090 | 9852 | 2007/05/30 |

Voltage dips and interruption / SR2

| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
|---|---|---|---|---|
| Schaffner NSG 2050 System Mainframe | N/A | N/A | N/A | 2006/12/28 |

| Schaffner NSG 2050 System Mainframe | | | | |
|---|---|---|---|---|
| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
| Burst 4.8KV/16A Generator with CDN | Schaffner | PNW2225 | 200123-098SC | 2006/12/28 |
| Damped osc. Wave 100kHz and 1MHz | Schaffner | PNW2056 | 200124-058SC | 2006/12/28 |
| Double AC Source Variator | Schaffner | NSG 642A | 30910014938 | 2006/12/28 |
| Hybrid surge pulse 1.2/50uS | Schaffner | PNW 2050 | 20532-514LU | 2006/12/28 |
| PQT Generator | Schaffner | PNW2003 | 200138-007SC | 2007/01/02 |
| Pulse COUPLING NETWORK | Schaffner | CDN131 | 200124-007SC | 2006/12/28 |



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| Schaffner NSG 2070 RF-Generator | | | | |
|---|---|---|---|---|
| Instrument | Manufacturer | Type No. | Serial No | Cal. Date |
| CDN | Schaffner | CAL U100A | 20405 | 2007/04/21 |
| CDN | Schaffner | TRA U150 | 20454 | 2007/04/21 |
| CDN M016S | Schaffner | CAL U100A | 20410 | 2007/04/21 |
| CDN M016S | Schaffner | TRA U150 | 21167 | 2007/04/21 |
| CDN T002 | Schaffner | CAL U100 | 20491 | 2007/04/21 |
| CDN T002 | Schaffner | TRA U150 | 21169 | 2007/04/21 |
| CDN T400 | Schaffner | CAL U100 | 17735 | 2007/04/21 |
| CDN T400 | Schaffner | TRA U150 | 21166 | 2007/04/21 |
| Coupling Decoupling Network | Schaffner | CDN M016S | 20822 | 2007/02/23 |
| Coupling Decoupling Network | Schaffner | CDN M016S | 20823 | 2007/04/21 |
| Coupling Decoupling Network | Schaffner | CDN T002 | 19018 | 2007/04/21 |
| Coupling Decoupling Network | Schaffner | CDN T400 | 21226 | 2007/04/21 |
| EM-CLAMP | Schaffner | KEMZ 801 | 21024 | 2007/04/21 |



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## 2.3. Measurement Uncertainty

Conducted Emission

The measurement uncertainty is evaluated as ± 2.26 dB.

Radiated Emission

The measurement uncertainty is evaluated as ± 3.19 dB.

Electrostatic Discharge

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2], the requirements for measurement uncertainty in ESD testing are deemed to have been satisfied, and the testing is reported in accordance with the relevant ESD standards. The immunity test signal from the ESD system meet the required specifications in IEC 61000-4-2 through the calibration report with the calibrated uncertainty for the waveform of voltage and timing as being 1.63 % and 2.76%.

Radiated susceptibility

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2], the requirements for measurement uncertainty in RS testing are deemed to have been satisfied, and the testing is reported in accordance with the relevant RS standards. The immunity test signal from the RS system meet the required specifications in IEC 61000-4-3 through the calibration for the uniform field strength and monitoring for the test level with the uncertainty evaluation report for the electrical filed strength as being 2.72 dB.

Electrical fast transient/burst

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2], the requirements for measurement uncertainty in EFT/Burst testing are deemed to have been satisfied, and the testing is reported in accordance with the relevant EFT/Burst standards. The immunity test signal from the EFT/Burst system meet the required specifications in IEC 61000-4-4 through the calibration report with the calibrated uncertainty for the waveform of voltage, frequency and timing as being 1.63 %, 2.8 10-10 and 2.76%.

Surge

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2]; the requirements for measurement uncertainty in Surge testing are deemed to have been satisfied, and the testing is reported in accordance with the relevant Surge standards. The immunity test signal from the Surge system meet the required specifications in IEC 61000-4-5 through the calibration report with the calibrated uncertainty for the waveform of voltage and timing as being 1.63 % and 2.76%.

Conducted susceptibility

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2], the requirements for measurement uncertainty in CS testing are deemed to have



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been satisfied, and the testing is reported in accordance with the relevant CS standards. The immunity test signal from the CS system meet the required specifications in IEC 61000-4-6 through the calibration for unmodulated signal and monitoring for the test level with the uncertainty evaluation report for the injected modulated signal level through CDN and EM Clamp/Direct Injection as being 3.72 dB and 2.78 dB.

Power frequency magnetic field

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2], the requirements for measurement uncertainty in PFM testing are deemed to have been satisfied, and the testing is reported in accordance with the relevant PFM standards. The immunity test signal from the PFM system meet the required specifications in IEC 61000-4-8 through the calibration report with the calibrated uncertainty for the Gauss Meter to verify the output level of magnetic field strength as being 2 %.

Voltage dips and interruption

As what is concluded in the document from Note2 of clause 5.4.6.2 of ISO/IEC 17025: 1999[2], the requirements for measurement uncertainty in DIP testing are deemed to have been satisfied, and the testing is reported in accordance with the relevant DIP standards. The immunity test signal from the DIP system meet the required specifications in IEC 61000-4-11 through the calibration report with the calibrated uncertainty for the waveform of voltage and timing as being 1.63 % and 2.76%.



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## 2.4. Test Environment

| Performed Item | Items | Required | Actual |
|---|---|---|---|
| Conducted Emission | Temperature (°C) | 15-35 | 25 |
| | Humidity (%RH) | 25-75 | 50 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Radiated Emission | Temperature (°C) | 15-35 | 25 |
| | Humidity (%RH) | 25-75 | 50 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Electrostatic Discharge | Temperature (°C) | 15-35 | 21 |
| | Humidity (%RH) | 30-60 | 58 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Radiated susceptibility | Temperature (°C) | 15-35 | 23 |
| | Humidity (%RH) | 25-75 | 53 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Electrical fast transient/burst | Temperature (°C) | 15-35 | 21 |
| | Humidity (%RH) | 25-75 | 52 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Surge | Temperature (°C) | 15-35 | 21 |
| | Humidity (%RH) | 10-75 | 52 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Conducted susceptibility | Temperature (°C) | 15-35 | 21 |
| | Humidity (%RH) | 25-75 | 52 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| | Temperature (°C) | 15-35 | 18.6 |
| Power frequency magnetic field | Temperature (°C) | 15-35 | 21 |
| | Humidity (%RH) | 25-75 | 52 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |
| Voltage dips and interruption | Temperature (°C) | 15-35 | 21 |
| | Humidity (%RH) | 25-75 | 52 |
| | Barometric pressure (mbar) | 860-1060 | 950-1000 |



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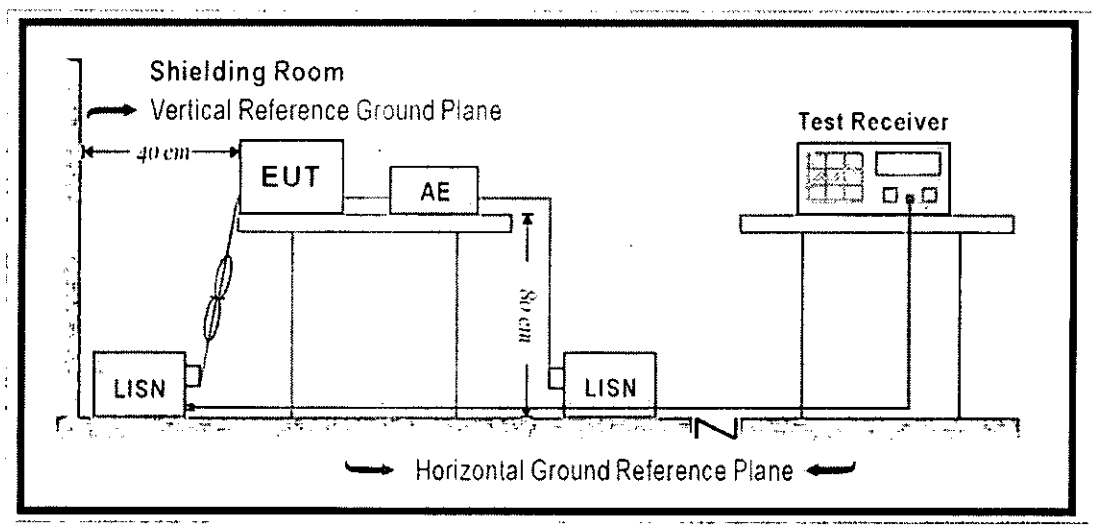
## 3. Conducted Emission

### 3.1. Test Specification

According to EMC Standard : EN 55011 (Group 1)

### 3.2. Test Setup




### 3.3. Limit

| Limits | | |
|---|---|---|
| Frequency (MHz) | QP (dBuV) | AV (dBuV) |
| 0.15 - 0.50 | 66 - 56 | 56 – 46 |
| 0.50-5.0 | 56 | 46 |
| 5.0 - 30 | 60 | 50 |

Remarks: In the above table, the tighter limit applies at the band edges.



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## 3.4. Test Procedure

The EUT and simulators are connected to the main power through a line impedance stabilization network (L.I.S.N.). This provides a 50 ohm /50uH coupling impedance for the measuring equipment. The peripheral devices are also connected to the main power through a LISN that provides a 50ohm/50uH coupling impedance with 50ohm termination.
(Please refers to the block diagram of the test setup and photographs.)
Both sides of A.C. line are checked for maximum conducted interference. In order to find the maximum emission, the relative positions of equipment and all of the interface cables must be changed on conducted measurement.
Conducted emissions were invested over the frequency range from 0.15MHz to 30MHz using a receiver bandwidth of 9kHz.

## 3.5. Deviation from Test Standard

No deviation.





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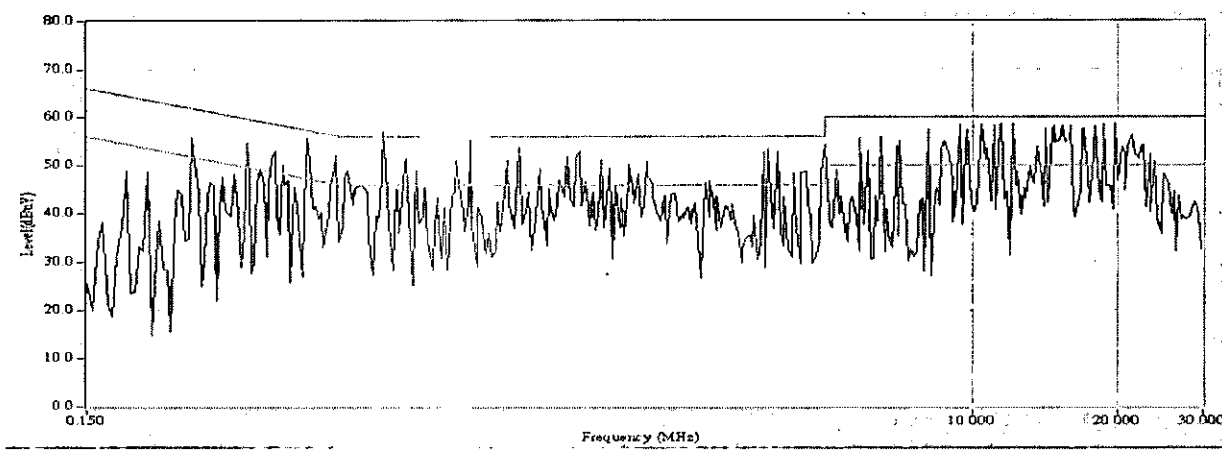
## 3.6. Test Result

| | |
|---|---|
| Site : SR-1 | Time : 2007/09/01 - 04:14 |
| Limit : CISPR_B_00M_QP | Margin : 10 |
| EUT : TENS | Probe : LISN-020(L) - Line1 |
| Power : AC 230V/60Hz | Note : Mode 1 |



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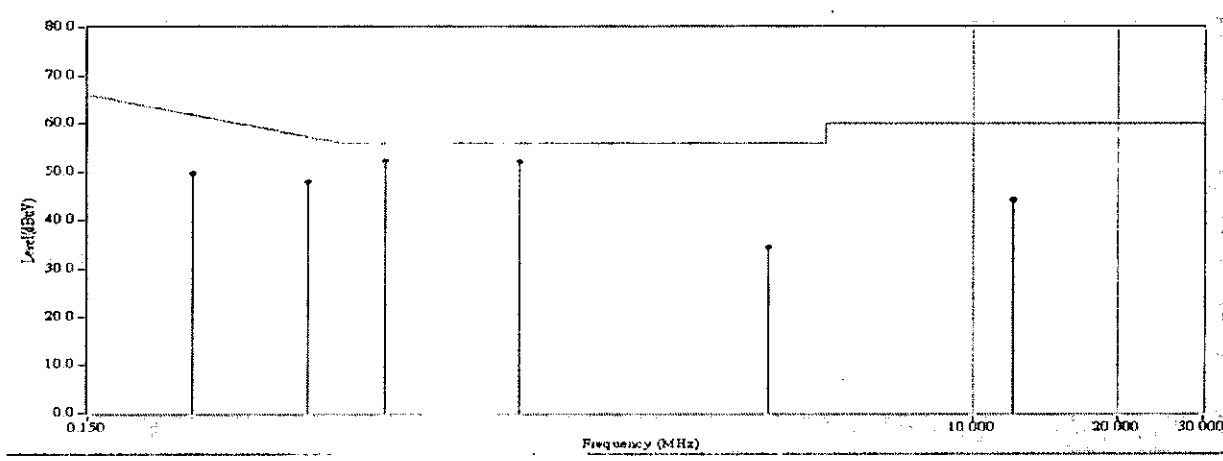
| | |
|---|---|
| Site : SR-1 | Time : 2007/09/01 - 04:17 |
| Limit : CISPR_B_00M_QP | Margin : 0 |
| EUT : TENS | Probe : LISN-020(L) - Line1 |
| Power : AC 230V/60Hz | Note : Mode 1 |




| | | Frequency (MHz) | Correct Factor (dB) | Reading Level (dBuV) | Measure Level (dBuV) | Margin (dB) | Limit (dBuV) | Detector Type |
|---|---|---|---|---|---|---|---|---|
| 1 | | 0.248 | 0.203 | 49.480 | 49.683 | -13.517 | 63.200 | QUASIPEAK |
| 2 | | 0.427 | 0.215 | 47.800 | 48.015 | -10.071 | 58.086 | QUASIPEAK |
| 3 | * | 0.615 | 0.218 | 52.170 | 52.388 | -3.612 | 56.000 | QUASIPEAK |
| 4 | | 1.166 | 0.245 | 51.910 | 52.155 | -3.845 | 56.000 | QUASIPEAK |
| 5 | | 3.814 | 0.340 | 34.090 | 34.430 | -21.570 | 56.000 | QUASIPEAK |
| 6 | | 12.146 | 0.742 | 43.440 | 44.182 | -15.818 | 60.000 | QUASIPEAK |

Note:

1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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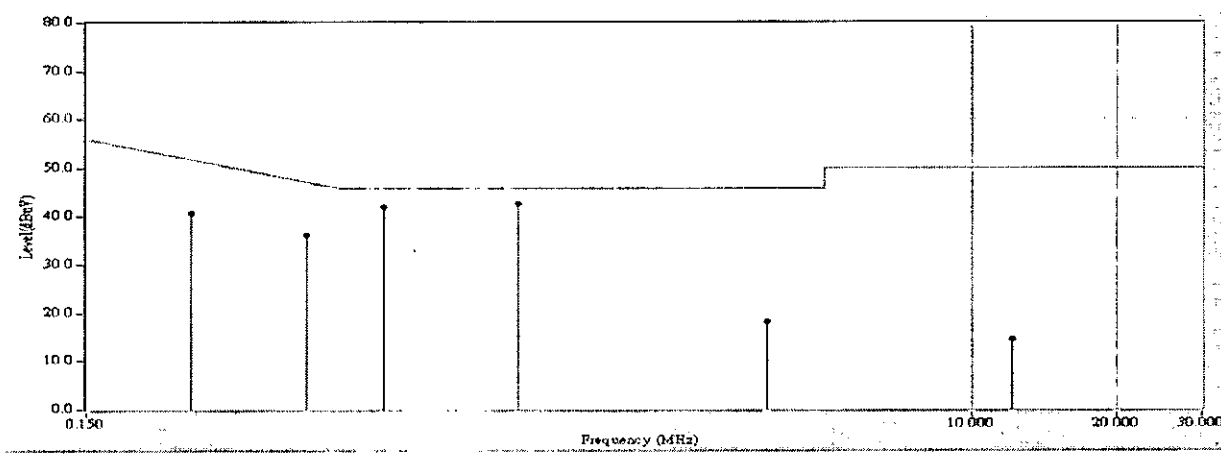
| | |
|---|---|
| Site : SR-1 | Time : 2007/09/01 - 04:17 |
| Limit : CISPR_B_00M_AV | Margin : 0 |
| EUT : TENS | Probe : LISN-020(L) - Line1 |
| Power : AC 230V/60Hz | Note : Mode 1 |




| | | Frequency (MHz) | Correct Factor (dB) | Reading Level (dBuV) | Measure Level (dBuV) | Margin (dB) | Limit (dBuV) | Detector Type |
|---|---|---|---|---|---|---|---|---|
| 1 | | 0.248 | 0.203 | 40.640 | 40.843 | -12.357 | 53.200 | AVERAGE |
| 2 | | 0.427 | 0.215 | 36.030 | 36.245 | -11.841 | 48.086 | AVERAGE |
| 3 | | 0.615 | 0.218 | 41.900 | 42.118 | -3.882 | 46.000 | AVERAGE |
| 4 | * | 1.166 | 0.245 | 42.530 | 42.775 | -3.225 | 46.000 | AVERAGE |
| 5 | | 3.814 | 0.340 | 17.940 | 18.280 | -27.720 | 46.000 | AVERAGE |
| 6 | | 12.146 | 0.742 | 13.940 | 14.682 | -35.318 | 50.000 | AVERAGE |

Note:

1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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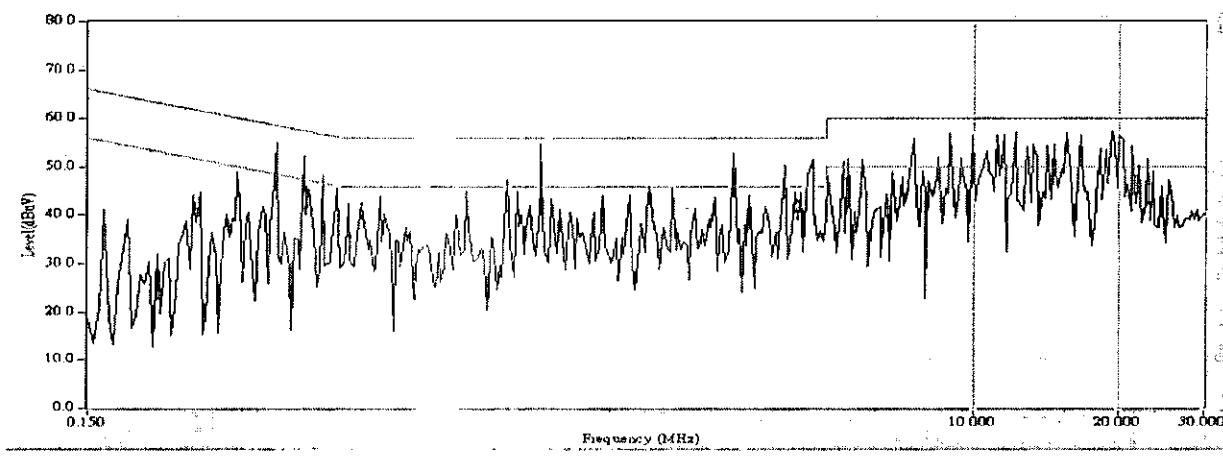
| | |
|---|---|
| Site : SR-1 | Time : 2007/09/01 - 04:18 |
| Limit : CISPR_B_00M_QP | Margin : 10 |
| EUT : TENS | Probe : LISN-020(N) - Line2 |
| Power : AC 230V/60Hz | Note : Mode 1 |



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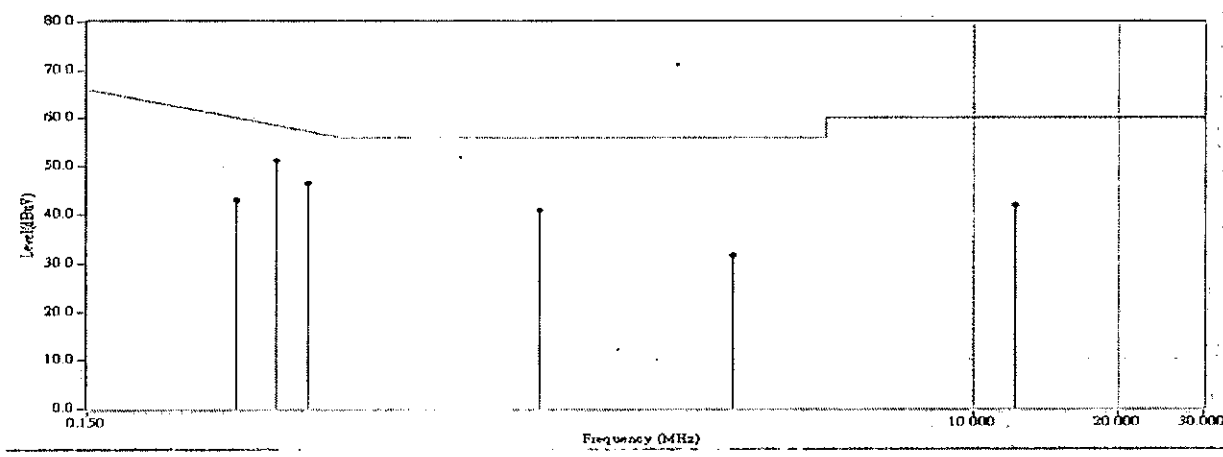
| | |
|---|---|
| Site : SR-1 | Time : 2007/09/01 - 04:21 |
| Limit : CISPR_B_00M_QP | Margin : 0 |
| EUT : TENS | Probe : LISN-020(N) - Line2 |
| Power : AC 230V/60Hz | Note : Mode 1 |




| | | Frequency (MHz) | Correct Factor (dB) | Reading Level (dBuV) | Measure Level (dBuV) | Margin (dB) | Limit (dBuV) | Detector Type |
|---|---|---|---|---|---|---|---|---|
| 1 | | 0.306 | 0.213 | 42.980 | 43.193 | -18.350 | 61.543 | QUASIPEAK |
| 2 | * | 0.369 | 0.214 | 51.130 | 51.344 | -8.399 | 59.743 | QUASIPEAK |
| 3 | | 0.427 | 0.215 | 46.400 | 46.615 | -11.471 | 58.086 | QUASIPEAK |
| 4 | | 1.283 | 0.247 | 40.700 | 40.947 | -15.053 | 56.000 | QUASIPEAK |
| 5 | | 3.209 | 0.322 | 31.430 | 31.752 | -24.248 | 56.000 | QUASIPEAK |
| 6 | | 12.185 | 0.652 | 41.380 | 42.032 | -17.968 | 60.000 | QUASIPEAK |

Note:

1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



3/2

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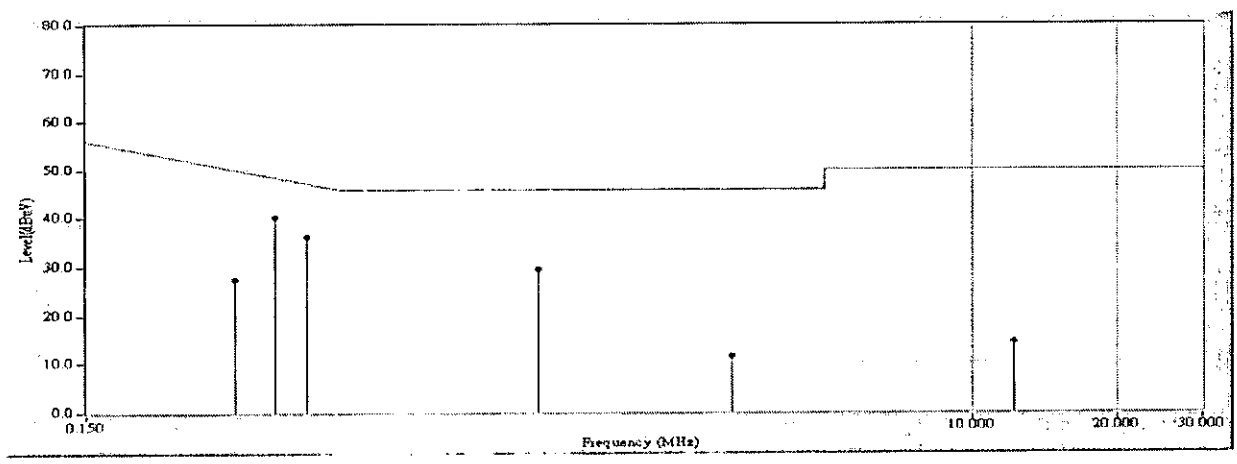
| | |
|---|---|
| Site : SR-1 | Time : 2007/09/01 - 04:21 |
| Limit : CISPR_B_00M_AV | Margin : 0 |
| EUT : TENS | Probe : LISN-020(N) - Line2 |
| Power : AC 230V/60Hz | Note : Mode 1 |




| | | Frequency (MHz) | Correct Factor (dB) | Reading Level (dBuV) | Measure Level (dBuV) | Margin (dB) | Limit (dBuV) | Detector Type |
|---|---|---|---|---|---|---|---|---|
| 1 | | 0.306 | 0.213 | 27.180 | 27.393 | -24.150 | 51.543 | AVERAGE |
| 2 | * | 0.369 | 0.214 | 40.020 | 40.234 | -9.509 | 49.743 | AVERAGE |
| 3 | | 0.427 | 0.215 | 36.030 | 36.245 | -11.841 | 48.086 | AVERAGE |
| 4 | | 1.283 | 0.247 | 29.330 | 29.577 | -16.423 | 46.000 | AVERAGE |
| 5 | | 3.209 | 0.322 | 11.200 | 11.522 | -34.478 | 46.000 | AVERAGE |
| 6 | | 12.185 | 0.652 | 13.640 | 14.292 | -35.708 | 50.000 | AVERAGE |

Note:

1. All Reading Levels are Quasi-Peak and average value.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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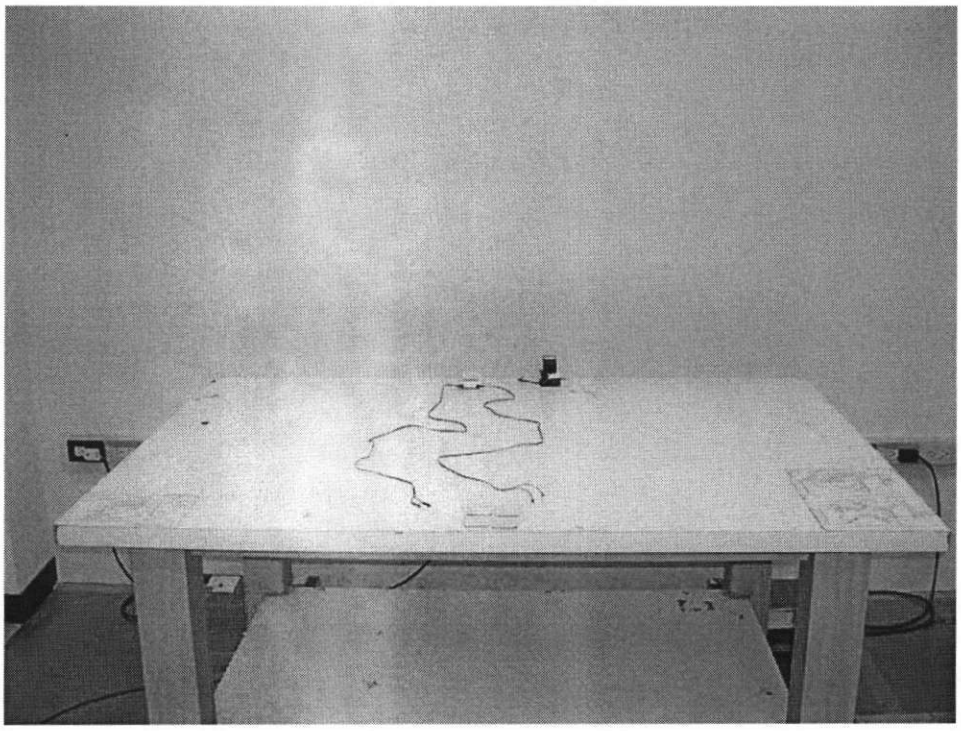
### 3.7. Test Photograph

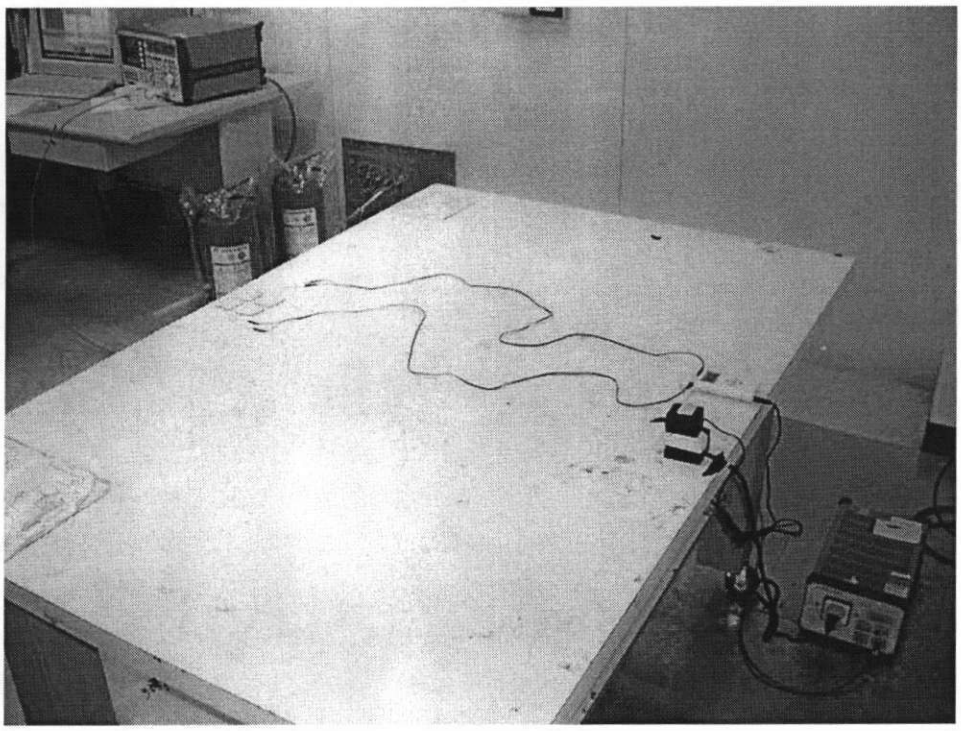
Test Mode : Mode 1:Normal Operation

Description : Front View of Conducted Test



Test Mode : Mode 1:Normal Operation

Description : Back View of Conducted Test





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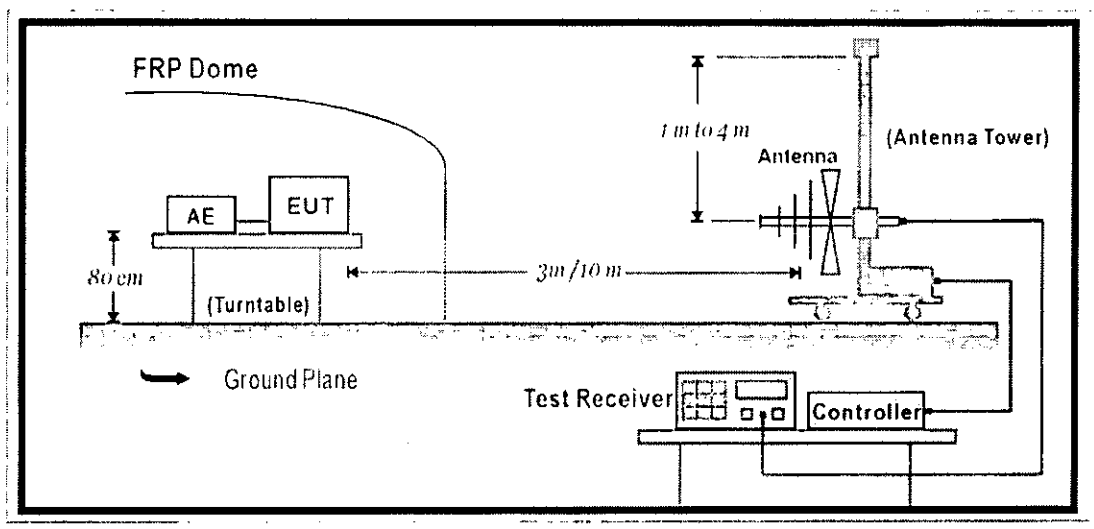
# 4. Radiated Emission

## 4.1. Test Specification

According to EMC Standard : EN 55011 (Group 1)

## 4.2. Test Setup




## 4.3. Limit

| Limits | | |
|---|---|---|
| Frequency (MHz) | Distance (m) | dBuV/m |
| 30 – 230 | 10 | 30 |
| 230 – 1000 | 10 | 37 |

Remark:

1. The tighter limit shall apply at the edge between two frequency bands.
2. Distance refers to the distance in meters between the measuring instrument antenna and the closed point of any part of the device or system..



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

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## 4.4. Test Procedure

The EUT and its simulators are placed on a turn table which is 0.8 meter above ground. The turn table can rotate 360 degrees to determine the position of the maximum emission level. The EUT was positioned such that the distance from antenna to the EUT was 10 meters. The antenna can move up and down between 1 meter and 4 meters to find out the maximum emission level.

Both horizontal and vertical polarization of the antenna are set on measurement. In order to find the maximum emission, all of the interface cables must be manipulated on radiated measurement.

Radiated emissions were invested over the frequency range from 30MHz to1GHz using a receiver bandwidth of 120kHz. Radiated was performed at an antenna to EUT distance of 10 meters.

## 4.5. Deviation from Test Standard

No deviation.



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

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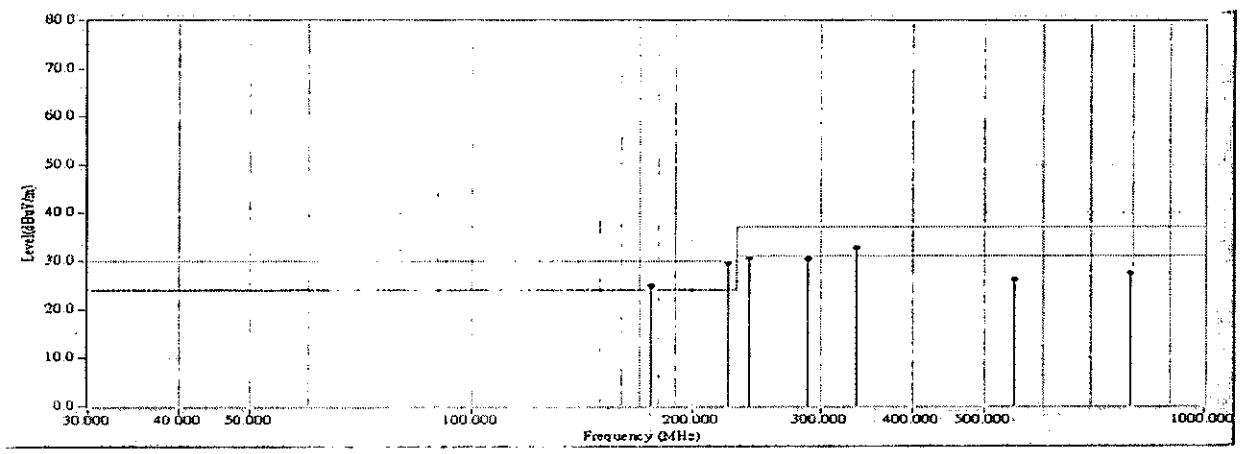
## 4.6. Test Result

| | |
|---|---|
| Site : OATS-5 | Time : 2007/11/14 - 13:11 |
| Limit : CISPR_B_10M_QP | Margin : 6 |
| EUT : TENS | Probe : LKANT_S4_2006_01 - HORIZONTAL |
| Power : AC 230V/50Hz | Note : Mode 1 |




| | | Frequency (MHz) | Correct Factor (dB) | Reading Level (dBuV) | Measure Level (dBuV/m) | Margin (dB) | Limit (dBuV/m) | Detector Type |
|---|---|---|---|---|---|---|---|---|
| 1 | | 176.025 | 12.523 | 12.340 | 24.863 | -5.137 | 30.000 | QUASIPEAK |
| 2 | * | 224.030 | 14.242 | 15.390 | 29.632 | -0.368 | 30.000 | QUASIPEAK |
| 3 | | 240.035 | 15.387 | 15.280 | 30.667 | -6.333 | 37.000 | QUASIPEAK |
| 4 | | 288.040 | 17.140 | 13.300 | 30.440 | -6.560 | 37.000 | QUASIPEAK |
| 5 | | 336.050 | 18.465 | 14.290 | 32.755 | -4.245 | 37.000 | QUASIPEAK |
| 6 | | 547.700 | 22.964 | 3.270 | 26.234 | -10.766 | 37.000 | QUASIPEAK |
| 7 | | 791.500 | 26.281 | 1.100 | 27.381 | -9.619 | 37.000 | QUASIPEAK |

Note:

1. All Readings below 1GHz are Quasi-Peak, above are performed with peak and/or average measurements as necessary.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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

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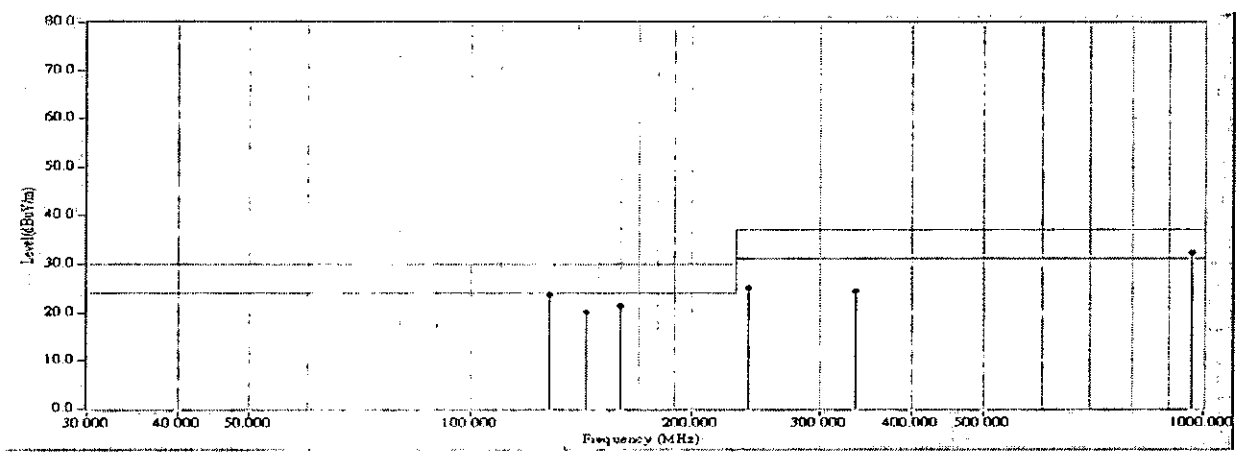
| | |
|---|---|
| Site : OATS-5 | Time : 2007/11/14 - 11:55 |
| Limit : CISPR_B_10M_QP | Margin : 6 |
| EUT : TENS | Probe : LKANT_S4_2006_01 - VERTICAL |
| Power : AC 230V/50Hz | Note : Mode 1 |




| | | Frequency (MHz) | Correct Factor (dB) | Reading Level (dBuV) | Measure Level (dBuV/m) | Margin (dB) | Limit (dBuV/m) | Detector Type |
|---|---|---|---|---|---|---|---|---|
| 1 | | 128.020 | 14.849 | 9.030 | 23.878 | -6.122 | 30.000 | QUASIPEAK |
| 2 | | 144.018 | 14.133 | 5.950 | 20.083 | -9.917 | 30.000 | QUASIPEAK |
| 3 | | 160.300 | 13.197 | 8.200 | 21.397 | -8.603 | 30.000 | QUASIPEAK |
| 4 | | 240.000 | 15.385 | 9.700 | 25.085 | -11.915 | 37.000 | QUASIPEAK |
| 5 | | 336.053 | 18.465 | 5.900 | 24.366 | -12.634 | 37.000 | QUASIPEAK |
| 6 | * | 965.300 | 29.165 | 3.200 | 32.365 | -4.635 | 37.000 | QUASIPEAK |

Note:

1. All Readings below 1GHz are Quasi-Peak, above are performed with peak and/or average measurements as necessary.
2. " * ", means this data is the worst emission level.
3. Measurement Level = Reading Level + Correct Factor



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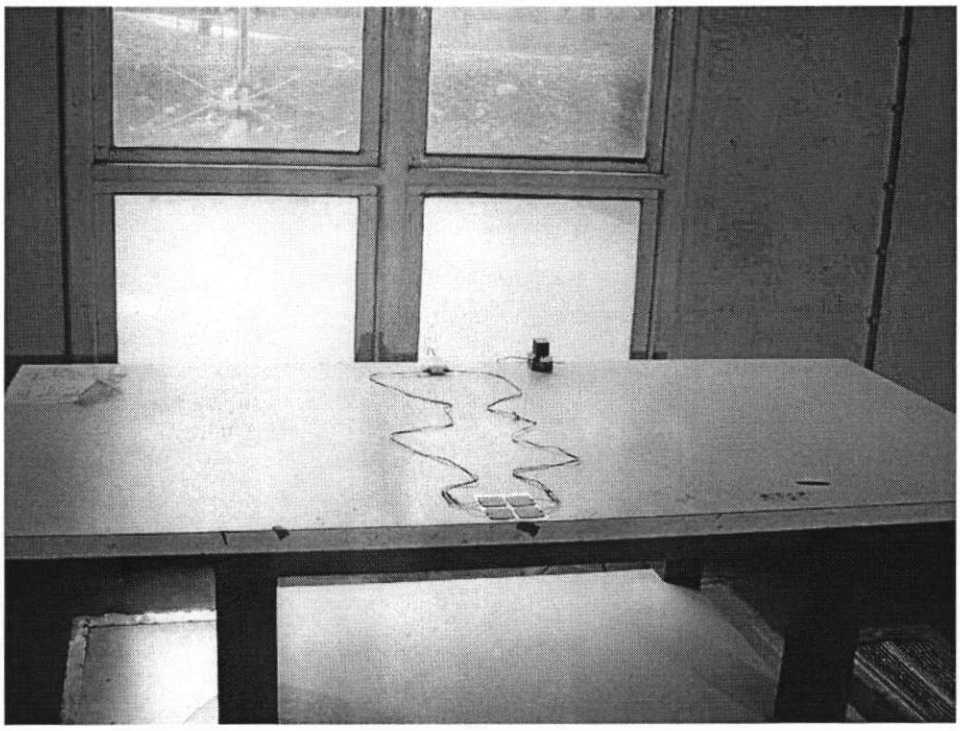
## 4.7. Test Photograph

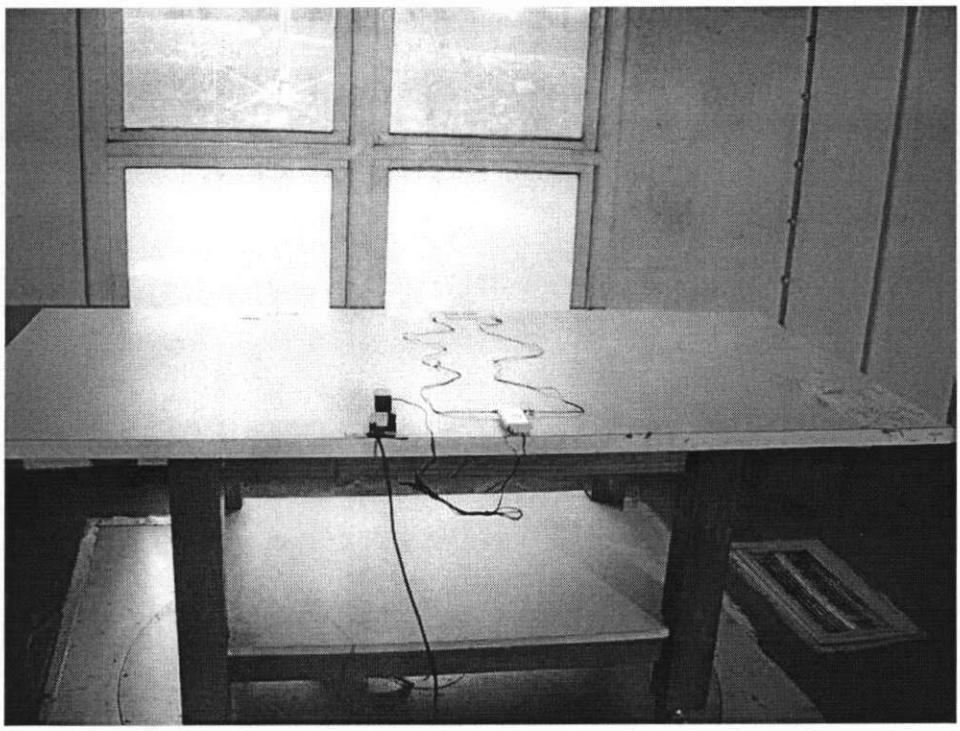
Test Mode : Mode 1:Normal Operation

Description : Front View of Radiated Test



Test Mode : Mode 1:Normal Operation

Description : Back View of Radiated Test





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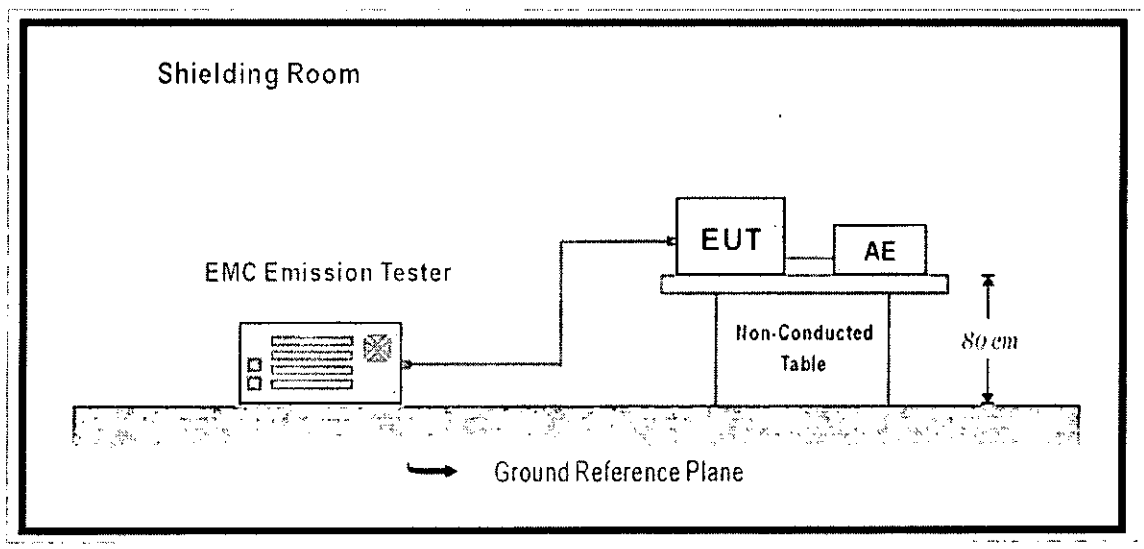
## 5. Harmonic Current Emission

### 5.1. Test Specification

According to EMC Standard : EN 61000-3-2

### 5.2. Test Setup




### 5.3. Limit

(a) Limits of Class A Harmonics Currents

| Harmonics Order n | Maximum Permissible harmonic current A | Harmonics Order n | Maximum Permissible harmonic current A |
|---|---|---|---|
| Odd harmonics | | Even harmonics | |
| 3 | 2.30 | 2 | 1.08 |
| 5 | 1.14 | 4 | 0.43 |
| 7 | 0.77 | 6 | 0.30 |
| 9 | 0.40 | $8 \le n \le 40$ | 0.23 * 8/n |
| 11 | 0.33 | | |
| 13 | 0.21 | | |
| $15 \le n \le 39$ | 0.15 * 15/n | | |



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

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(b) Limits of Class B Harmonics Currents

For Class B equipment, the harmonic of the input current shall not exceed the maximum permissible values given in table that is the limit of Class A multiplied by a factor of 1.5.

(c) Limits of Class C Harmonics Currents

| Harmonics Order<br>n | Maximum Permissible harmonic current Expressed as a percentage of the input current at the fundamental frequency<br>% |
|---|---|
| 2 | 2 |
| 3 | 30 · λ* |
| 5 | 10 |
| 7 | 7 |
| 9 | 5 |
| 11 ≤ n ≤ 39<br>(odd harmonics only) | 3 |
| ∗λ is the circuit power factor | |

(d) Limits of Class D Harmonics Currents

| Harmonics Order<br>n | Maximum Permissible harmonic current per watt<br>mA/W | Maximum Permissible harmonic current<br>A |
|---|---|---|
| 3 | 3.4 | 2.30 |
| 5 | 1.9 | 1.14 |
| 7 | 1.0 | 0.77 |
| 9 | 0.5 | 0.40 |
| 11 | 0.35 | 0.33 |
| 11 ≤ n ≤ 39<br>(odd harmonics only) | 3.85/n | See limit of Class A |



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## 5.4. Test Procedure

The EUT is supplied in series with power analyzer from a power source having the same normal voltage and frequency as the rated supply voltage and the equipment under test. And the rated voltage at the supply voltage of EUT of 0.94 times and 1.06 times shall be performed.

## 5.5. Deviation from Test Standard

No deviation.





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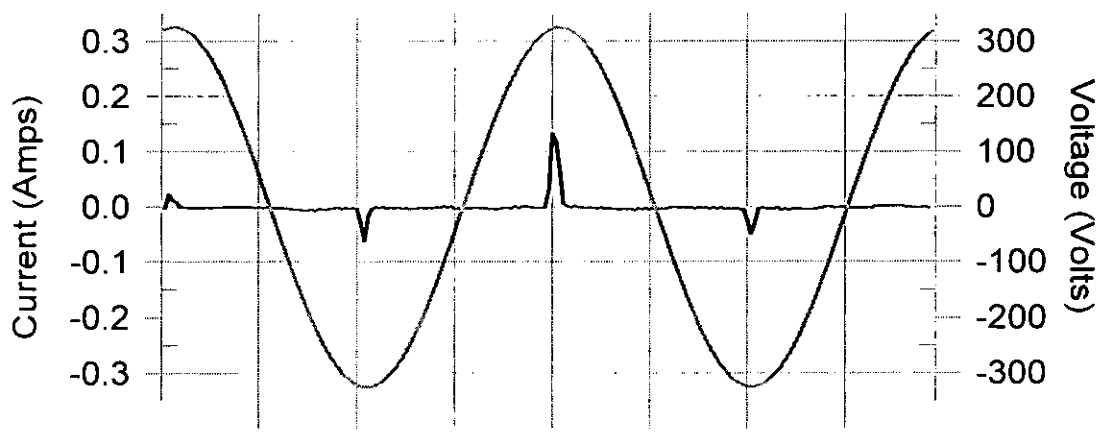
## 5.6. Test Result

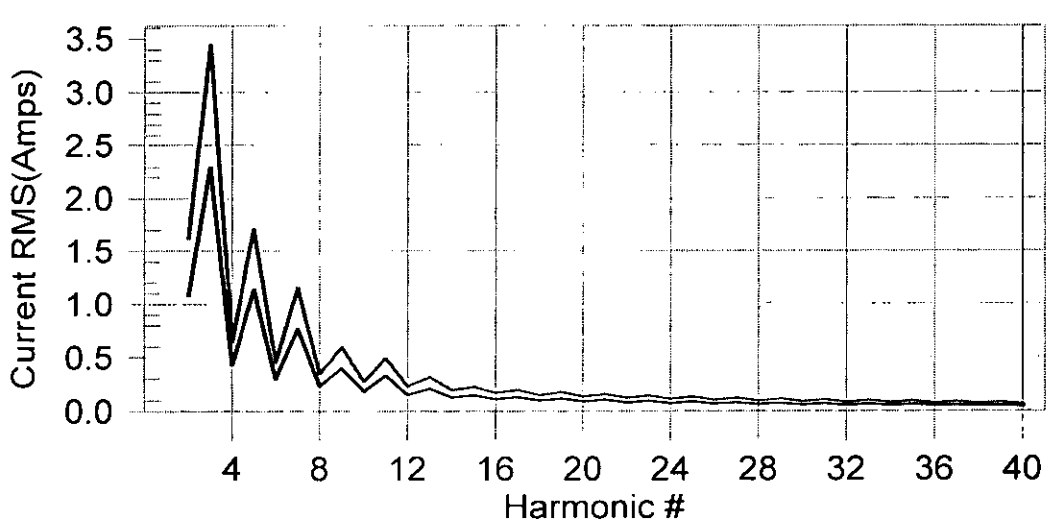
| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Power Harmonics | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/09/01 | Test Site | No.3 Shielded Room |

Test Result: Pass Source qualification: Normal

Current & voltage waveforms




Harmonics and Class A limit line European Limits




Test result: Pass Worst harmonic was #19 with 1.52% of the limit.



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Test Result: Pass Source qualification: Normal
THC(A): 0.01 I-THD(%): 255.11 POHC(A): 0.003 POHC Limit(A): 0.251
Highest parameter values during test:

| | | | |
|---|---|---|---|
| V_RMS (Volts): | 229.68 | Frequency(Hz): | 50.00 |
| I_Peak (Amps): | 0.176 | I_RMS (Amps): | 0.015 |
| I_Fund (Amps): | 0.005 | Crest Factor: | 16.072 |
| Power (Watts): | 1.2 | Power Factor: | 0.344 |

| Harm# | Harms(avg) | 100%Limit | %of Limit | Harms(max) | 150%Limit | %of Limit | Status |
|---|---|---|---|---|---|---|---|
| 2 | 0.000 | 1.080 | 0.0 | 0.000 | 1.620 | 0.03 | Pass |
| 3 | 0.003 | 2.300 | 0.1 | 0.005 | 3.450 | 0.13 | Pass |
| 4 | 0.000 | 0.430 | 0.0 | 0.000 | 0.645 | 0.06 | Pass |
| 5 | 0.003 | 1.140 | 0.3 | 0.004 | 1.710 | 0.26 | Pass |
| 6 | 0.000 | 0.300 | 0.1 | 0.001 | 0.450 | 0.15 | Pass |
| 7 | 0.003 | 0.770 | 0.4 | 0.004 | 1.155 | 0.37 | Pass |
| 8 | 0.000 | 0.230 | 0.1 | 0.000 | 0.345 | 0.11 | Pass |
| 9 | 0.003 | 0.400 | 0.7 | 0.004 | 0.600 | 0.69 | Pass |
| 10 | 0.000 | 0.184 | 0.1 | 0.000 | 0.276 | 0.13 | Pass |
| 11 | 0.003 | 0.330 | 0.8 | 0.004 | 0.495 | 0.78 | Pass |
| 12 | 0.000 | 0.153 | 0.1 | 0.000 | 0.230 | 0.18 | Pass |
| 13 | 0.003 | 0.210 | 1.2 | 0.004 | 0.315 | 1.15 | Pass |
| 14 | 0.000 | 0.131 | 0.1 | 0.000 | 0.197 | 0.17 | Pass |
| 15 | 0.002 | 0.150 | 1.5 | 0.003 | 0.225 | 1.48 | Pass |
| 16 | 0.000 | 0.115 | 0.1 | 0.000 | 0.173 | 0.18 | Pass |
| 17 | 0.002 | 0.132 | 1.6 | 0.003 | 0.199 | 1.52 | Pass |
| 18 | 0.000 | 0.102 | 0.2 | 0.000 | 0.153 | 0.20 | Pass |
| 19 | 0.002 | 0.118 | 1.6 | 0.003 | 0.178 | 1.52 | Pass |
| 20 | 0.000 | 0.092 | 0.2 | 0.000 | 0.138 | 0.20 | Pass |
| 21 | 0.002 | 0.107 | 1.6 | 0.002 | 0.161 | 1.48 | Pass |
| 22 | 0.000 | 0.084 | 0.2 | 0.000 | 0.125 | 0.20 | Pass |
| 23 | 0.001 | 0.098 | 1.5 | 0.002 | 0.147 | 1.42 | Pass |
| 24 | 0.000 | 0.077 | 0.2 | 0.000 | 0.115 | 0.20 | Pass |
| 25 | 0.001 | 0.090 | 1.4 | 0.002 | 0.135 | 1.32 | Pass |
| 26 | 0.000 | 0.071 | 0.2 | 0.000 | 0.106 | 0.20 | Pass |
| 27 | 0.001 | 0.083 | 1.3 | 0.002 | 0.125 | 1.21 | Pass |
| 28 | 0.000 | 0.066 | 0.2 | 0.000 | 0.099 | 0.20 | Pass |
| 29 | 0.001 | 0.078 | 1.2 | 0.001 | 0.116 | 1.09 | Pass |
| 30 | 0.000 | 0.061 | 0.2 | 0.000 | 0.092 | 0.21 | Pass |
| 31 | 0.001 | 0.073 | 1.0 | 0.001 | 0.109 | 0.96 | Pass |
| 32 | 0.000 | 0.058 | 0.2 | 0.000 | 0.086 | 0.19 | Pass |
| 33 | 0.001 | 0.068 | 0.9 | 0.001 | 0.102 | 0.84 | Pass |
| 34 | 0.000 | 0.054 | 0.2 | 0.000 | 0.081 | 0.19 | Pass |
| 35 | 0.000 | 0.064 | 0.7 | 0.001 | 0.096 | 0.73 | Pass |
| 36 | 0.000 | 0.051 | 0.2 | 0.000 | 0.077 | 0.20 | Pass |
| 37 | 0.000 | 0.061 | 0.6 | 0.001 | 0.091 | 0.64 | Pass |
| 38 | 0.000 | 0.048 | 0.2 | 0.000 | 0.073 | 0.20 | Pass |
| 39 | 0.000 | 0.058 | 0.5 | 0.000 | 0.087 | 0.56 | Pass |
| 40 | 0.000 | 0.046 | 0.2 | 0.000 | 0.069 | 0.20 | Pass |

1.Dynamic limits were applied for this test. The highest harmonics values in the above table may not occur at the same window as the maximum harmonics/limit ratio.

2:According to EN61000-3-2 paragraph 7 the note 1 and 2 are valid for all applications having an active input power >75W. Others the result should be pass.



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

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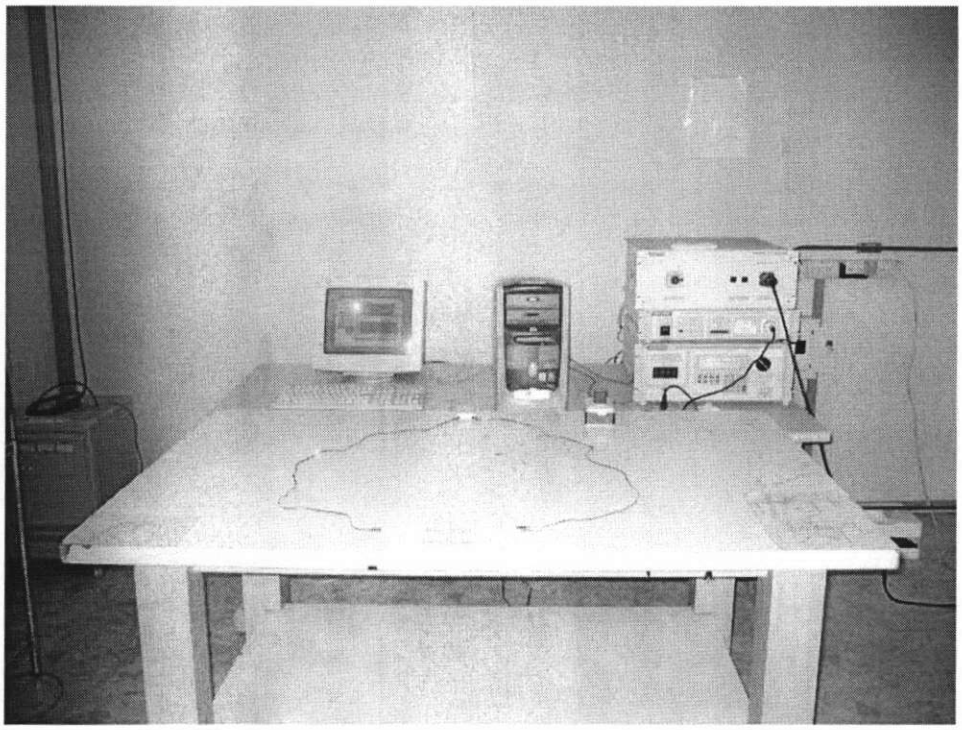
## 5.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : Power Harmonics Test Setup





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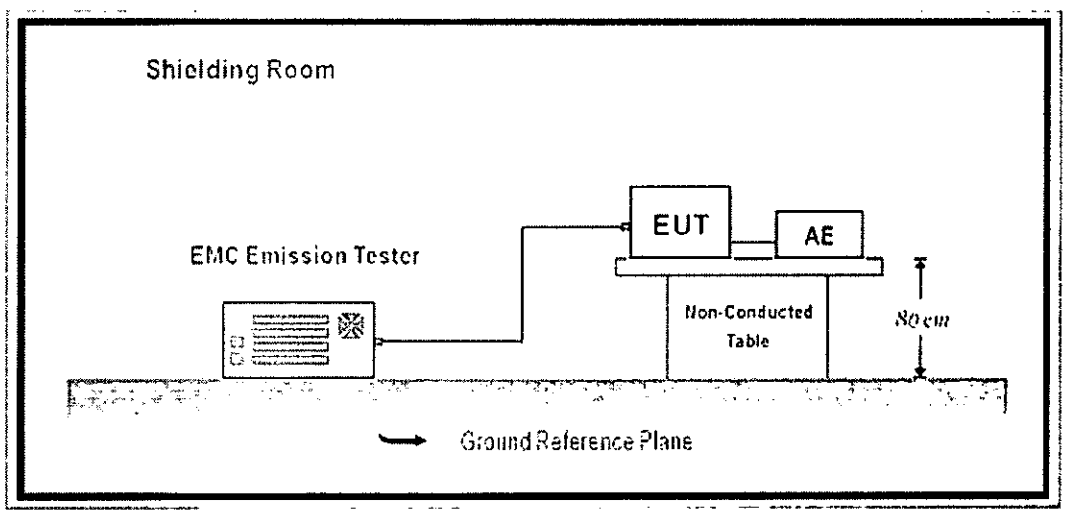
# 6. Voltage Fluctuation and Flicker

## 6.1. Test Specification

According to EMC Standard : EN 61000-3-3

## 6.2. Test Setup




## 6.3. Limit

The following limits apply:

- the value of $P_{st}$ shall not be greater than 1.0;
- the value of $P_{lt}$ shall not be greater than 0.65;
- the value of d(t) during a voltage change shall not exceed 3.3 % for more than 500 ms;
- the relative steady-state voltage change, $d_c$, shall not exceed 3.3 %;
- the maximum relative voltage change, $d_{max}$, shall not exceed;

a) 4 % without additional conditions;

b) 6 % for equipment which is:

- switched manually, or
- switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.

NOTE The cycling frequency will be further limited by the $P_{st}$ and $P_{1t}$ limit.

For example: a $d_{max}$ of 6%producing a rectangular voltage change characteristic twice per hour will give a $P_{1t}$ of about 0.65.



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c) 7 % for equipment which is:
- attended whilst in use (for example: hair dryers, vacuum cleaners, kitchen equipment such as mixers, garden equipment such as lawn mowers, portable tools such as electric drills), or
- switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart, after a power supply interruption.

$P_{st}$ and $P_{lt}$ requirements shall not be applied to voltage changes caused by manual switching.

## 6.4. Test Procedure

The EUT is supplied in series with power analyzer from a power source having the same normal voltage and frequency as the rated supply voltage and the equipment under test. And the rated voltage at the supply voltage of EUT of 0.94 times and 1.06 times shall be performed.

## 6.5. Deviation from Test Standard

No deviation.



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

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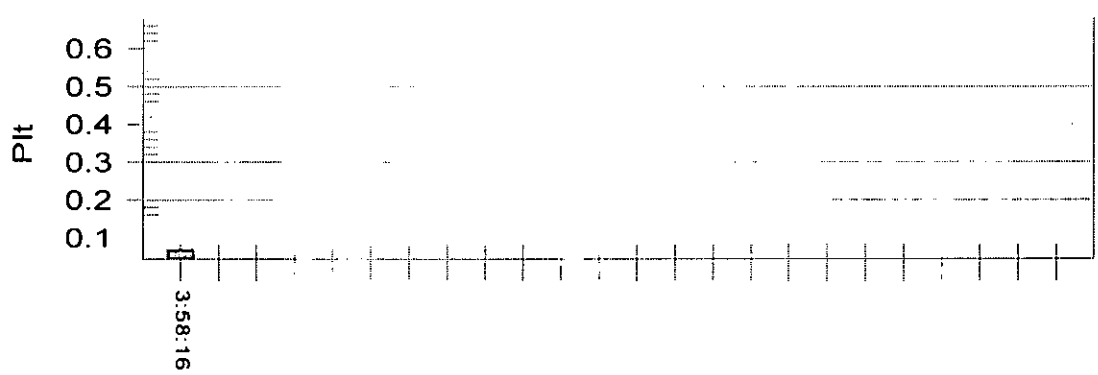
## 6.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Voltage Fluctuation and Flicker | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/09/01 | Test Site | No.3 Shielded Room |

Test Result: Pass Status: Test Completed

Pst and limit line European Limits

Plt and limit line




Parameter values recorded during the test:

| | | | | |
|---|---|---|---|---|
| Vrms at the end of test (Volt): | 229.65 | | | |
| Highest dt (%): | 0.00 | Test limit (%): | 3.30 | Pass |
| Time(mS) > dt: | 0.0 | Test limit (mS): | 500.0 | Pass |
| Highest dc (%): | 0.00 | Test limit (%): | 3.30 | Pass |
| Highest dmax (%): | 0.00 | Test limit (%): | 4.00 | Pass |
| Highest Pst (10 min. period): | 0.160 | Test limit: | 1.000 | Pass |
| Highest Plt (2 hr. period): | 0.070 | Test limit: | 0.650 | Pass |



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

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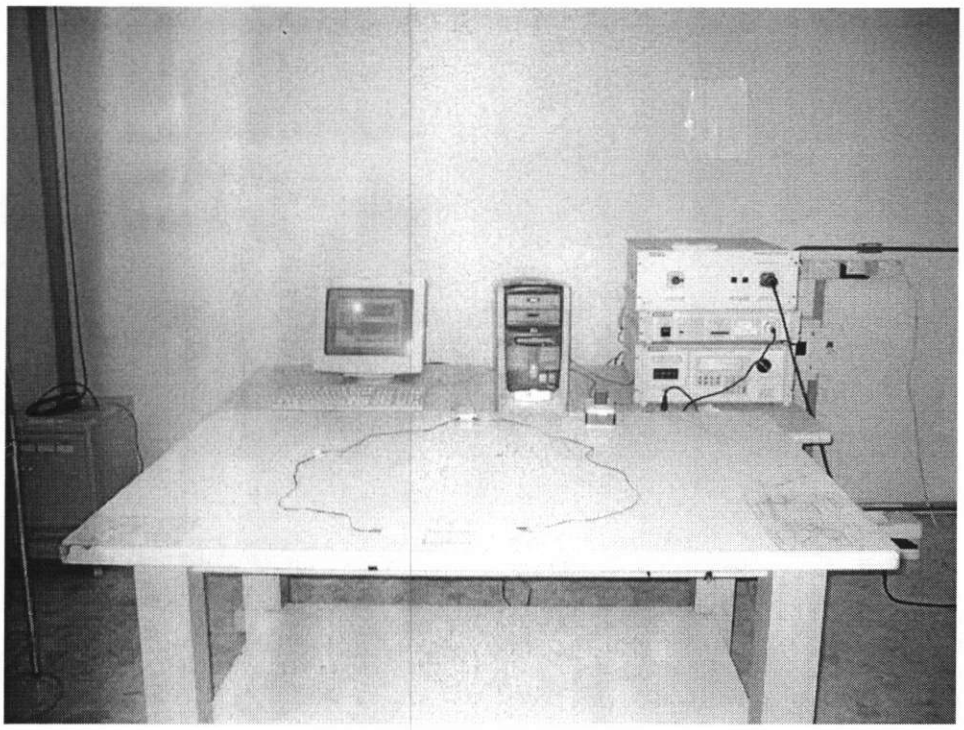
## 6.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : Flicker Test Setup





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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

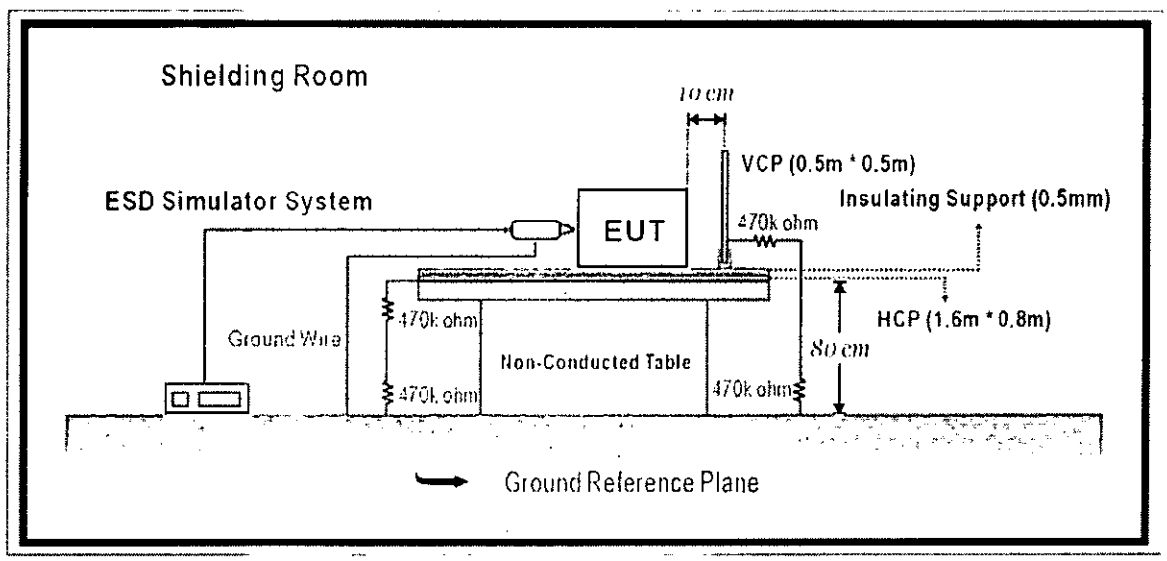


# 7. Electrostatic Discharge

## 7.1. Test Specification

According to Standard : IEC 61000-4-2

## 7.2. Test Setup




## 7.3. Limit

| Item | Environmental Phenomena | Units | Test Specification | Performance Criteria |
|---|---|---|---|---|
| Enclosure Port | | | | |
| | Electrostatic Discharge | kV(Charge Voltage) | ±8 Air Discharge<br>±6 Contact Discharge | B |



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

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## 7.4. Test Procedure

Direct application of discharges to the EUT:

Contact discharge was applied only to conductive surfaces of the EUT.

Air discharges were applied only to non-conductive surfaces of the EUT.

During the test, it was performed with single discharges. For the single discharge time between successive single discharges will be keep longer 1 second. It was at least ten single discharges with positive and negative at the same selected point.

The selected point, which was performed with electrostatic discharge, was marked on the red label of the EUT.

Indirect application of discharges to the EUT:

Vertical Coupling Plane (VCP):

The coupling plane, of dimensions 0.5m x 0.5m, is placed parallel to, and positioned at a distance 0.1m from, the EUT, with the Discharge Electrode touching the coupling plane.

The four faces of the EUT will be performed with electrostatic discharge. It was at least ten single discharges with positive and negative at the same selected point.

Horizontal Coupling Plane (HCP):

The coupling plane is placed under to the EUT. The generator shall be positioned vertically at a distance of 0.1m from the EUT, with the Discharge Electrode touching the coupling plane.

The four faces of the EUT will be performed with electrostatic discharge. It was at least ten single discharges with positive and negative at the same selected point.

## 7.5. Deviation from Test Standard

No deviation.



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

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### 7.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Electrostatic Discharge | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/19 | Test Site | No.6 Shielded Room |

| Item | Amount of Discharge | Voltage | Required Criteria | Complied To Criteria (A,B,C) | Results |
|---|---|---|---|---|---|
| Air Discharge | 10 | +8kV | B | B | Pass |
| | 10 | -8kV | B | B | Pass |
| Contact Discharge | 25 | +6kV | B | A | Pass |
| | 25 | -6kV | B | A | Pass |
| Indirect Discharge (HCP) | 50 | +6kV | B | A | Pass |
| | 50 | -6kV | B | A | Pass |
| Indirect Discharge (VCP Front) | 50 | +6kV | B | A | Pass |
| | 50 | -6kV | B | A | Pass |
| Indirect Discharge (VCP Left) | 50 | +6kV | B | A | Pass |
| | 50 | -6kV | B | A | Pass |
| Indirect Discharge (VCP Back) | 50 | +6kV | B | A | Pass |
| | 50 | -6kV | B | A | Pass |
| Indirect Discharge (VCP Right) | 50 | +6kV | B | A | Pass |
| | 50 | -6kV | B | A | Pass |

Note:

The testing performed is from lowest level up to the highest level as required by standard, but only highest level is shown on the report.

NR: No Requirement

- ☒ Meet criteria A: Operate as intended during and after the test
- ☒ Meet criteria B: Operate as intended after the test
- ☐ Meet criteria C: Loss/Error of function
- ☐ Additional Information
  - ☐ EUT stopped operation and could / could not be reset by operator at ____ kV.
  - ☒ No false alarms or other malfunctions were observed during or after the test.

Remark:

The Contact discharges were applied at least total 200 discharges at a minimum of four test points.



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

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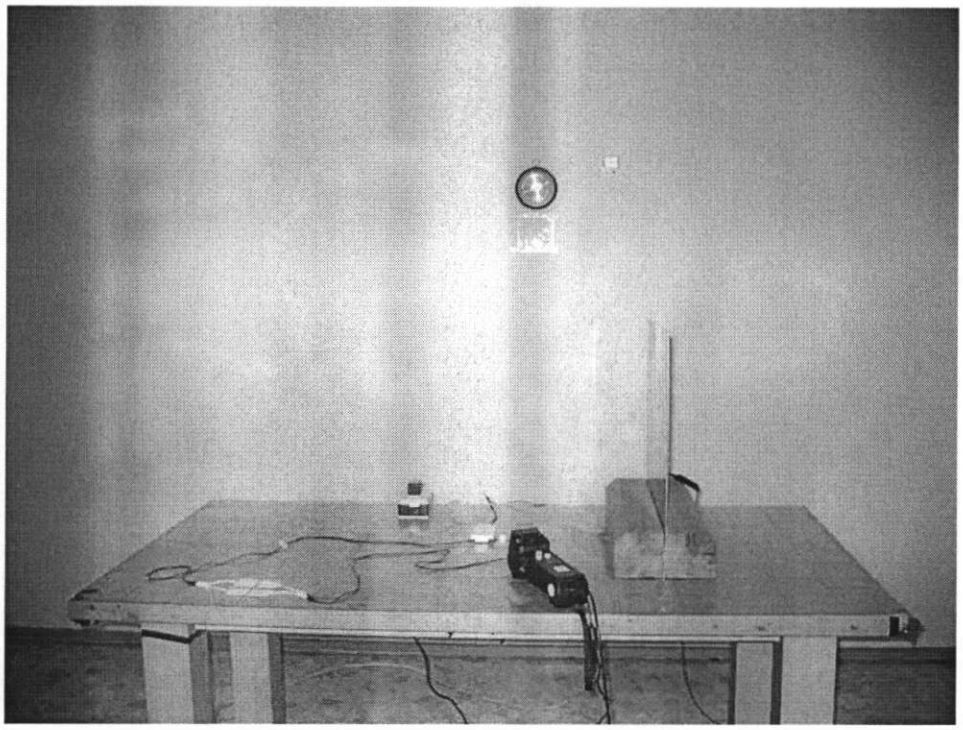
## 7.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : ESD Test Setup





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

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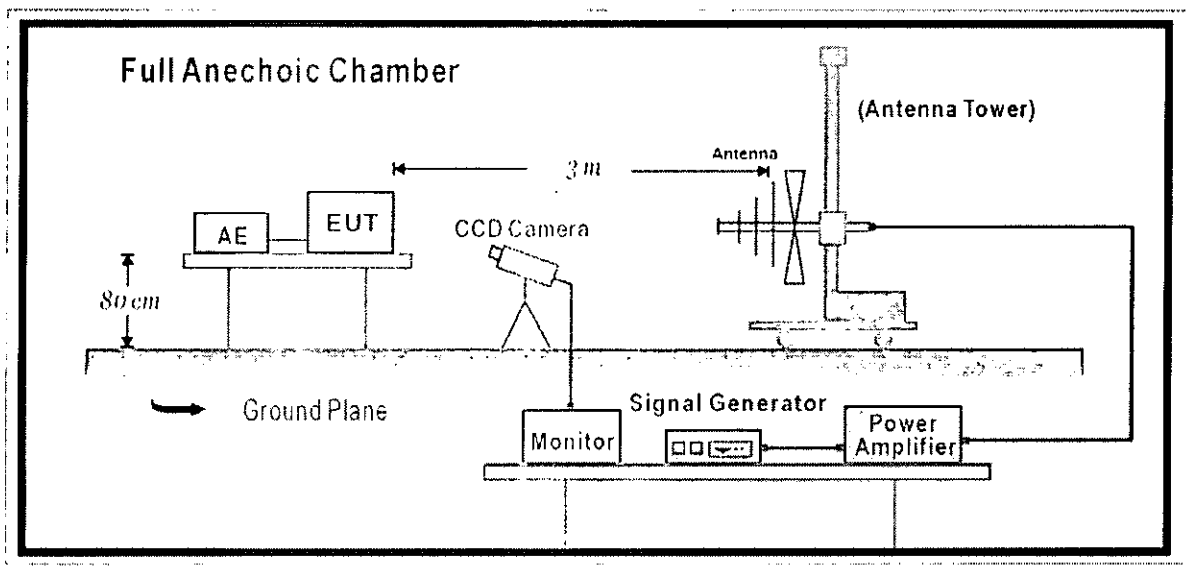
## 8. Radiated Susceptibility

### 8.1. Test Specification

According to Standard : IEC 61000-4-3

### 8.2. Test Setup




### 8.3. Limit

| Item | Environmental Phenomena | Units | Test Specification | Performance Criteria |
|---|---|---|---|---|
| Enclosure Port | | | | |
| | Radio-Frequency Electromagnetic Field Amplitude Modulated | MHz<br>V/m(Un-modulated, rms)<br>% AM (1kHz) | 80-2500<br>3<br>80 | A |



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

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## 8.4. Test Procedure

The EUT and load, which are placed on a table that is 0.8 meter above ground, are placed with one coincident with the calibration plane such that the distance from antenna to the EUT was 3 meters.

Both horizontal and vertical polarization of the antenna and four sides of the EUT are set on measurement.

In order to judge the EUT performance, a CCD camera is used to monitor EUT screen.

All the scanning conditions are as follows:

| | Condition of Test | Remarks |
|---|---|---|
| 1. | Field Strength | 3 V/m Level 2 |
| 2. | Radiated Signal | AM 80% Modulated with 1kHz |
| 3. | Scanning Frequency | 80MHz - 2500MHz |
| 4 | Dwell Time | 3 Seconds |
| 5. | Frequency step size $\Delta f$ : | 1% |
| 6. | The rate of Swept of Frequency | $1.5 \times 10^{-3}$ decades/s |

## 8.5. Deviation from Test Standard

No deviation.



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

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## 8.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Radiated susceptibility | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/17 | Test Site | Chamber5 |

| Frequency (MHz) | Position (Angle) | Polarity (H or V) | Field Strength (V/m) | Required Criteria | Complied To Criteria (A,B,C) | Results |
|---|---|---|---|---|---|---|
| 80-2500 | FRONT | H | 3 | A | A | PASS |
| 80-2500 | FRONT | V | 3 | A | A | PASS |
| 80-2500 | BACK | H | 3 | A | A | PASS |
| 80-2500 | BACK | V | 3 | A | A | PASS |
| 80-2500 | RIGHT | H | 3 | A | A | PASS |
| 80-2500 | RIGHT | V | 3 | A | A | PASS |
| 80-2500 | LEFT | H | 3 | A | A | PASS |
| 80-2500 | LEFT | V | 3 | A | A | PASS |
| 80-2500 | UP | H | 3 | A | A | PASS |
| 80-2500 | UP | V | 3 | A | A | PASS |
| 80-2500 | DOWN | H | 3 | A | A | PASS |
| 80-2500 | DOWN | V | 3 | A | A | PASS |

Note:

The testing performed is from lowest level up to the highest level as required by standard, but only highest level is shown on the report.

☒ Meet criteria A: Operate as intended during and after the test
☐ Meet criteria B: Operate as intended after the test
☐ Meet criteria C: Loss/Error of function
☐ Additional Information
  ☐ There was no observable degradation in performance.
  ☐ EUT stopped operation and could / could not be reset by operator at _____ V/m at frequency _____MHz.

☒ No false alarms or other malfunctions were observed during or after the test.



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

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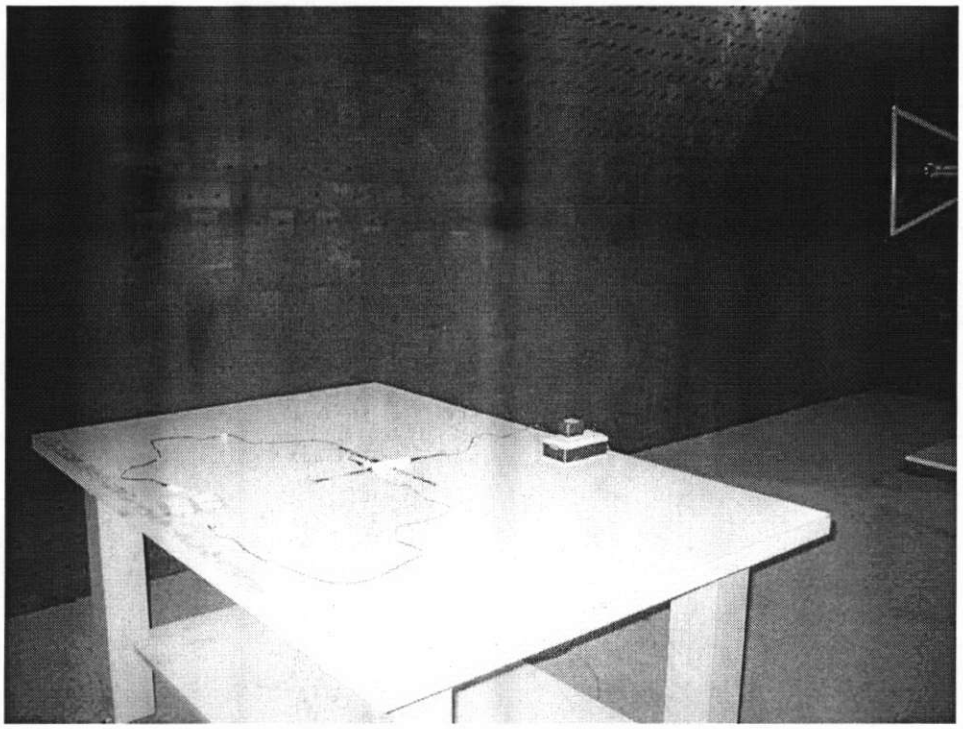
## 8.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : Radiated Susceptibility Test Setup





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

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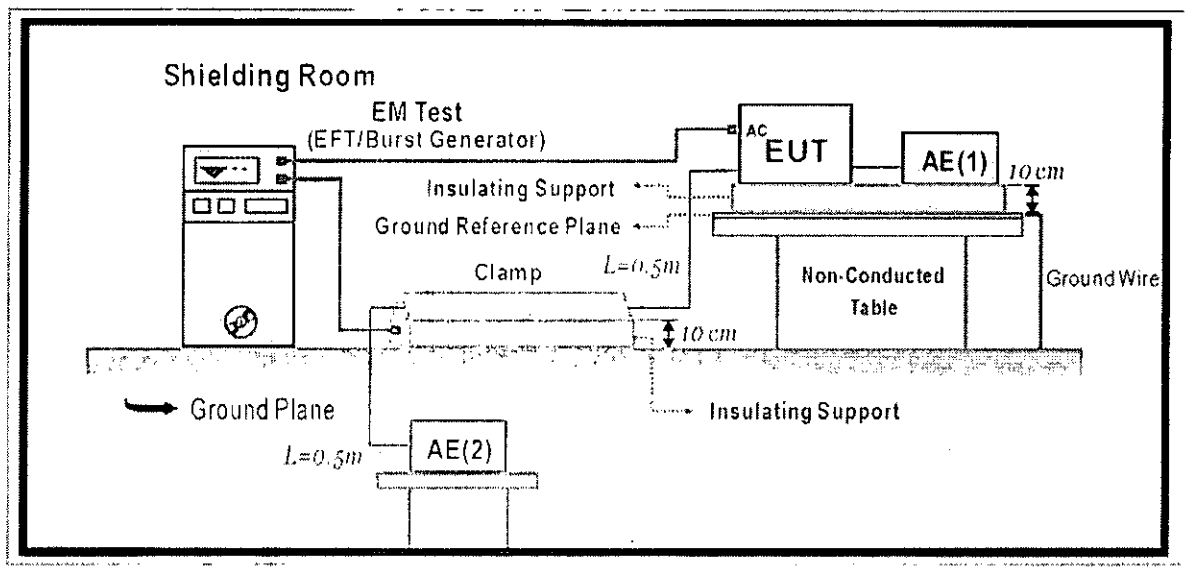
## 9. Electrical Fast Transient/Burst

### 9.1. Test Specification

According to Standard : IEC 61000-4-4

### 9.2. Test Setup




### 9.3. Limit

| Item | Environmental Phenomena | Units | Test Specification | Performance Criteria |
|---|---|---|---|---|
| I/O and communication ports | | | | |
| | Fast Transients Common Mode | kV (Peak)<br>Tr/Th ns<br>Rep. Frequency kHz | ±1<br>5/50<br>5 | B |
| Input DC Power Ports | | | | |
| | Fast Transients Common Mode | kV (Peak)<br>Tr/Th ns<br>Rep. Frequency kHz | ±1<br>5/50<br>5 | B |
| Input AC Power Ports | | | | |
| | Fast Transients Common Mode | kV (Peak)<br>Tr/Th ns<br>Rep. Frequency kHz | ±2<br>5/50<br>5 | B |



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

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## 9.4. Test Procedure

The EUT is placed on a table that is 0.8 meter height. A ground reference plane is placed on the table, and uses a 0.1m insulation between the EUT and ground reference plane.
The minimum area of the ground reference plane is 1m*1m, and 0.65mm thick min, and projected beyond the EUT by at least 0.1m on all sides.

Test on I/O and communication ports:
The EFT interference signal is through a coupling clamp device couples to the signal and control lines of the EUT with burst noise for 1minute.

Test on power supply ports:
The EUT is connected to the power mains through a coupling device that directly couples the EFT/B interference signal.
Each of the Line and Neutral conductors is impressed with burst noise for 1 minute.

The length of the signal and power lines between the coupling device and the EUT is 0.5m.

## 9.5. Deviation from Test Standard

No deviation.



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

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## 9.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Electrical fast transient/burst | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/14 | Test Site | No.2 Shielded Room |

| Inject Line | Polarity | Voltage kV | Inject Time (Second) | Inject Method | Required Criteria | Complied to Criteria | Result |
|---|---|---|---|---|---|---|---|
| L+N | ± | 2kV | 60 | Direct | B | A | PASS |

Note:

The testing performed is from lowest level up to the highest level as required by standard, but only highest level is shown on the report.

☒ Meet criteria A : Operate as intended during and after the test
☐ Meet criteria B : Operate as intended after the test
☐ Meet criteria C : Loss/Error of function
☐ Additional Information
  ☐ EUT stopped operation and could / could not be reset by operator at _____ kV of Line _____.
☒ No false alarms or other malfunctions were observed during or after the test.



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

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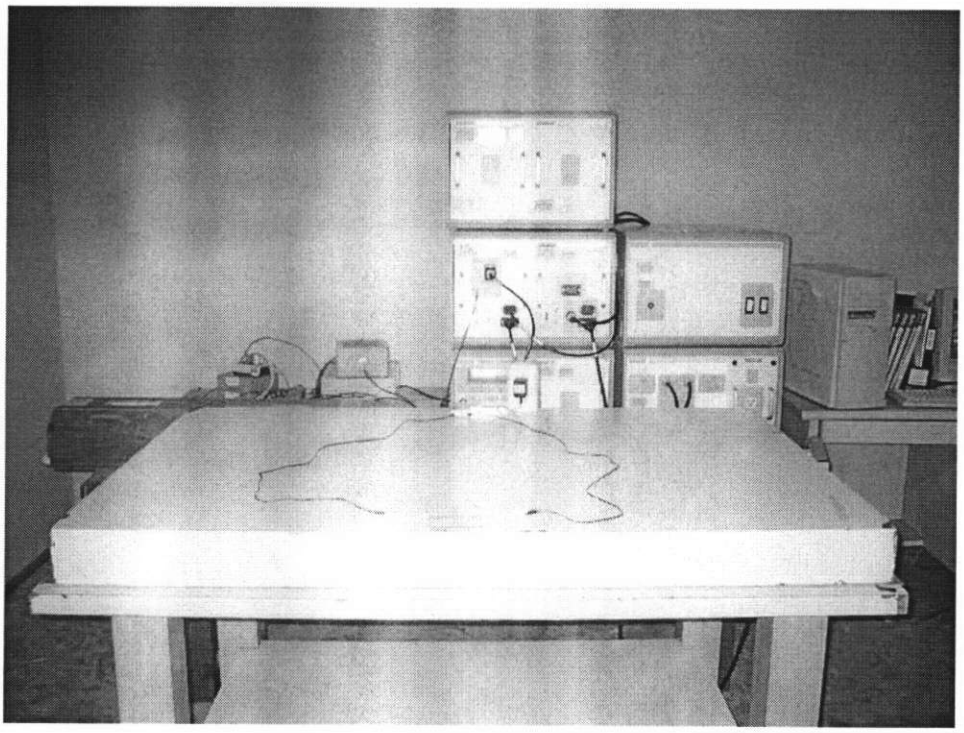
## 9.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : EFT/B Test Setup





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

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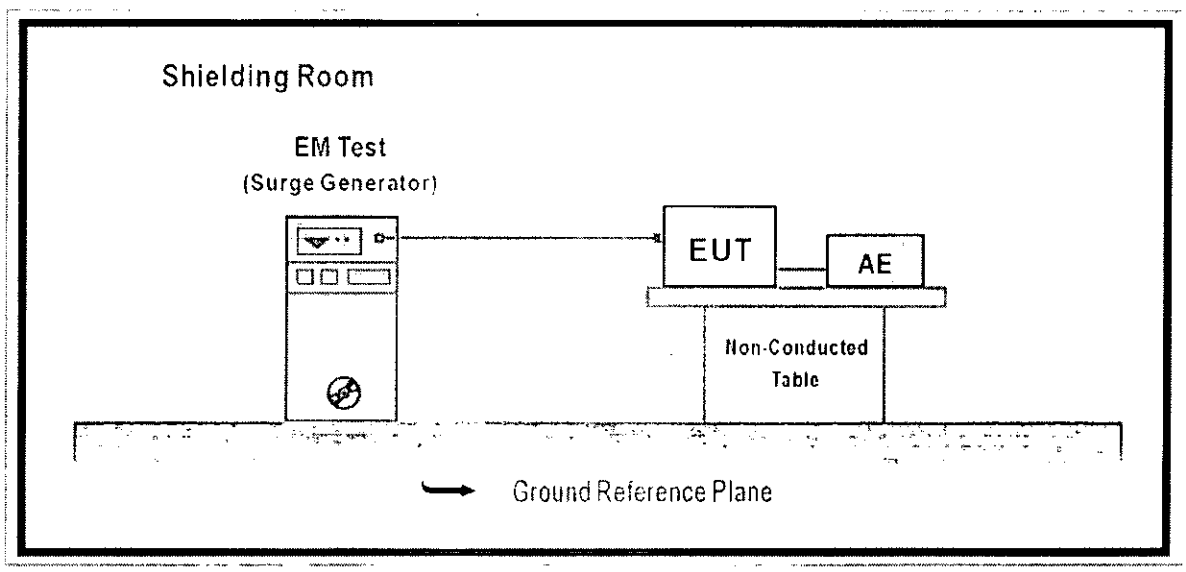
## 10. Surge

### 10.1. Test Specification

According to Standard : IEC 61000-4-5

### 10.2. Test Setup




### 10.3. Limit

| Item | Environmental Phenomena | Units | Test Specification | Performance Criteria |
|---|---|---|---|---|
| AC Input and AC Output Power Ports | | | | |
| | Surges | Tr/Th us | 1.2/50 (8/20) | |
| | Line to Line | kV | ± 1 | B |
| | Line to Ground | kV | ± 2 | |

Notes:

1) Applicable only to ports which according to the manufacturer's may directly to outdoor cables.
2) Where normal functioning cannot be achieved because of the impact of the CDN on the EUT, no immunity test shall be required.



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

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## 10.4. Test Procedure

The EUT and its load are placed on a table that is 0.8 meter above a metal ground plane measured 1m*1m min. and 0.65mm thick min. And projected beyond the EUT by at least 0.1m on all sides. The length of power cord between the coupling device and the EUT shall be 2m or less.

For Input and Output AC Power or DC Input and DC Output Power Ports:

The EUT is connected to the power mains through a coupling device that directly couples the Surge interference signal.

The surge noise shall be applied synchronized to the voltage phase at $0^0$, $90^0$, $180^0$, $270^0$ and the peak value of the a.c. voltage wave. (Positive and negative)

Each of Line-Earth and Line-Line is impressed with a sequence of five surge voltages with interval of 1 min.

## 10.5. Deviation from Test Standard

No deviation.



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

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## 10.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Surge | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/15 | Test Site | No.2 Shielded Room |

| Inject Line | Polarity | Angle | Voltage kV | Time Interval (Second) | Inject Method | Required Criteria | Complied to Criteria | Result |
|---|---|---|---|---|---|---|---|---|
| L-N | ± | 0 | 1kV | 60 | Direct | B | A | PASS |
| L-N | ± | 90 | 1kV | 60 | Direct | B | A | PASS |
| L-N | ± | 180 | 1kV | 60 | Direct | B | A | PASS |
| L-N | ± | 270 | 1kV | 60 | Direct | B | A | PASS |
| N-PE | ± | 0 | 2kV | 60 | Direct | B | A | PASS |
| N-PE | ± | 90 | 2kV | 60 | Direct | B | A | PASS |
| N-PE | ± | 180 | 2kV | 60 | Direct | B | A | PASS |
| N-PE | ± | 270 | 2kV | 60 | Direct | B | A | PASS |
| L-PE | ± | 0 | 2kV | 60 | Direct | B | A | PASS |
| L-PE | ± | 90 | 2kV | 60 | Direct | B | A | PASS |
| L-PE | ± | 180 | 2kV | 60 | Direct | B | A | PASS |
| L-PE | ± | 270 | 2kV | 60 | Direct | B | A | PASS |

Note:

The testing performed is from lowest level up to the highest level as required by standard, but only highest level is shown on the report.

☒ Meet criteria A : Operate as intended during and after the test
☐ Meet criteria B : Operate as intended after the test
☐ Meet criteria C : Loss/Error of function
☐ Additional Information
  ☐ EUT stopped operation and could / could not be reset by operator at _____ kV of Line _____.

☒ No false alarms or other malfunctions were observed during or after the test.



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

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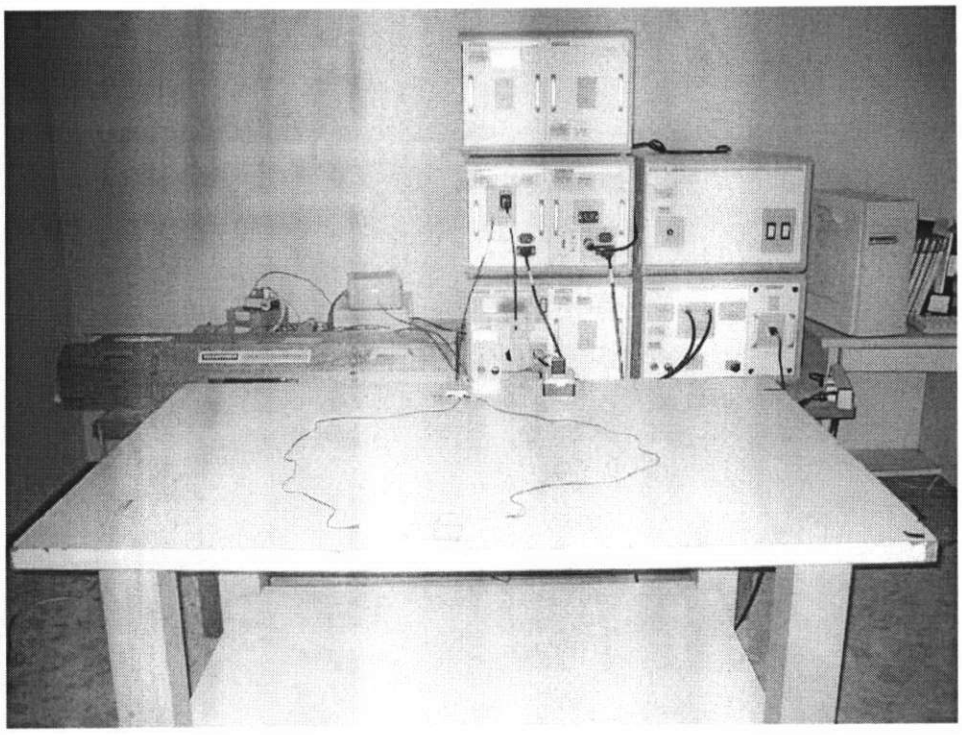
## 10.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : SURGE Test Setup





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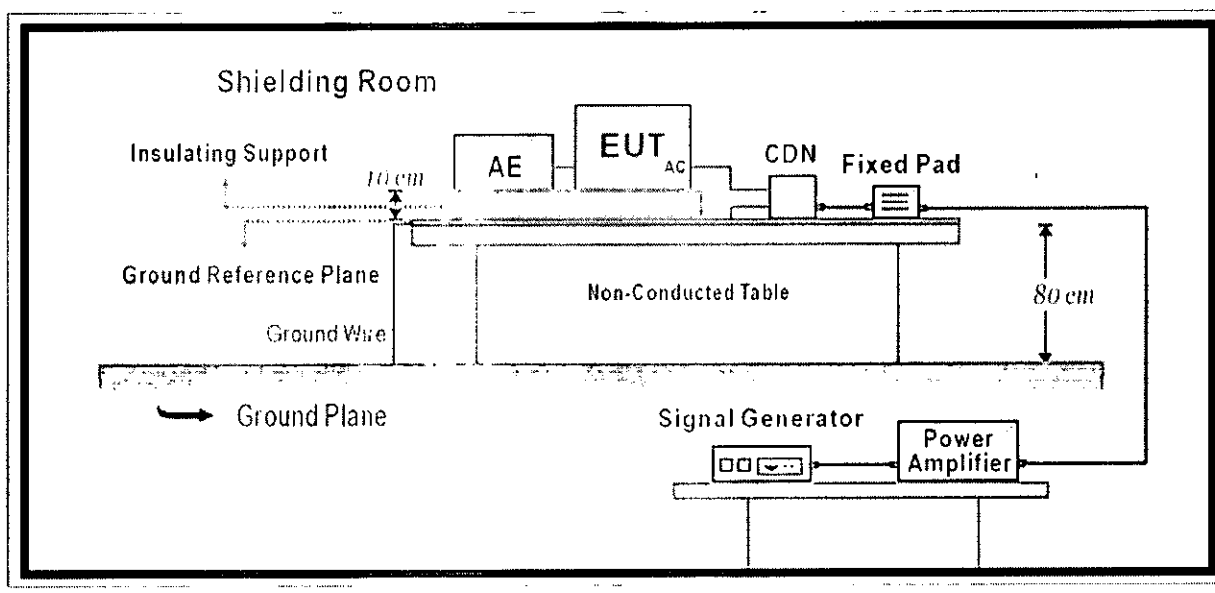
## 11. Conducted Susceptibility

### 11.1. Test Specification

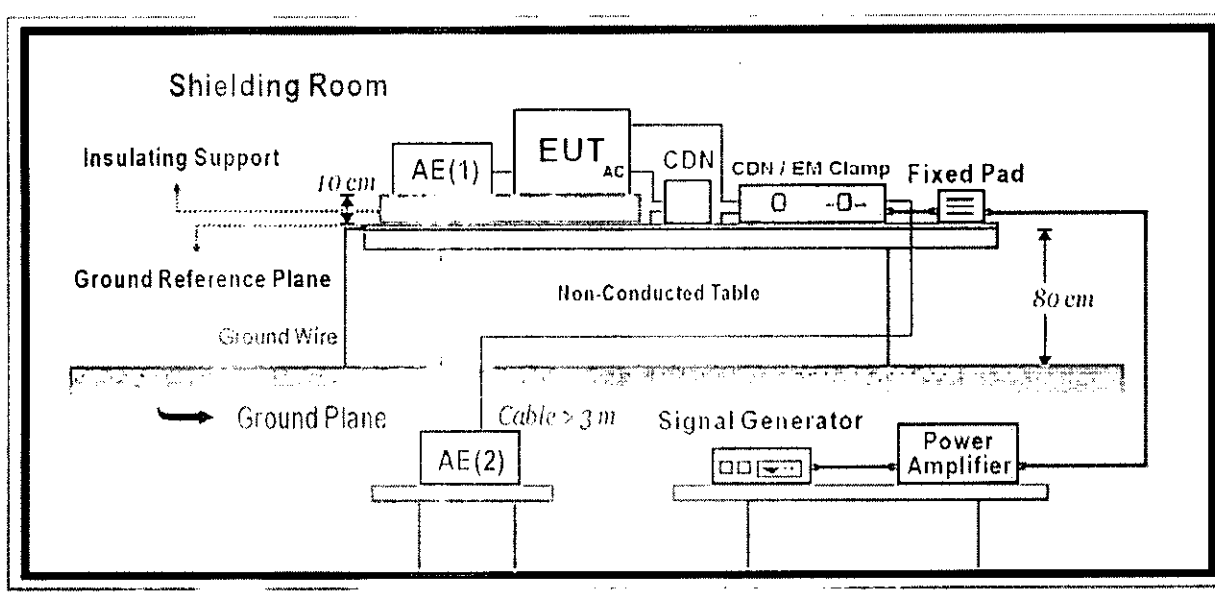
According to Standard : IEC 61000-4-6

### 11.2. Test Setup

**CDN Test Mode**




EM Clamp Test Mode






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

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## 11.3. Limit

| Item | Environmental Phenomena | Units | Test Specification | Performance Criteria |
|---|---|---|---|---|
| Signal Ports and Telecommunication Ports | | | | |
| | Radio-Frequency Continuous Conducted | MHz<br>V (rms, Un-modulated)<br>% AM (1kHz) | 0.15-80<br>3<br>80 | A |
| Input DC Power Ports | | | | |
| | Radio-Frequency Continuous Conducted | MHz<br>V (rms, Un-modulated)<br>% AM (1kHz) | 0.15-80<br>3<br>80 | A |
| Input AC Power Ports | | | | |
| | Radio-Frequency Continuous Conducted | MHz<br>V (rms, Un-modulated)<br>% AM (1kHz) | 0.15-80<br>3<br>80 | A |

## 11.4. Test Procedure

The EUT are placed on a table that is 0.8 meter height, and a Ground reference plane on the table, EUT are placed upon table and use a 10cm insulation between the EUT and Ground reference plane.
For Signal Ports and Telecommunication Ports
The disturbance signal is through a coupling and decoupling networks (CDN) or EM-clamp device couples to the signal and Telecommunication lines of the EUT.
For Input DC and AC Power Ports
The EUT is connected to the power mains through a coupling and decoupling networks for power supply lines. And directly couples the disturbances signal into EUT.
Used CDN-M2 for two wires or CDN-M3 for three wires.
All the scanning conditions are as follows:

| | Condition of Test | Remarks |
|---|---|---|
| 1. | Field Strength | 130dBuV(3V) Level 2 |
| 2. | Radiated Signal | AM 80% Modulated with 1kHz |
| 3. | Scanning Frequency | 0.15MHz – 80MHz |
| 4 | Dwell Time | 3 Seconds |
| 5. | Frequency step size $\Delta f$ : | 1% |
| 6. | The rate of Swept of Frequency | $1.5 \times 10^{-3}$ decades/s |

## 11.5. Deviation from Test Standard

No deviation.



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## 11.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Conducted susceptibility | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/15 | Test Site | No.6 Shielded Room |

| Frequency Range (MHz) | Voltage Applied dBuV(V) | Inject Method | Tested Port of EUT | Required Criteria | Performance Criteria Complied To | Result |
|---|---|---|---|---|---|---|
| 0.15~80 | 130 (3V) | CDN 04 | AC IN | A | A | PASS |

Note:

The testing performed is from lowest level up to the highest level as required by standard, but only highest level is shown on the report.

☒ Meet criteria A : Operate as intended during and after the test
☐ Meet criteria B : Operate as intended after the test
☐ Meet criteria C : Loss/Error of function
☐ Additional Information
- ☐ EUT stopped operation and could / could not be reset by operator at _____ dBuV(V) at frequency _____MHz.
- ☒ No false alarms or other malfunctions were observed during or after the test. The acceptance criteria were met, and the EUT passed the test.



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

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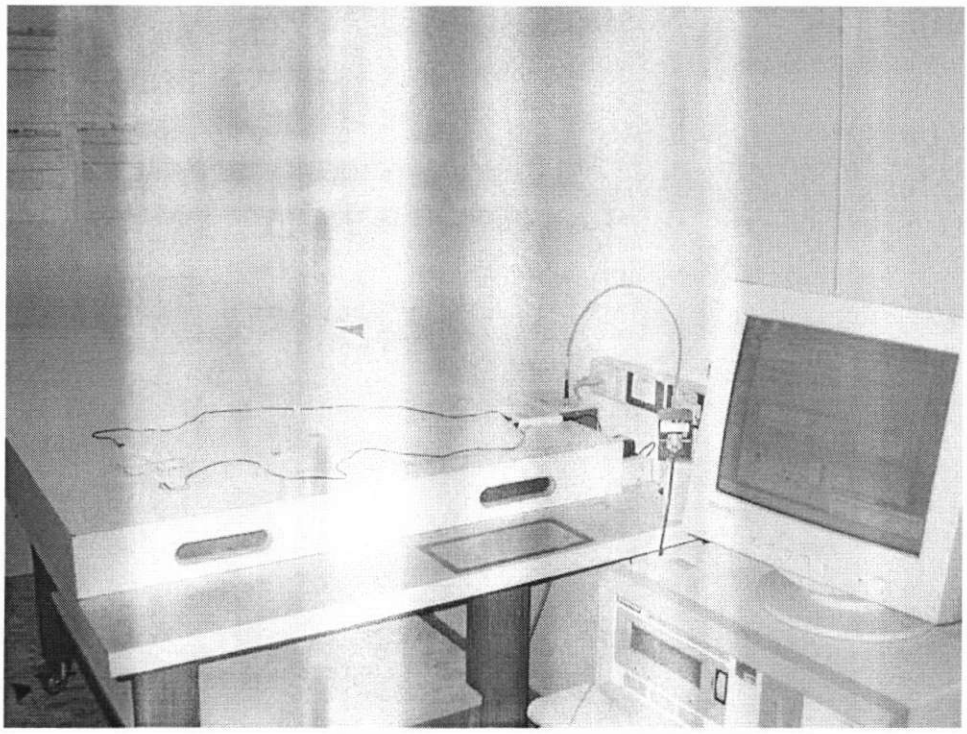
## 11.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : Conducted Susceptibility Test Setup





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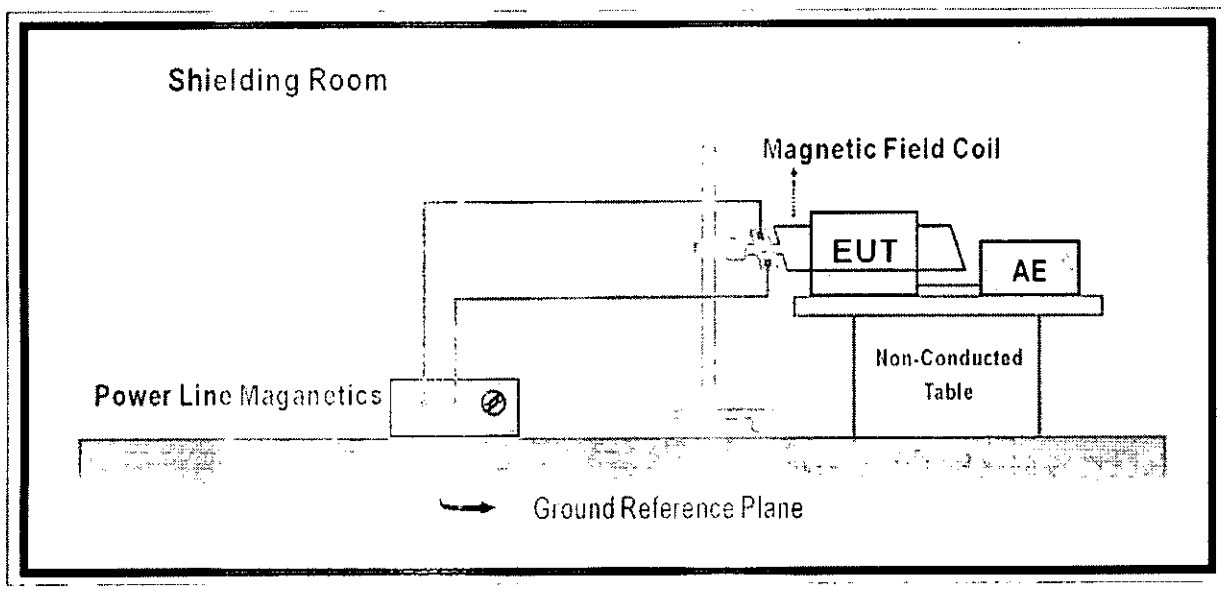
## 12. Power Frequency Magnetic Field

### 12.1. Test Specification

According to Standard : IEC 61000-4-8

### 12.2. Test Setup




### 12.3. Limit

| Item | Environmental Phenomena | Units | Test Specification | Performance Criteria |
|---|---|---|---|---|
| Enclosure Port | | | | |
| | Power-Frequency Magnetic Field | Hz<br>A/m (r.m.s.) | 50<br>3 | A |

### 12.4. Test Procedure

The EUT and its load are placed on a table which is 0.8 meter above a metal ground plane measured at least 1m*1m min. The test magnetic field shall be placed at central of the induction coil.

The test magnetic Field shall be applied 10 minutes by the immersion method to the EUT. And the induction coil shall be rotated by 90° in order to expose the EUT to the test field with different orientation (X, Y, Z Orientations).

### 12.5. Deviation from Test Standard

No deviation.



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## 12.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Power frequency magnetic field | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/15 | Test Site | No.3 Shielded Room |

| Polarization | Frequency (Hz) | Magnetic Strength (A/m) | Required Performance Criteria | Performance Criteria Complied To | Test Result |
|---|---|---|---|---|---|
| X Orientation | 50 | 3 | A | A | PASS |
| Y Orientation | 50 | 3 | A | A | PASS |
| Z Orientation | 50 | 3 | A | A | PASS |

☒ Meet criteria A: Operate as intended during and after the test
☐ Meet criteria B: Operate as intended after the test
☐ Meet criteria C: Loss/Error of function
☐ Additional Information
☐ EUT stopped operation and could / could not be reset by operator at _____ kV of Line _____.

☒ No false alarms or other malfunctions were observed during or after the test. The acceptance criteria were met, and the EUT passed the test.



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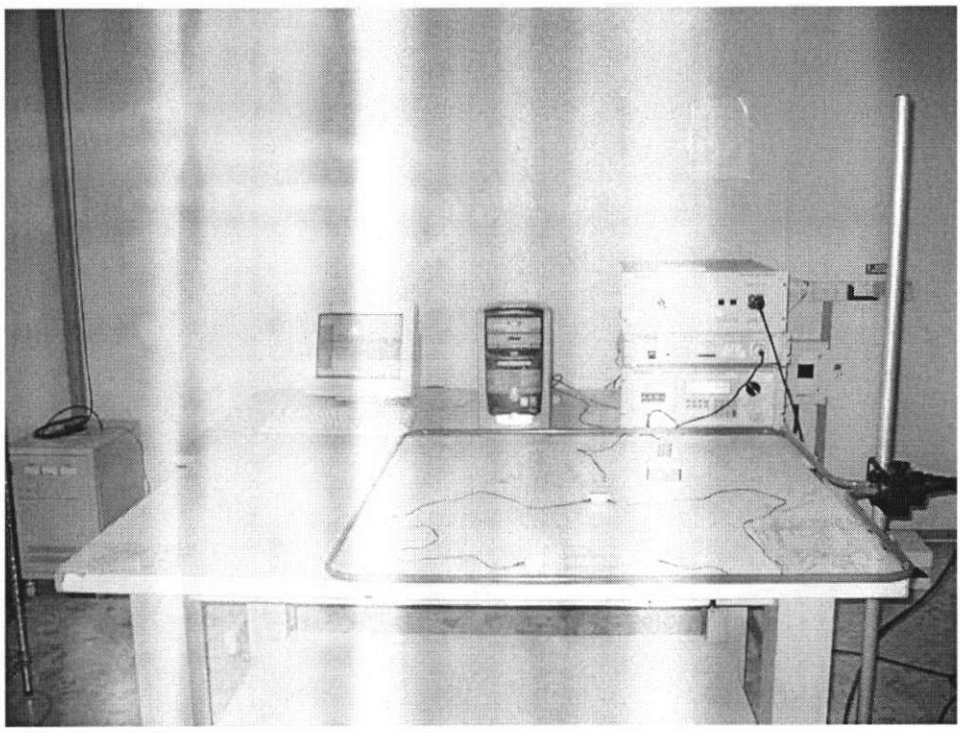
## 12.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : Power Frequency Magnetic Field Test Setup





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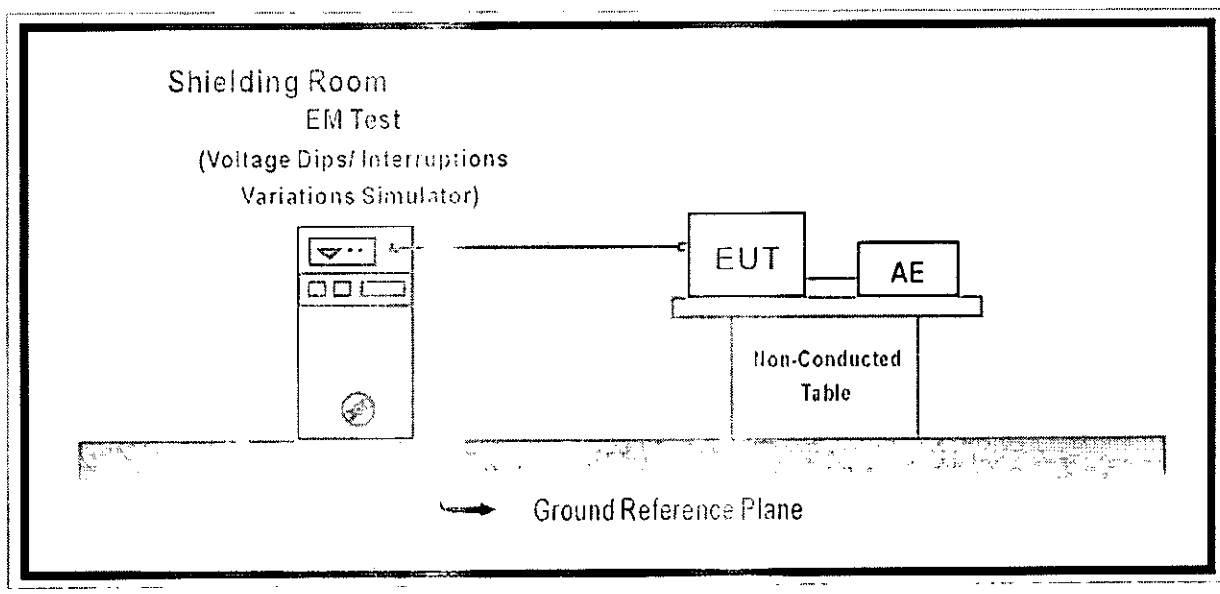
## 13. Voltage Dips and Interruption

### 13.1. Test Specification

According to Standard : IEC 61000-4-11

### 13.2. Test Setup




### 13.3. Limit

| Item | Environmental | Units | Test Specification | Performance |
|---|---|---|---|---|
| Input AC Power Ports | | | | |
| | Voltage Dips | % Reduction<br>Period | >95<br>0.5 | B |
| | | % Reduction<br>Period | 60<br>5 | C |
| | | % Reduction<br>Period | 30<br>25 | C |
| | Voltage Interruptions | % Reduction<br>Period | > 95<br>5000 | C |



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## 13.4. Test Procedure

The EUT and its load are placed on a table which is 0.8 meter above a metal ground plane measured 1m*1m min. And 0.65mm thick min. And projected beyond the EUT by at least 0.1m on all sides. The power cord shall be used the shortest power cord as specified by the manufacturer.

For Voltage Dips/ Interruptions test:

The selection of test voltage is based on the rated power range. If the operation range is large than 20% of lower power range, both end of specified voltage shall be tested. Otherwise, the typical voltage specification is selected as test voltage.

The EUT is connected to the power mains through a coupling device that directly couples to the Voltage Dips and Interruption Generator.

The EUT shall be tested for 30% voltage dip of supplied voltage and duration 25 Periods, for 95% voltage dip of supplied voltage and duration 0.5 Periods with a sequence of three voltage dips with intervals of 10 seconds, and for 95% voltage interruption of supplied voltage and duration 250 Periods with a sequence of three voltage interruptions with intervals of 10 seconds.

Voltage phase shifting are shall occur at $0^0$, $45^0$, $90^0$ ,$135^0$ ,$180^0$ ,$225^0$, $270^0$ ,$315^0$ of the voltage.

## 13.5. Deviation from Test Standard

No deviation.



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### 13.6. Test Result

| | | | |
|---|---|---|---|
| Product | Transcutaneous Electrical Nerve Stimulator (TENS) & Powered Muscle Stimulator(EMS) | | |
| Test Item | Voltage dips and interruption | | |
| Test Mode | Mode 1:Normal Operation | | |
| Date of Test | 2007/11/15 | Test Site | No.2 Shielded Room |

| Voltage Dips and Interruption Reduction(%) | Angle | Test Duration (Periods) | Required Performance Criteria | Performance Criteria Complied To | Test Result |
|---|---|---|---|---|---|
| 30 | 0 | 25 | C | A | PASS |
| 30 | 45 | 25 | C | A | PASS |
| 30 | 90 | 25 | C | A | PASS |
| 30 | 135 | 25 | C | A | PASS |
| 30 | 180 | 25 | C | A | PASS |
| 30 | 225 | 25 | C | A | PASS |
| 30 | 270 | 25 | C | A | PASS |
| 30 | 315 | 25 | C | A | PASS |
| 100 | 0 | 0.5 | B | A | PASS |
| 100 | 45 | 0.5 | B | A | PASS |
| 100 | 90 | 0.5 | B | A | PASS |
| 100 | 135 | 0.5 | B | A | PASS |
| 100 | 180 | 0.5 | B | A | PASS |
| 100 | 225 | 0.5 | B | A | PASS |
| 100 | 270 | 0.5 | B | A | PASS |
| 100 | 315 | 0.5 | B | A | PASS |
| 60 | 0 | 5 | C | A | PASS |
| 60 | 45 | 5 | C | A | PASS |
| 60 | 90 | 5 | C | A | PASS |
| 60 | 135 | 5 | C | A | PASS |
| 60 | 180 | 5 | C | A | PASS |
| 60 | 225 | 5 | C | A | PASS |
| 60 | 270 | 5 | C | A | PASS |
| 60 | 315 | 5 | C | A | PASS |
| 100 | 0 | 250 | C | C | PASS |
| 100 | 45 | 250 | C | C | PASS |
| 100 | 90 | 250 | C | C | PASS |
| 100 | 135 | 250 | C | C | PASS |
| 100 | 180 | 250 | C | C | PASS |
| 100 | 225 | 250 | C | C | PASS |
| 100 | 270 | 250 | C | C | PASS |
| 100 | 315 | 250 | C | C | PASS |

☒ Meet criteria A: Operate as intended during and after the test
☐ Meet criteria B: Operate as intended after the test
☒ Meet criteria C: Loss/Error of function
☐ Additional Information
  ☐ The nominal voltage of EUT is 230V.
  ☐ EUT stopped operation and could / could not be reset by operator at _____ kV of Line _____.

☒ No false alarms or other malfunctions were observed during or after the test. The acceptance criteria were met, and the EUT passed the test.



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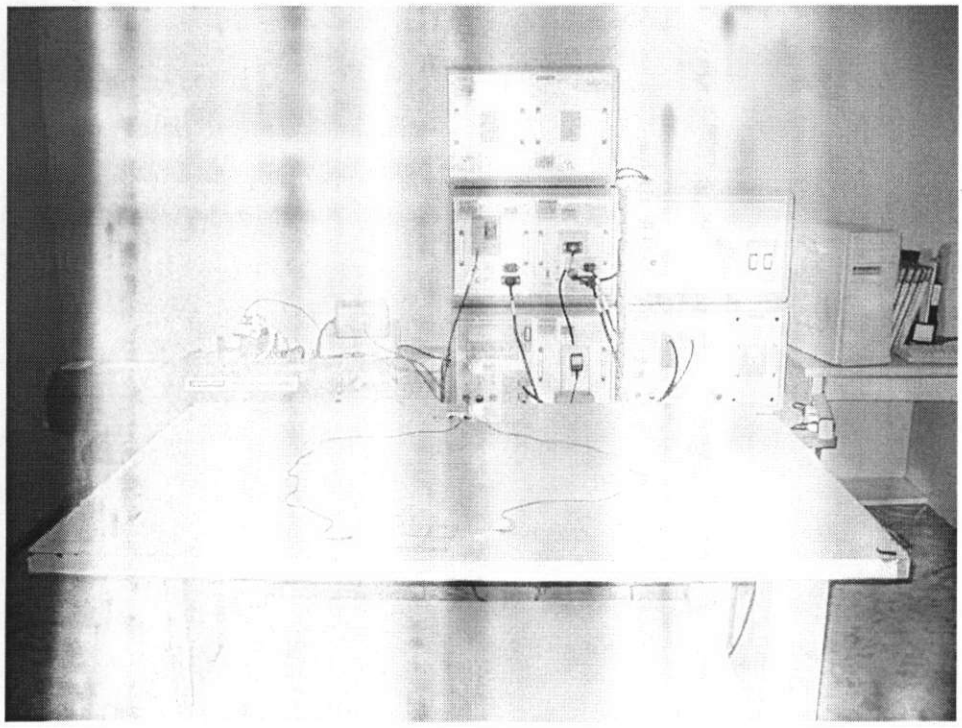
## 13.7. Test Photograph

Test Mode : Mode 1:Normal Operation

Description : Voltage Dips Test Setup





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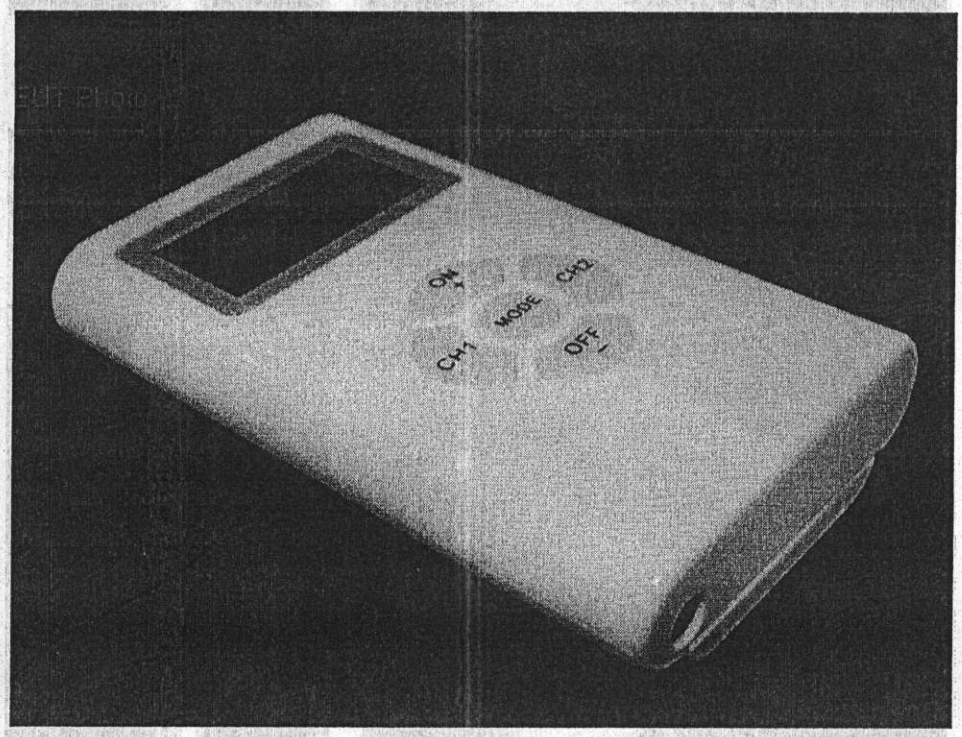
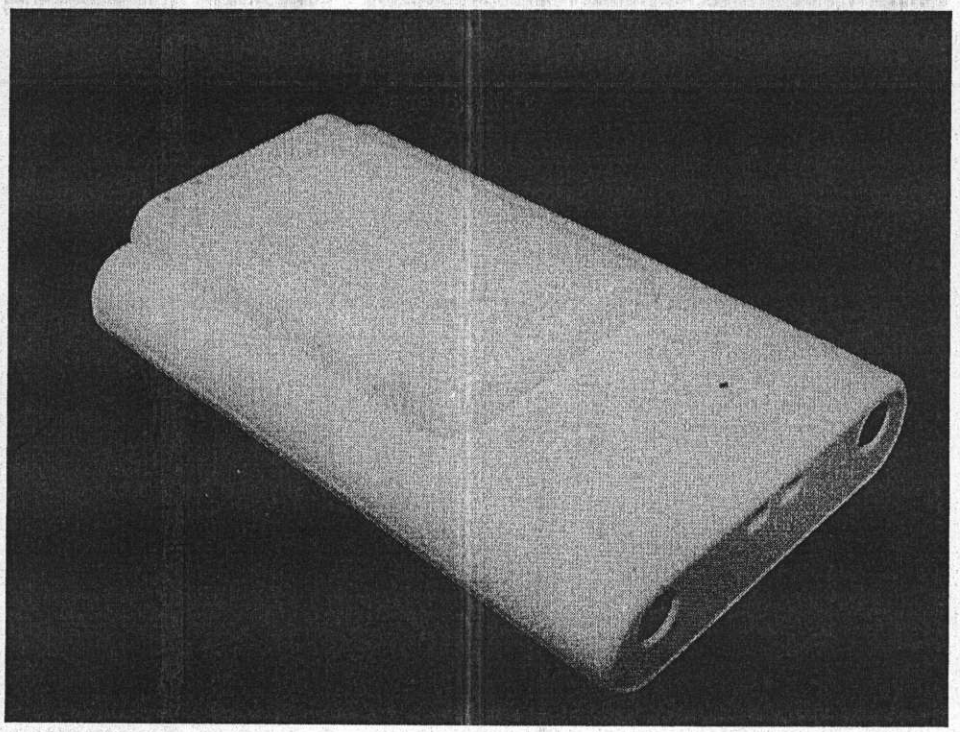
## 14. Attachment

- **EUT Photograph**

(1) EUT Photo




(2) EUT Photo





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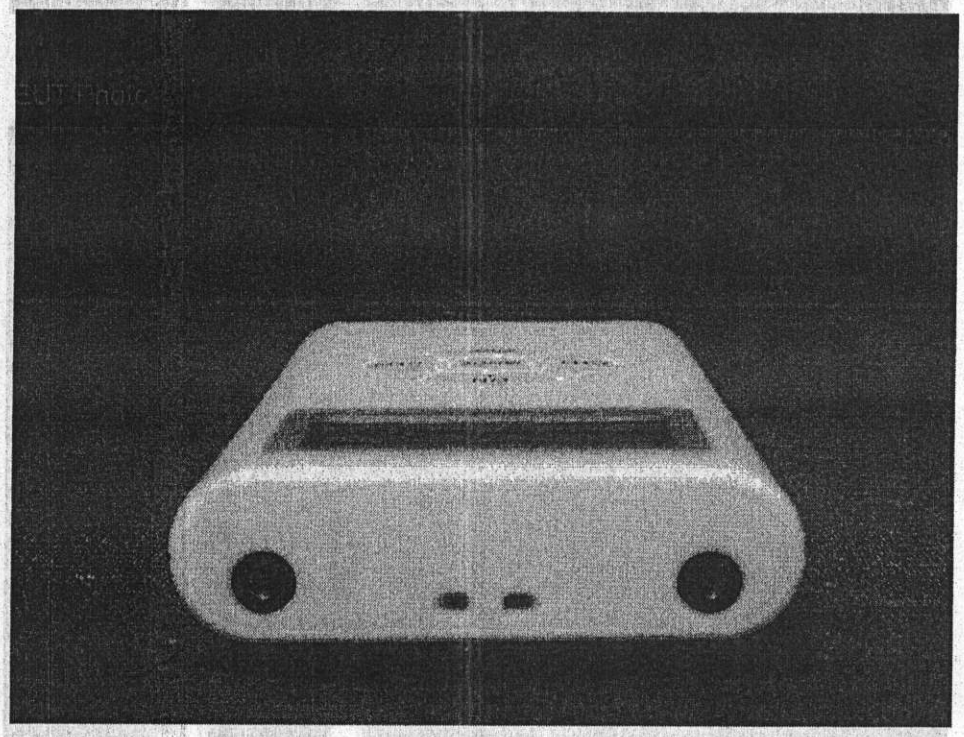
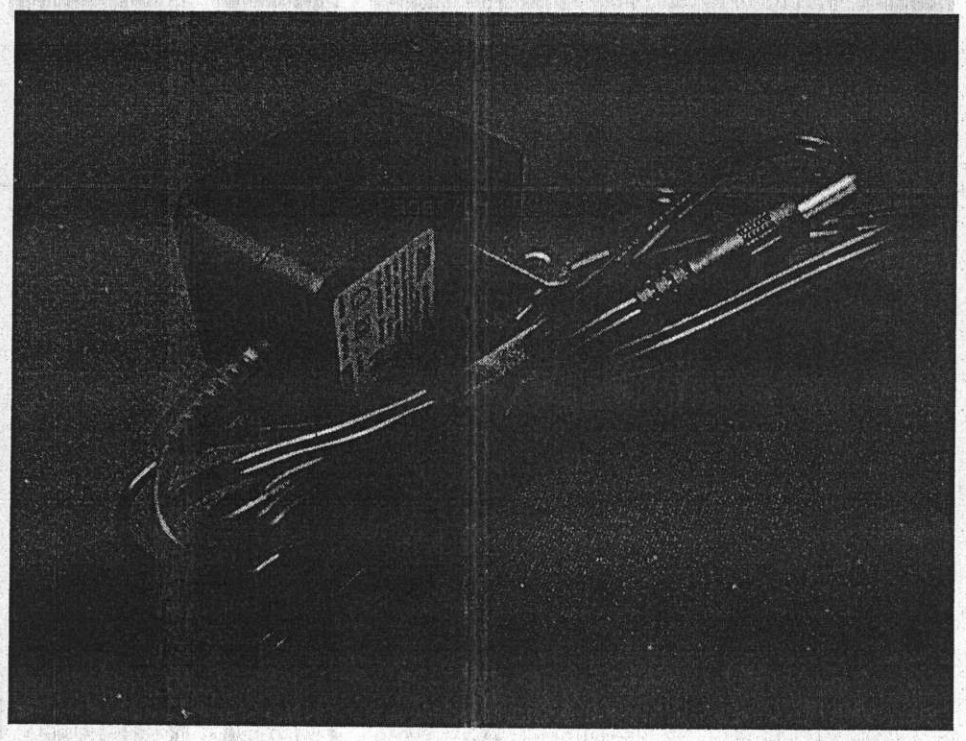
(3) EUT Photo



(4) EUT Photo





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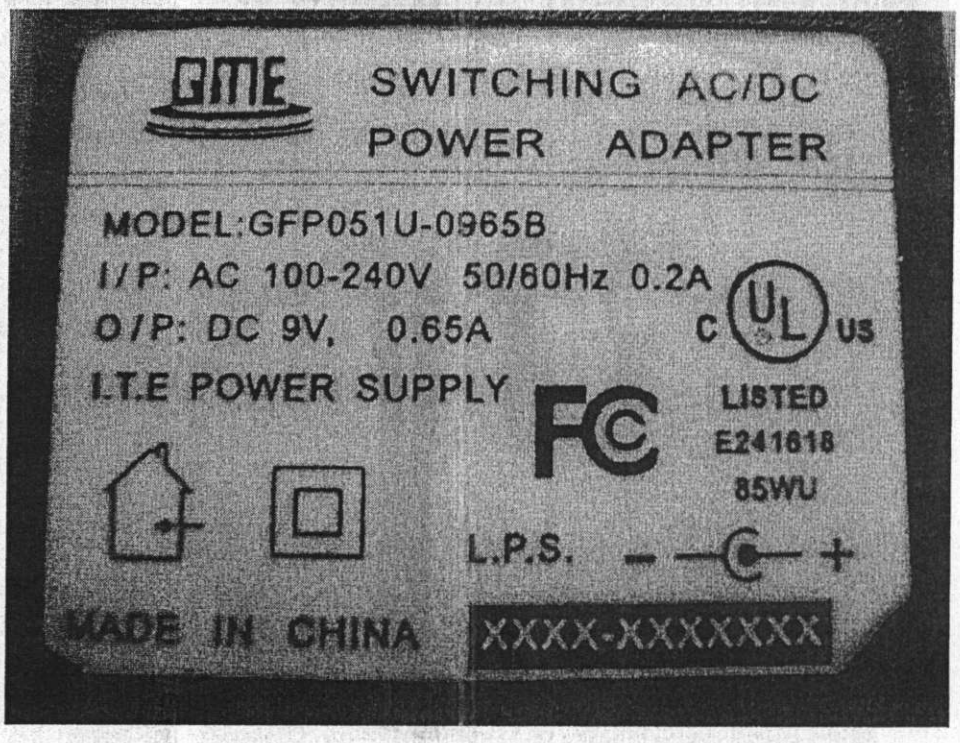
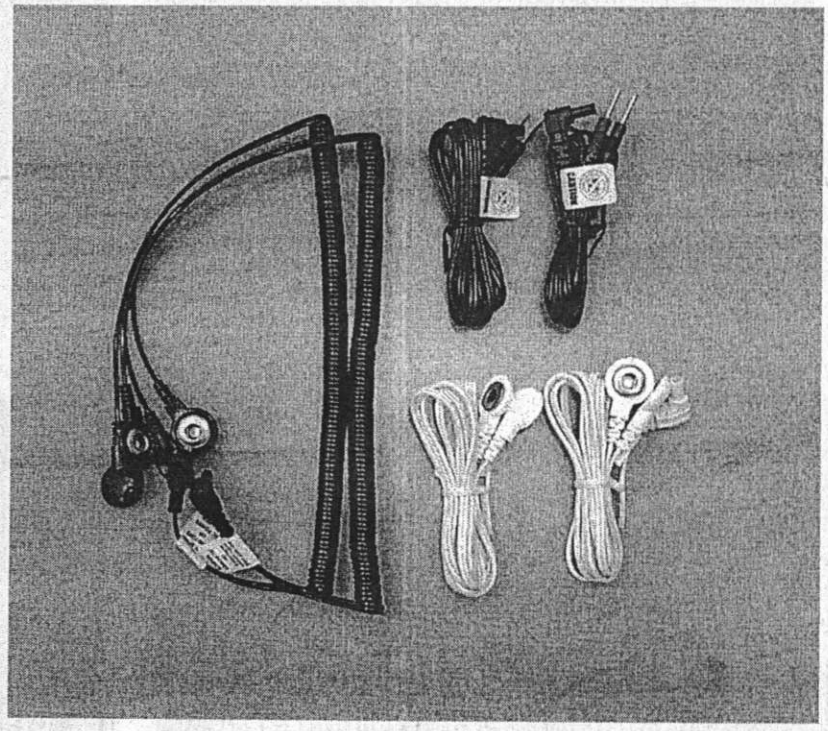
(5) EUT Photo




(6) EUT Photo





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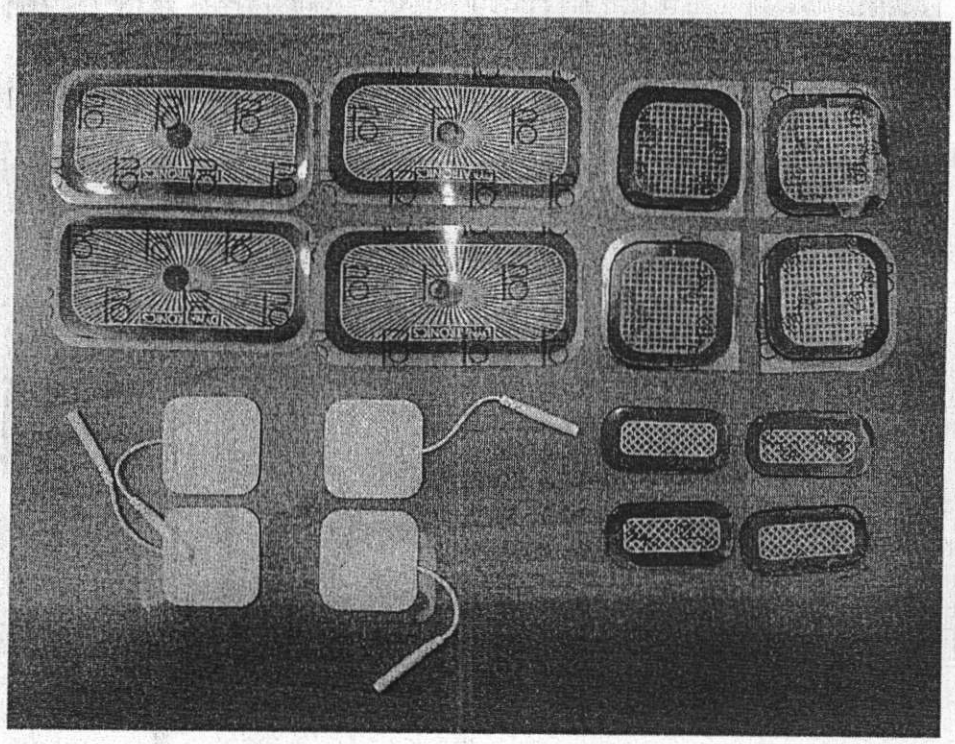
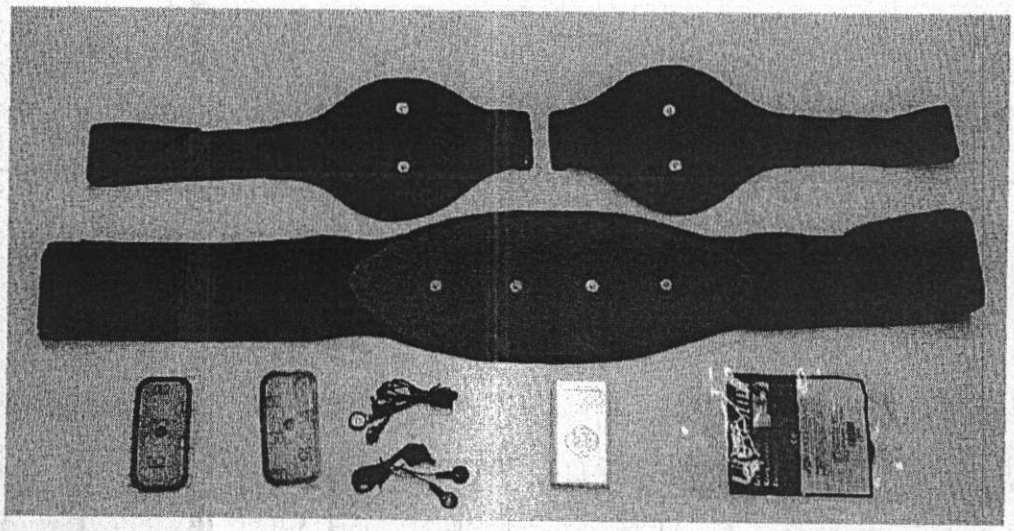
(7) EUT Photo



(8) EUT Photo





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# Attachment 9.



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# TEST REPORT

## EN60601-1

**Medical electrical equipment**

**Part 1 : General requirements for safety**

| | | |
|---|---|---|
| Name and address of the testing laboratory | *WELL-LIFE HEALTHCARE LTD.* | Tel: 886-2-2928-2112<br>Fax: 886-2-2928-1880 |
| Name and address of the applicant | *WELL-LIFE HEALTHCARE LTD.*<br>*1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C.* | |
| Name and address of the manufacturer | *WELL-LIFE HEALTHCARE LTD.*<br>*1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C.* | |
| Name and address of the factory (production sites) | *WELL-LIFE HEALTHCARE LTD.*<br>*1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County, Taiwan, R.O.C.* | |
| Product | *TENS (Transcutaneous Electrical Nerve Stimulators) Device* | |
| Trademark | *Well-Life* | |
| Model/type reference | *WL-2407* | |
| Rating and principal characteristics | *Please make reference to specifications* | |
| Tested according to | *EN 60601-1: 1990 + amendment A1, A2, and A13:1996.* | |
| Test Report No. | *WL-2007-01* | |
| Work carried out by | *Tony C. S. Chang* | C. S. Chang |
| | *Manager* | *Signatures* |
| Work verified by | *Jenny Hsieh* | |
| | *Sales Manager* | *Signatures* |
| Date of issue | *May 12, 2007* | |

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## ADDITIONAL INFORMATION

**General information:**

The test results presented in this report relate only to the object tested and information given from applicant or manufacturer.

Test case verdicts:
Pass = Pass, Fail = Fail, N.A. = Not applicable. Placed in the column marked "Verdict".

This is a Computer generated Test Report.
Information written in *"Italic"* or "***Italic and bold***" font style is written by project Engineer during testing.
All other information in "Regular" or "**Regular and bold**" font style is a part of this "Test Report Form".



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## SECTION 1 : GENERAL.

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 1. | **SCOPE.** | - | - |
| | This Standard applies to medical electrical equipment. | *The TENS is within the scope of this standard.* | *Pass* |
| 3. | **GENERAL REQUIREMENT.** | - | - |
| | Tools shall be designed and constructed that function safely so as to cause no danger to persons or to surroundings. | *The TENS has been designed and constructed that function safely so as to cause no danger to persons or to surroundings.* | *Pass* |
| 4. | **GENERAL NOTES ON TESTS.** | - | - |
| | Tests are performed according to Cl. 4, e.g. correct ambient temperature range, nature ofsupply, sequence of testing, most unfavourable position etc. | *All the relational tests have been carried out according to the requirements specified in this standard.* | *Pass* |
| 5. | **CLASSIFICATION.** | - | - |
| 5.1 | Type of protection against electric shock :<br>a) Class I /II equipment.<br>b) Internally powered equipment. | *b) Internally powered equipment.* | *Pass* |
| 5.2 | Degree of protection against electric shock :<br>- Type B.<br>- Type BF.<br>- Type CF. | *Type BF equipment.* | *Pass* |
| 5.3 | Degree of protection against ingress or foreign bodies and moisture (ordinary, drip-proof, splash-proof, watertight). | *Ordinary.* | *Pass* |
| 5.4 | According to methods of sterilization or disinfection. | *There is no this requirement.* | *NA* |
| 5.5 | According to presence of a flammable anaesthetic mixture with air or with Oxygen or Nitrous oxide.<br>- Not Suitable.<br>- Category AP equipment.<br>- Category APG equipment. | *Not suitable.* | *NA* |
| 5.6 | According to mode of operation.<br>- Continuous Operation.<br>- Short time operation.<br>- Intermittent operation.<br>- Cont. Op. With short time load.<br>- Cont. Op, with intermittent load. | *Continuous operation.* | *Pass* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 6. | **IDENTIFICATION, MARKING, & DOCUMENTS.** | - | - |
| | The following meanings shall apply to identification & marking : | - | |
| | - Permanently affixed : Removable with tools only or by appreciate force. | *No particular comments.* | ***Pass*** |
| | - Clearly legible :<br>* Affixed in a prominent location and legible with normal vision.<br>* Discernible in its position of normal use. | *It is in conformity with the requirement of this clause.* | ***Pass*** |
| | - Major part :<br>* On or near the control panel or relevant part.<br>* Usually on the outside of the part that contains the supply mains connection and preferably adjacent to the connection point. | *It is in compliance with the requirement of this clause.* | ***Pass*** |
| 6.1 | Marking on the outside of equipment. | - | - |
| a) | Main operated equipment.<br>* Shall be provided at least with permanently affixed and clearly legible marking on the major part of equipment as described in Table II, Column 3. | *The TENS does not belong to this kind of equipment.* | *NA* |
| b) | Internally powered equipment.<br>*Shall be provided at least with permanently affixed and clearly legible marking on the major part of equipment as described in Table II, Column 4. | *The relevant appropriate markings have been provided for this equipment.* | ***Pass*** |
| c) | Equipment supplied from a specified power supply.<br>* Shall be provided at least with permanently affixed and clearly legible marking on the major part of equipment as described in Table II, Column 5. | *The TENS does not belong to this kind of equipment.* | *NA* |
| d) | Minimum requirements :<br>* For the reasons of size, at least 6.1e), 6.1f), and 6.1g) shall be affixed, the others shall be recorded in accompanying documents.<br>Where no marking is practicable, all information shall be included in document. | *The relational requirements specified in this clause have been complied with.* | ***Pass*** |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| e) | Indication of origin.<br>* Name or trademark claiming that the equipment comply with this standard. | *The relevant information (name, address....etc.) for this product have been provided.* | *Pass* |
| f) | Model or type reference. | *All the model numbers have been provided. Please make reference to specifications provided in the TCF.* | *Pass* |
| g) | Connection to the supply.<br>* The rated voltage or rated range.<br>* Nature of supply, e.g. phase & current type. | *The power supply for the TENS is a D.C. battery.* | *Pass* |
| h) | Supply frequency. (Hertz). | *D.C. power supply.* | *NA* |
| j) | Power input.<br>* The power input shall be indicated where the power factor exceed 0.9. | *Not applicable.* | *NA* |
| k) | Main power output.<br>* The max. allowable power output shall be indicated for auxiliary main socket outlet. | *The main power output has been provided.* | *Pass* |
| l) | Classification.<br>* Symbol of class II, if relevant.<br>* IP degree.<br>* Degree of protection against electric shock ( Type B/BF/CF ). | *The appropriate classification for the TENS have been used. (Type BF)* | *Pass* |
| m) | Operation Mode.<br>* If no marking is provided, equipment is assumed to be continuous operation. | *All the relational operation modes have been marked on the TENS.* | *Pass* |
| n) | Fuses.<br>* Type & rating shall be marked adjacent to the fuse holder. | *There is not any fuse used for this equipment.* | *NA* |
| p) | Output.<br>* Rated output voltage, current or power where applicable.<br>* Output frequency where applicable. | *The rated output current has been provided.* | *Pass* |
| q) | Physiologic effects ( symbol & warning statements ).<br>* In a prominent position where used. * Appropriate symbolIEC-417 or Table DII of Appendix D. | *The relevant symbols and warning statements have been provided in the instruction manual.* | *Pass* |
| r) | Category AP/APG. | *The TENS does not belong to Category AP/APG.* | *NA* |
| s) | Danger Voltage symbol for high voltage device. | *There is no danger voltage.* | *NA* |
| t) | Cooling condition. | *There is no this situation.* | *NA* |
| u) | Mechanical stability. | *Not applicable.* | *NA* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| v) | Protective packing.<br>* According to 6.8.3, and 10.1, and ISO-R780. | *The appropriate packing has been provided for the TENS.* | *Pass* |
| w) | Not Used. | - | - |
| x) | Not Used. | - | - |
| y) | Earth terminal :<br>* Symbol 9 of TableDI for terminal of potential equalization conductor.<br>* Symbol 7 of table DI for functional earth terminal. | *Because the power for the TENS is D.C. power, there is no earth terminal used for this device.* | *NA*<br>*NA* |
| z) | Removable protective means : | - | - |
| | Compliance checking of 6.1.<br>* By inspection of marking.<br>* By the durability test. | *The relevant inspection and test have been carried out with an acceptable result.* | *Pass* |
| 6.2 | Marking on the inside of equipment. | - | - |
| a) | * Clearly legible as 6.1<br>* Shall not be subject to the rubbing test as that of 6.1.<br>* Nominal supply voltage shall be marked adjacent to the terminal. | *It is in compliance with the relational requirements.* | *Pass* |
| b) | Maximum power loading of heating elements shall be marked near the heater. | *There is not any heating element for this device.* | *NA* |
| e) | Fuse ID by type & rating, or reference. | *There is no fuse for this device.* | *NA* |
| f) | Symbol 6 of table DI for protective earth terminal. | *There is no protective earth terminal.* | *NA* |
| | For heating elements or lampholders designed for use with heating lamps not intended to be changed by the operator and which can be changed only with the use of a tool, an identifying marking referring to information stated in the accompanying document is sufficient. | *There is not any heating element for this device.* | *NA* |
| c) | Dangerous voltage marking for high voltage. | *There is no danger voltage marking for high voltage.* | *NA* |
| d) | Type of battery and mode of insertion. | *The type of battery has been provided.* | *Pass* |
| g) | Symbol 7 of table DI for functional earth terminal. | *There is no functional earth terminal.* | *NA* |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| h) | Symbol 8 of table DI for neutral supply conductor in permanently installed equipment. | *There is no neutral supply conductor.* | *NA* |
| j) | * Marking of 6.2 f), h), k), & l) shall not be affixed to parts which has to be removed.<br>* Mark on or near terminal shall comply with IEC-445. | *There is no this situation.* | *NA* |
| k) | * Terminal marking for supply connectors shall be marked adjacent to terminal, unless no safety hazard if connection are interchanged.<br>* If marking is impossible due to small size, it shall be indicated in document. | *Not applicable.* | *NA* |
| l) | * Appropriate marking or statement for terminal or wiring which attains a temperature of more than 75°C. | *Not applicable.* | *NA* |
| m) | Not used. | - | - |
| n) | Capacitor and/or the connected circuit parts shall be marked as sub-clause 15c) | *Not applicable.* | *NA* |
| 6.3 | Marking of controls and instruments. | - | - |
| a) | Appropriate ON/OFF marking of main switch. | *Appropriate ON/OFF marking has been provided.* | *Pass* |
| b) | Appropriate position indication according to symbol 17 & 18 of table DI. | *Not applicable.* | *NA* |
| c) | If safety hazard could be caused by the setting of control, one of the followings shall be provided :<br>- An associated indicating device.<br>- An indication of the direction in which the magnitude of the function change. | *There is no any safety hazard caused by the setting of control.* | *NA* |
| d) | Not used. | - | - |
| e) | Not used. | - | - |
| f) | Control and indicators with safety functions shall be identified. | *NO additional safety function is used for this device.* | *NA* |
| 6.4 | Symbols. | - | - |
| a) | Symbols of Appendix D shall be used for clause 6.1 ~ 6.3. | *The relevant symbols of Appendix D have been used. Please see the information provided in this TCF.* | *Pass* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| b) | Symbols of IEC-878 shall be used for controls and performance, if applicable. | *No any symbols defined in IEC-878 is used for this device.* | *NA* |
| 6.5 | Colours of the insulation of conductors. | - | - |
| a) | Yellow/green for protective earth conductor. (PEC) | *There is no protective earth conductor used for this device.* | *NA* |
| b) | Yellow/green for connection between PEC & Accessible metal part or functional protective terminal. | *There is no protective earth conductor used for this device.* | *NA* |
| c) | Identification by yellow/green insulation shall only be used for :<br>- PEC (protective earth conductor).<br>- Conductors specified in 6.5b).<br>- Potential equalization conductors.<br>- Functional earth conductors. | *There is no protective earth conductor used for this device.* | *NA* |
| d) | Neutral conductor shall be coloured "light blue".(IEC-227 or IEC-245) | *There is no any neutral conductor.* | *NA* |
| e) | Power supply cords shall be coloured according to IEC-227 or IEC-245 | *No any power supply cord.* | *NA* |
| f) | A secondary Y/G conductor connected in parallel shall be used for multiple conductor cord and the max. allowed resistance would be exceeded. | *Not this situation.* | *NA* |
| 6.7 | Indicator lights and push-buttons. | - | - |
| a) | Colours of indicator lights:<br>- Colour red shall be used exclusively to indicate a warning of danger and/or a need for urgent action.<br>- Dot-matrix and other alphanumeric displays are not considered to be indicator light. | *Appropriate colour has been used for indicator lights.* | *Pass* |
| b) | Colour of unilluminated push-buttons:<br>* Colour red shall be used only for the push button by which a function is interrupted in case of emergency. | *No this kind of push button.* | *NA* |
| c) | Not used. | - | - |
| d) | Not used. | - | - |
| 6.8 | Accompanying documents. | - | - |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 6.8.1 | General :<br>- At least including instruction for use, technical description, and an address. | *The instruction manual includes instruction for use, technical description and an address.* | **Pass** |
| | - Be regarded as part of equipment. | *The instruction manual is regarded as part of equipment.* | **Pass** |
| | - All applicable classification of clause 5 shall be included in both the instruction for use and technical description. | *All applicable classification have been included in the relevant document.* | **Pass** |
| | - All marking of clause 6.1 shall be included, if they are not affixed to equipment. | *All markings which are not affixed to equipment have been included in the instruction manual.* | **Pass** |
| | - Warning statement & explanation of warning symbols shall be included. | *All warning statement and explanation of warning symbols are included in the instruction manual.* | **Pass** |
| | - Indication on recognised accessories, detachable parts and material, if use of the others could degrade min. safety. | *All relational information about accessories have been included in the instruction manual.* | **Pass** |
| 6.8.2 | -Instruction for use. | - | - |
| a) | General :<br>- Information necessary for operation in accordance with its specification.<br>This shall include explanation of :<br>* Function of control.<br>* Display & signals.<br>* Sequence of operation.<br>* Connection & disconnection.<br>* Replacement of consuming material. | *All necessary information for operation according to the specification has been provided.* | **Pass** |
| | - Sufficient detail concerning cleaning, preventive inspection & maintenance which are carried out by operator including the frequency, routine maintenance for safety performance. | *The "troubleshooting" has been provided for the operator.* | **Pass** |
| | - Indication the preventive inspection & maintenance which are carried out by the others including the frequency but no necessarily including the detail. | *It is in compliance with the requirement specified in this clause.* | **Pass** |
| | - The meanings of figures, symbols, warning statement & abbreviations shall be explained in instruction for use. | *The relevant explanation for warning statement and symbols have been provided.* | **Pass** |
| b) | Responsibility of manufacturer :<br>Not used. | - | - |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| c) | Signal input & output :<br>- If I/O is intended only for connection to specified equipment, this shall be stated in instruction for use. | *It is in accordance with the requirement for signal input/output.* | *Pass* |
| d) | Cleaning, disinfection, and sterilization of parts:<br>- If equipment contact patient during normal use, the items described above shall be included in instruction for use. | *The TENS is not the accessory which requires the work of cleaning, dis-infection or sterilization.* | *NA* |
| | - Or identify suitable agent, and list the temperature, humidity, and time limits where necessary. | *Some information for operation condition have been provided.* | *Pass* |
| e) | Mains operated equipment with additional power source : | - | - |
| | Warning statement referring to the necessity for the periodical checking and replacement of additional power source shall be indicated in instruction manual, where used. | *Not mains operated equipment.* | *NA* |
| f) | Removal of primary batteries : | - | - |
| | Warning statement referring to the removal of batteries if equipment is not likely to be used for some time shall be included in instruction for use. | *It is in conformity with this requirement.* | *Pass* |
| g) | Rechargeable batteries : | - | - |
| | Instruction for this equipment shall contain instructions to ensure safety use and adequate maintenance. | *No rechargeable battery.* | *NA* |
| h) | Equipment with a specified power supply or battery charger : | - | - |
| | Instruction for this equipment shall identify power supplier or battery charger necessary to ensure compliance with the requirement of this standard. | *There is no this situation.* | *Pass* |
| 6.8.3 | Technical description. | - | - |
| a) | General :<br>- Technical description shall included all items of clause 6.1, and all characteristics knowledge of which is essential for safety operation. | *All adequate technical description has been provided for safety operation.* | *Pass* |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | - The technical description shall state whether particular measures or condition are to be observed for installing equipment and bring equipment into use. | *The chapter "Preparation for use" has been provided in the instruction manual.* | *Pass* |
| b) | Replacement of fuses & other parts - Type & rating of fuses external to permanently installed equipment shall be stated in technical description. | *There is no fuse.* | *NA* |
| | - Technical description shall contain instruction for replacement of interchangeable part which are subject to deterioration during normal use. | *The information about the choice of accessories have been provided.* | *Pass* |
| c) | Circuit Diagram & Component part list. | - | - |
| | - Technical description shall contain statement that the supplier willmake available on request circuit diagram, component part list or other information which assist to repair equipment by qualified personnel. | *The circuit diagram and standard accessories have been provided.* | *Pass* |
| d) | Condition for transport & storage. | - | - |
| | Environment condition for transport & storage shall be repeated on the outside of packaging, if equipment is not capable of withstanding the condition specified in Sub-clause 10.1. | *The relevant environment condition have been included.* | *Pass* |
| 6.8.4 | Not used. | - | - |
| 6.8.5 | Not used. | - | - |
| | Compliance of clause 6.8 is checked by inspection. | *The relational requirements of clause 6.8 has been complied with.* | *Pass* |
| 7 | **POWER INPUT.** | - | - |
| 7.1 -a) | Motor drive equipment. - +25% for rating < 100W. - +15% for rating > 100W. | *Not a motor drive equipment.* | *NA* |
| -b) | The other equipment. - +15% for rating < 100W. - +10% for rating > 100W. | *D.C. power equipment with rating ≤ 100W.* | *NA* |
| | Compliance checked by testing. | *Not applicable.* | *NA* |
| 7.2 | Not Used. | - | - |



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## SECTION 2 : ENVIRONMENTAL CONDITIONS.

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 8. | **BASIC SAFETY CATEGORIES.** | - | |
| | See Appendix A1-1. | *The TENS complies with the relational safety requirements.* | *Pass* |
| 9. | **REMOABLE PROTECTIVE MEANS.** | - | |
| | Not Used. | - | - |
| 10. | **ENVIRONMENT CONDITION.** | - | - |
| 10.1 | Transportation & Storage : Within 15 weeks under the following Condition : - Humidity : 10 % ~ 100 %. - Pressure Range : 500 ~1060hPa. - Temperature : - 40°C ~ + 70°C. | *The transportation and storage conditions for TENS are constructed in accordance with this requirement.* | *Pass* |
| 10.2 | Operation : | - | - |
| 10.2.1 | Environment : - Humidity : 30 % ~ 75 %. - Pressure Range : 700 ~1060hPa. - Temperature : -10°C ~ + 40°C. | *The operation environment for TENS are in compliance with the requirements.* | *Pass* |
| 10.2.2 | Power Supply : | - | - |
| a) | - Rated Voltage : ( Not Exceeding ) * 250 V for hand-held. * 250V Dc or single phase, 500V for 3 phase while rating < 4 KVA. * 500 V for the others. | *DC 9V.* | *Pass* |
| | - Low internal impedance. | *Not applicable.* | *NA* |
| | - Voltage fluctuation not exceeding. | *Not applicable.* | *NA* |
| | - +10 % of Nominal Voltage, Not exceeding. | *Not applicable.* | *NA* |
| | - Frequency not more than 1 kHz. | *Not applicable.* | *NA* |
| | - Frequency deviate : not more than 1 Hz or 1 %. | *Not applicable.* | *NA* |
| | - Protective measures : IEC-364. | *Not applicable.* | *NA* |
| b) | - Internal power source, specified by the manufacturer. | *It is in conformity with this requirement.* | *Pass* |
| 11. | **NOT USED.** | - | - |
| 12. | **NOT USED.** | - | - |



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## SECTION 3 : PROTECTION AGAINST ELECTRIC SHOCK HAZARDS.

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 13. | GENERAL. | - | - |
| | Equipment shall be designed that the risk of electric shock in normal use and in single fault condition is obviated as far as practicable. | *Because that the power for TENS is DC battery, there is no electric shock situation could be occurred.* | *Pass* |
| 14. | CLASSIFICATION. | - | - |
| 14.1 | Class I equipment :<br>* Have parts with Double insulation or reinforce insulation or SELV.<br>* Separate protective earth conduct. | *Class I equipment.* | *Pass* |
| 14.2<br>-a) | Class II equipment :<br>* Insulation enclosed class II.<br>* Metal enclosed class II.<br>* Combination class II. | *Not class II equipment.* | *NA* |
| b) | Class I / II interchangable :<br>* Clear indicate.<br>* Comply with the requirement.<br>* Protective into Functional earth conductor for class II. | *Not class II equipment.* | *NA* |
| 14.3 | Not used. | - | - |
| 14.4<br>-a) | Additional protection according to the requirement of class I or class II. | *There is no additional protection.* | *NA* |
| -b) | No safety hazard develop when a connection with wrong polarity is made for equipment with DC power. | *No any safety hazard could be found while wrong polarity is made.* | *Pass* |
| 14.5<br>-a) | Dual classification for internal power equipment (e.g. class I, internal powered equipment ) | *Class I, internal powered equipment* | *Pass* |
| -b) | Comply with requirement of class I or class II. | *Not applicable.* | *NA* |
| 14.6 | Type B, BF and CF Equipment :<br>a); b); Not used.<br>c) Direct Cardiac shall be of CF.<br>d) Direct Cardiac Application having one or more CF may have one or more parts of type B or BF.<br>e) requirement applied also to equipment with mixture of B & BF. | *Type BF equipment.* | *Pass* |
| 14.7 | Not used. | - | - |
| 15. | LIMITATION OF VOLTAGE AND/OR ENERGY. | - | - |



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| Clause | Requirement - test | Result | | Verdict | |
|---|---|---|---|---|---|
| 15.1 -b) | For plug device : Voltage drop under 60 V within 1 sec after disconnection. | *Not a plug device.* | | *NA* | |
| | Test 10 times. | *Not applicable.* | | *NA* | |
| | Appropriate testing for device with capacitors. | *Not applicable.* | | *NA* | |
| 15.1. -c) | Live parts of capacitors or circuit parts connected to them, which become accessible after removal of some parts, shall not have a voltage exceeding 60V, or residual energy exceeding 2 mJ. | *Not applicable.* | | *NA* | |
| | Checked by appropriate testing. | *Not applicable.* | | *NA* | |
| **16.** | **ENCLOSURE AND PROTECTIVE COVERS.** | - | | - | |
| -a) | Protection against contact with live parts in single fault condition.<br>- After the opening of lid or door.<br>- Consider the insert/ removal of lamp<br>- Taking into account thefollowings:<br>1) Does not apply to the electrode directly connected to the patients body.<br>2) Varnishing,..... could not considered as enclosure.<br>3) If the conductive connection is impossible in normal use, such a part may assume a voltage to earth not exceeding 25 V a.c or 60 V d.c. | *Not applicable.* | | *NA* | |
| | Instruction shall instruct the operator not to touch such a part and the patient simultaneously. | *Not applicable.* | | *NA* | |
| | Testing by test finger and by inspection. | *Not applicable.* | | *NA* | |
| b) | Opening in a top cover is test by test rod 4ϕ x 100 mm. | *No unacceptable opening in the top cover is found.* | | *NA* | |
| c) | Conductive part accessible after removal of handles, knobs... shall either :<br>- Not more than 0.2 Ω to PET/testing, or<br>- Be separated according to 17g.<br>Note: Dose not apply to control of secondary circuits which is isolated from main part by ..... | *Not applicable.* | | *NA* | |

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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| d) | Part still live after disconnection and with voltage exceeding 25 Vac or 60 Vdc shall be protected by additional cover and shall be marked with "Live". | *Not applicable.* | *NA* | |
| e) | Enclosure shall be of fixed guard or movable guard with interlock. | *Not applicable.* | *NA* | |
| | Excluded situation:<br>-Voltage not exceeding 25 Vac or 60 Vdc, or peak with separation according to 17g.<br>- Lampholder. | *Voltage not exceeding 60Vdc.* | *Pass.* | |
| f) | Opening for adjustments by using tools shall be designed in such a way that the tools is not able to touch the inside the opening basic insulation or any live parts or parts not protectively earthed and separated from the mains part by basic insulation only. | *Not applicable.* | *NA* | |
| **17.** | **SEPARATION.** | - | - | |
| a) | Applied parts shall be electrically separated from live parts of equipment in normal condition and in single fault condition, in such a way that allowable leakage current will not exceed. | *It is in conformity with the requirement.* | *Pass* | |
| | This requirement is fulfilled by the followings : | - | - | |
| | 1) Separated by basic insulation only, but has such a low internal impedance to earth that the leakage current does not exceed. ( Applied Parts ) | *Leakage current does not exceed.* | *Pass* | |
| | 2) Separated by a protected earthed metal part, which may be a full enclosing metal screen. ( Applied parts ) | *No protected earthed metal part.* | *NA* | |
| | 3) Separated by an intermediate protected earthed circuit, which could keep leakage current within a limit value even at the insulation fail. ( Applied parts ) | *No intermediate protected earthed circuit.* | *NA* | |
| | 4) Separated by double or reinforced insulation. ( Applied parts ) | *No double or reinforced insulation.* | *NA* | |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | 5) Use of impedance of components to prevent the patient leakage current or patient auxiliary current exceeding the limit. ( Applied parts ) | *No this situation.* | *NA* |
| | Compliance check by : - Short circuit the creepage distance and air clearance if not fulfilled. -The patient leakage current is kept under limit. | *The patient leakage current is kept under limit. Please see the relevant clauses of leakage current test.* | *Pass* |
| c) | Applied part has no conductive connection to accessible metal part which are not protectively earthed. | *There is no this situation.* | *NA* |
| d) | Hand held flexible shafts of class I shall be separated from the motor shaft by supplementary insulation. | *No hand held flexible shaft.* | *NA* |
| g) | Accessible parts not being an applied part shall be electrically separated from live parts of equipment in normal condition and in single fault condition, in such a way that allowable leakage current will not exceed. | *Appropriate provision has been provided so as to keep the leakage current not exceed.* | *Pass* |
| | This requirement is fulfilled by the followings : | - | |
| | 1) Separated by basic insulation only , but has such a low internal impedance to earth that the leakage current does not exceed. ( Accessible parts ) | *Separated by this way.* | *Pass* |
| | 2) Separated by a protected earthed metal part, which may be a full enclosing metal screen. ( Accessible parts) | *Not this situation.* | *NA* |
| | 3) Separated by an intermediate protected earthed circuit, which could keep leakage current within a limit value even at the insulation fail. ( Accessible parts ) | *Not this situation.* | *NA* |
| | 4) Separated by double or reinforced insulation. ( Accessible parts ) | *Not this situation.* | *NA* |
| | 5) Use of impedance of components to prevent the patient leakage current or patient auxiliary current exceeding the limit. ( Accessible parts ) | *Not this situation.* | *NA* |



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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| | Compliance check by:<br>- Short circuit the creepage distance and air clearance if not fulfilled.<br>- The enclosure leakage current is kept under limit. | *Appropriate testing has been done with acceptable result.* | *Pass* | |
| 18. | **PROTECTION EARTHING, FUNCTIONAL EARTHING & POTENTIAL EQUALIZATION.** | - | - | |
| a) | Class I / Accessible part separated from live part by basic insulation shall be connected to protective earth terminal (PET) by sufficiently low impedance. (test of 18f & 18g) | *Because that the power for TENS is DC power, there is no protective earth terminal.* | *NA* | |
| b) | The PET shall be suitable for connection to the protective earth conductor of the power system. ( Plug or by a fixed and permanently install ), For constructional requirements please see clause 58. | *No PET.* | *NA* | |
| e) | Requirements for potential equalization conductor :<br>- Be readily accessible.<br>- Prevent accidental disconnection.<br>- Can be detached without tool<br>- Shall not incorporate the power supply cord.<br>- Shall be marked with symbol 9. | *Not applicable.* | *NA* | |
| f) | Impedance for equipment without a power supply cord shall not exceed 0.1 Ω between PET & accessible metal part. | *No PET.* | *NA* | |
| | Impedance for equipment with an appliance inlet shall not exceed 0.1 Ω between protective contact in the appliance inlet & accessible metal part. | *No appliance inlet.* | *NA* | |
| | Impedance for equipment with a non-detachable power supply cord shall not exceed 0.2 Ω between protective contact in main plug & accessible metal part. | *No non-detachable power supply cord.* | *NA* | |
| | Compliance is checked by testing. | *Not applicable.* | *NA* | |
| g) | Impedance for the others is allowed to exceed 0.1 Ω in case of ..... | *Not applicable.* | *NA* | |
| k) | Functional earth terminals shall not be used to provide protective earthing. | *No functional earth terminal.* | *NA* | |

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| Clause | Requirement - test | Result | | | Verdict | |
|---|---|---|---|---|---|---|
| l) | For class II with cord having 3 conductors, the third conductor shall be used as functional earth and shall be coloured yellow and green. | *Not a class II equipment.* | [illegible] | [illegible] | *NA* | [illegible] |
| | The insulation of internal screen shall be of double insulation or reinforce insulation for class II equipment. | *Not a class II equipment.* | [illegible] | [illegible] | *NA* | [illegible] |
| | Functional earth terminal shall be marked so as to be distinguished from protective earth terminal and shall be described in instruction manual. | *No functional earth terminal.* | [illegible] | [illegible] | *NA* | [illegible] |
| 19. | **CONTINUOUS LEAKAGE CURRENT & PATIENT AUXILIARY CURRENTS.** | - | 19. | CONTINUOUS LEAKAGE [illegible] PATIENT | - | |
| 19.1. | General Requirements. | - | 19.1 | General Requirements. | - | |
| a) | Protection against shock in such a way that current flowing through that are limited to the specified value. | *It is in accordance with the requirement of this clause.* | [illegible] | [illegible] | *Pass* | [illegible] |
| b) | The specified values are : Continuous Earth Leakage Current(CELC), Enclosure Leakage Current (ELC), Patient Leakage Current (PLC), and Patient Auxiliary Current (PAC). | - | b) | [illegible] | - | |
| | All of them are applied in the combination of the following condition :<br>- Operating / after humidity treatment.<br>- In normal & single fault condition.<br>- In stand-by; full operation; and in any position.<br>- With highest rated supply frequency.<br>- With 110% rated voltage. | *The conditions described in this clause have been followed.* | [illegible] | [illegible] | *Pass* | [illegible] |
| | The measured value not exceeding the values given in 19.3. | *Please see the relational tests provided in this test report.* | [illegible] | [illegible] | *Pass* | [illegible] |
| c) | SELV & internal power equipment; investigated for ELC but only as far as described in 19.4g) 3). | *Please see the relational tests provided in this test report.* | [illegible] | [illegible] | *Pass* | [illegible] |
| d) | ELC for class I shall only be performed :<br>- To earth from each part/not earth.<br>- Between parts / not protected earth. | *Please see the relational tests provided in this test report.* | [illegible] | [illegible] | *Pass* | [illegible] |

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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| e) | PLC shall only be measured in :<br>- Type B equipment.<br>- Type BF equipment.<br>- Type CF equipment. | *Please see the relational tests provided in this test report.* | *Pass* | |
| f) | PAC shall only be measured between:<br>- Any single patient connection, and;<br>- All other patient connected together. | *Because that the function of TENS is to provide a current for the patient, the PAC value specified in Table IV is not applicable for TENS.* | *NA* | |
| 19.2. | Single fault condition. | - | - | |
| a) | The CELC, ELC, PLC, & PAC shall be measured under the following single fault conditions :<br>- Interruption of each supply conductor<br>- Interruption of earth conductor<br>- See also sub-clause 17a) & 17g). | *The relevant requirements have been complied with.* | *Pass* | |
| b) | The PLC shall be measured under the following additional single fault conditions :<br>- 110% of rated voltage between earth and signal I/O part, not earth. | *Because the TENS belongs to Type BF equipment, this requirement has not been applied.* | *NA* | |
| | This requirement shall not apply in the following cases :<br>* The single input or single output parts are designated by the manufacturer for exclusive connection to equipment which complied with requirements specified in the accompanying documents for such equipment;<br>* For equipment of Type B, unless inspections of the circuits and physical arrangement shows a safety hazard exists;<br>* For equipment of Types CF and BF. | *Because the TENS belongs to Type BF equipment, this requirement has not been applied.* | *Pass* | |
| | - A voltage equal to 110% of the highest rated mains voltage applied between any F-Type applied part and earth. | *Because the TENS belongs to Type BF equipment, this requirement has not been applied.* | *NA* | |
| | - A voltage equal to 110% of the highest rated mains voltage applied between earth and any accessible metal parts not protectively earthed. | *Because the TENS belongs to Type BF equipment, this requirement has not been applied.* | *NA* | |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | This requirement does not apply : * For equipment of Type B, unless inspection of the circuits and physical arrangement shows that a safety hazard exists; * For equipment of Types CF and BF. | *Because the TENS belongs to Type BF equipment, this requirement has not been applied.* | *Pass* |
| c) | The ELC shall be measured with a voltage equal to 110% of the highest rated mains voltage, applied between earth and any signal input or signal output part, not protectively earthed. | *The power for the TENS is a D.C. battery.* | *NA* |
| | This requirement is not applied where the signal input or signal output parts are designated by the manufacturer for exclusive connection to equipment which complies with requirements specified in the accompanying documents for such equipment. | *Not applicable.* | *NA* |
| 19.3. | Allowable values | *According to Table IV.* | *Pass* |
| 19.4. | Tests | - | - |
| a) | All of them are measured in the following condition : - Operating / after humidity treatment. - With 110% rated voltage. - For 3 phases, measurement is tested as single phase with 3 sections connected in parallel. - If no possibility of safety hazard, the test number may be reduced. | *The relevant tests has been carried out according to the conditions defined in this clause.* | *Pass* |
| b) | Measuring supply circuits: Choose between Figure 10 ~ 14. | *Adequate measuring supply circuit has been used.* | *Pass* |
| c) | Appropriate connection of equipment to the measuring supply circuit ? | *Appropriate connection of equipment to the measuring supply circuit has been done.* | *Pass* |
| d) | Measuring arrangement | | *Pass* |
| e) | Measuring device | | *Pass* |
| f) | Measuring of CELC | *This test has not been carried out.* | *NA* |
| g) | Measuring of ELC | *This test has been carried out according to the relevant requirements, and the test result is within the value specified in Table IV.(Much lower than 0.001mA)* | *Pass* |
| h) | Measuring of PLC | *This test has been carried out according to the relevant requirements, and the test result is within the value specified in Table IV.(Much lower than 0.001mA)* | *Pass* |

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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| j) | Measuring of PAC | *Not applicable. ( See clause 19.1f ).* | *NA* | |
| **20.** | **DIEELECTRIC STRENGTH.** | - | - | |
| 20.1. | The following dielectric strength shall be tested : | - | - | |
| A-a1 | Live / Accessible metal; earthing; basic insulation. | *Not applicable.* | *NA* | |
| A-a2 | Live / Enclosure; not earthing; double & reinforce insulation. | *Not applicable.* | *NA* | |
| A-b | Live / Conductive part; part of double insulation isolated by basic insulation. | *Not applicable.* | *NA* | |
| A-c | Enclosure / Conductive part; part of double insulation isolated by basic insulation. | *Not applicable.* | *NA* | |
| A-e | Live; not signal I/O & signal I/O not earth. | *Not applicable.* | *NA* | |
| A-f | Part of opposite polarity of main part. | *Not applicable.* | *NA* | |
| A-g | Metal enclosure / metal foil. | *Not applicable.* | *NA* | |
| A-j | Accessible part likely to become live while the failure of insulation of power supply cord. | *Not applicable.* | *NA* | |
| A-k | Signal I/O part & Accessible part not earthing. | *Not applicable.* | *NA* | |
| 20.2. | The following dielectric strength shall be tested for equipment with applied part : | - | - | |
| B-a | Live / Applied part. | *Not applicable.* | *NA* | |
| B-b | Between part of applied part or applied part. | *This test has been carried out, and there is no breakdown has been found.* | *Pass* | |
| B-c | Applied part / part; not earthing. | *Not applicable.* | *NA* | |
| B-d | F-type Applied part / Enclosure including signal I/O. | *Not applicable.* | *NA* | |
| B-e | F-type Applied part / Enclosure where the F-type applied part contain voltage stressing the insulation to the enclosure in normal use. | *This test has been carried out, and there is no breakdown has been found.* | *Pass* | |
| 20.3. | Values of test voltage. ( See Table V) | *The test voltage for TENS is 500V.* | *Pass* | |

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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| 20.4. | Tests : | - | - | |
| a) | Test voltage is applied under the following situation :<br>- Immediately after warming up to OP.<br>- Heating element shall be kept.<br>- Immediately after humidity treatment.<br>- After any sterilization procedure. | *This test has been done according to the relevant situation mentioned in this clause.* | *Pass* | |
| b). | Appropriate waveform & frequency. | *Appropriate waveform and frequency have been provided.* | *Pass* | |
| f). | No flashover & breakdown. | *There is no flashover or breakdown has been found after the test.* | *Pass* | |
| g). | Voltage applied to reinforced insulation does not overstress basic insulation or supplementary insulation. | *There is no voltage applied to reinforced insulation.* | *NA* | |
| h). | Where metal foil is applied, tested according to clause 19.4g) 5). | *No metal foil has been used.* | *NA* | |
| j). | Power consuming voltage-limiting device shall be disconnected from the earthed side of the circuit. | *There is no this situation.* | *NA* | |
| k). | Terminal of main part, signal I/O part and the applied part are short circuit for some testing items. | *No this situation.* | *NA* | |
| l). | For motor with start capacitors, 2Uc + 1000 V shall be applied to the testing. | *There is not any motor used for this device.* | *NA* | |

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## SECTION 4 : PROTECTION AGAINST MECHANICAL HAZARDS:

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| **21.** | **MECHANICAL STRENGTH.** | - | - |
| | General. | - | - |
| | Enclosure or Access cover shall have sufficient strength & rigidity. | *The appropriate strength and rigidity have been provided on the enclosure for this product.* | **Pass** |
| | Compliance is checked by the following tests : | - | |
| a) | Apply 45 N over an area of 625 $mm^2$ anywhere on the surface. No appreciable damage or reduction of the creepage distance & air clearance. | *The test has been carried out, and there is no appreciable damage on the surface.* | **Pass** |
| b) | Impact test of 0.5 J for enclosure. | *This test has been carried out, and there is no damage on the enclosure.* | **Pass** |
| c) | Carrying handle or grip furnished on the portable equipment shall withstand appropriate loading. - Compliance is checked by testing. | *There is no carrying handle or grip.* | **NA** |
| 21.3 | Equipment part serving for support and/or immobilization of patient shall minimise the risk of physical injuries or accidental loosening of fixing. - Compliance is checked by testing. | *No this situation.* | **NA** |
| 21.4 | Not used. | - | - |
| 21.5 | Hand held equipment shall not present any safety hazard as a result of a free fall from a height of 1 m onto a hard surface. - Compliance is checked by testing. | *The falling test from a height of 1 m for this product has been carried out, and there is not any safety hazard has been found.* | **Pass** |
| 21.6 | Portable and mobile equipment shall be capable of withstanding the stress caused by rough handling. - Compliance is checked by testing. | *The relational test has been done, and the TENS is capable to withstand the stress cause by rough handling.* | **Pass** |
| **22.** | **MOVING PARTS.** | - | - |
| 22. 1 | Not used. | - | - |
| 22.2 | Exposed moving parts, which does not need to expose shall : - Be provided with adequate guards (for transportable MD). - Be similarly guarded or instruction to provide separated guard. | *No this situation.* | **NA** |



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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| 22.3 | Code, chains, and bands shall be confined to prevent safety hazard. | *The relational requirements have been complied with.* | *Pass* | |
| 22.4 | Dangerous movements shall be possible only by the continuous activation of the control by the operator. | *No this situation.* | *NA* | |
| 22.6 | Likely wear parts to result in a safety hazard shall be accessible for inspection. | *There is no wear part.* | *NA* | |
| 22.7 | Use of emergency switching, if necessary :<br>- Shall not introduce a further safety hazard nor interfere with the complete operation of emergency.<br>- Be able to break the full load current.<br>- Stopping shall be a result of one single action. | *The use of emergency switching is not necessary.* | *NA* | |
| **23.** | **SURFACE, CORNERS & EDGES.** | 23. | SURFACE, CORNERS & EDGES. | |
| | Injury caused by dangerous rough surface, sharp corners, and edges shall be avoided . | *No any dangerous rough surface, sharp corners, and edges were found for this device.* | *Pass* | |
| | Pay attention to the flange or frame edges & removal of burrs. | *It is in accordance with the requirement.* | *Pass.* | |
| **24.** | **STABILITY IN NORMAL USE.** | | | |
| 24.1 | Equipment shall either<br>- Not overbalance; at 10° tilting, or<br>- Satisfy sub-clause 24.3. | *The requirement has been complied with.* | *Pass* | |
| 24.3 | If overbalance at 10° tilting, the following requirements shall be met :<br>- Not overbalance at 15°.<br>- Shall carry a warning notice.<br>- In position specified for transport, not overbalance at 10° tilting. | *There is no the situation described in this clause.* | *NA* | |
| | Compliance is checked by testing. | *Not applicable.* | *NA* | |
| 24.6 | Grips and other handling device : | - | | |
| a) | Equipment, exceeding 20 kgs and needed to be handle for normal use, shall either<br>- Be provided with handling devices.<br>- Or documentation to indication point of lifting safely. | *The weight of the product is not exceeding 20 kgs.* | *NA* | |

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| Clause | Requirement - test | Result | | | Verdict | |
|---|---|---|---|---|---|---|
| b) | Portable equipment, exceeding 20 kgs shall<br>- Has handle system, which enable this equipment to be carried by 2 or more persons. | *The weight of the product is under 300 gs, not exceeding 20 kgs.* | | [illegible] | *NA* | *The weight of [illegible]* |
| 25. | **EXPELLED PARTS.** | - | 25. | EXPELLED PARTS. | - | |
| 25.1 | Protective means shall be provided for the expelled parts which will constitute a safety hazard. | *There is no expelled part.* | | Protective means shall be provided for the expelled parts which will constitute a safety hazard. | *NA* | *There is no exp[illegible]* |
| 25.2 | The particular requirement for the 16 cm face dimensions graphic vacuum tube. | *No graphic vacuum tube.* | | The particular requirement for the 16 cm face dimensions graphic vacuum tube. | *NA* | *No graphic va[illegible]* |
| 26. | **VIBRATION : Not used.** | - | 26. | VIBRATION : Not used. | - | |
| 27. | **PNEUMATIC & HYDRAULIC POWER :**<br>**Under consideration.** | - | 27. | PNEUMATIC & HYDRAULIC POWER :<br>Under consideration. | - | |
| 28. | **SUSPENDED MASSES** | - | 28. | SUSPENDED MASSES | - | |
| 28.1 | General. | - | 28.1 | General. | - | |
| | Where the mechanical defeat of mass suspension could constitute a safety hazard, the following requirements shall be taken into consideration, and Clause 22 shall be complied with for any moving part. | *Because the weight of the TENS is under 300 gs only, the relational requirements are not applicable.* | | Where the mechanical defeat of mass suspension could constitute a safety hazard, the following requirements shall be taken into consideration, and Clause 22 shall be complied with for any moving part. | *NA* | *Because the w[illegible] relational req[illegible]* |
| 28.2 | Not used. | - | 28.2 | Not used. | - | |
| 28.3 | With safety device :<br>Safety Device shall be provided unless excess travel in the event of breakdown is limited, for the following situation :<br>- Suspension part may due to the manufacturing process have hidden defeats,<br>- Or safety factor does not comply with Sub-clause 28.4. | *There is no relevant safety device.* | | With safety device :<br>Safety Device shall be provided unless excess travel in the event of breakdown is limited, for the following situation :<br>- Suspension part may due to the manufacturing process have hidden defeats,<br>- Or safety factor does not comply with Sub-clause 28.4. | *NA* | *There is no rel[illegible]* |
| | Safety factor shall comply with Sub-clause 28.4.2. | *Not applicable.* | | Safety factor shall comply with Sub-clause 28.4.2 | *NA* | *Not applicable* |
| | If the equipment is stillbe used after failure of suspension means, it shall become obvious to the operator that the safety device has been activated. | *There is no the situation specified in this clause.* | | If the equipment is stillbe used after failure of suspension means, it shall become obvious to the operator that the safety device has been activated. | *NA* | *There is no [illegible]* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 28.4 | Without Safety Device :<br>The following requirements shall be complied with.<br>- 1) Total load < Safe working load.<br>- 2) Safety Factor > 4, for safety is unlikely to be impaired by wear,....<br>- 3) Where impaired bywear, safety factor > 8.<br>- 4) if specified elongation < 5 %, the safety factor shall be X1.5.<br>- 5) life time shall be taken into consideration for the sheave, sprockets, and bandwheels. | *It is in conformity with the relevant requirements.* | ***Pass*** |
| 28.5 | Dynamic Loads : Not used. | - | - |
| 28.6 | Not used. | - | - |

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## SECTION 5 : PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION.

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | **GENERAL.** | - | - |
| | Adequate provisions shall be made to protect patient, operator, and sensitive device in the vicinity of the equipment from unwanted or excessive radiation. Limit of radiation is specified in particular standards. | *There is no unwanted or excessive radiation emission has been found from the TENS. Please see the test report of EMC.* | ***Pass*** |
| **29.** | **X RADIATION :** | | |
| 29.2 | For no X-radiation device, the ionizing radiation shall not produce an exposure exceeding 130 nC/kg(0.5mR) in 1 h at a distanceof 5 cm from any accessible surface of the equipment. ( Emitted by vacuum tube ) | *There is no ionizing radiation has been found.* | *NA* |
| **30.** | **ALPHA, BETA, GAMMA, NEUTRON RADIATION OR OTHER PARTICLE : - Not used.** | *Not applicable.* | *NA* |
| **31.** | **MICROWAVE RADIATION : - UNDER CONSIDERATION.** | *Not applicable.* | *NA* |
| **32.** | **LIGHT RADIATION : ( LASER ) - Under consideration.** | *Not applicable.* | *NA* |
| **33.** | **INFRA-RED RADIATION : - Under consideration.** | *Not applicable.* | *NA* |
| **34.** | **ULTRAVIOLET RADIATION : - Under consideration.** | *Not applicable.* | *NA* |
| **35.** | **ACOUSTICAL RADIATION : ( ULTRA-SONICS ) - Under consideration.** | *Not applicable.* | *NA* |
| **36.** | **ELECTROMAGNETIC COMPATIBILITY : - Under consideration.** | *The testing according to EN 60601-1-2 have been done. Please see the EMC test report.* | *Pass* |

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## SECTION 6 -PROTECTION AGAINST HAZARD OF FLAMMABLE ANANESTHTIC MIXTURES

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 37. | **LOCATION & BASIC REQUIREMENYS.** | - | - |
| 37.1 | Not used. | - | - |
| 37.2 | Not used. | - | - |
| 37.3 | Not used. | - | - |
| 37.4 | Not used. | - | - |
| 37.5 | Flammable anaesthetic mixture with air. (FAMA) | Not this situation. | NA |
| | If FAMA occurs due to a leakage or discharge from enclosure, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm. | *The TENS is not used for the condition which has flammable anaesthetic mixture with air.* | *NA* |
| 37.6 | Flammable anaesthetic mixture with oxygen or nitrous oxide. (FAMON) | - | - |
| | If FAMON occurs due to a leakage or discharge from enclosure, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm. | *The TENS is not used for the condition which has flammable anaesthetic mixture with oxygen or nitrous oxide.* | *NA* |
| 37.7 | FAMA shall be category AP or APG, and shall comply with the requirement of clause 39 and 40. | *Not applicable.* | *NA* |
| 37.8 | FAMON shall be category APG, and shall comply with the requirement of clause 39 and 41. | *Not applicable.* | *NA* |
| | Parts of APG shall be category AP or APG, and shall comply with the requirement of clause 38,39 and 40. | *Not a category APG equipment.* | *NA* |



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## SECTION 7 -PROTECTION AGAINST EXCESSIVE TEMPERATURE & OTHER SAFETY HAZARD.

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| **42.** | **EXCESSIVE TEMPERATURE.** | - | - |
| 42.1 | Temperature of equipment having a safety function shall not exceed the value of Table Xa. At normal use and normal condition specified in 10.2.1. | *After operating the TENS in continuous operation, the temperature in all parts does not excess the specified value of Table Xa.* | ***Pass*** |
| 42.2 | Temperature of equipment having a safety function shall not exceed the value of Table Xb. At normal use and normal condition at an ambient temperature of 25°C. | *After operating the product in continuous operation, the temperature in all parts does not excess the specified value of Table Xb.* | ***Pass*** |
| 42.3 | Applied parts of equipment not intended to supply heat to a patient shall not have surface temperature exceeding 41°C . | *The surface temperature of the applied part of the TENS does not exceed the specified value.* | ***Pass*** |
| | Temperature test according to the specified procedure. | *The temperature test has been carried according to the specified procedure.* | ***Pass*** |
| 42.4 | Not used. | - | - |
| 42.5 | Guards : Guards intended to prevent contact with hot accessible hot surface shall be removable only with the aid of a tool. | *There is no guard intended to prevent contact with hot accessible surface has been used.* | *NA* |
| **43.** | **FIRE PREVENTION.** | - | - |
| 43.1 | Equipment shall have the strength and rigidity necessary to avoid a fire hazard. | *Appropriate strength and rigidity have been provided for the TENS to avoid a fire hazard.* | ***Pass*** |
| **44.** | **OVERFLOW, SPILLAGE, LEAKAGE, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION.** | - | - |
| 44.1 | Sufficient degree of protection against safety hazard caused by the reasons described above. | *Appropriate protection degree against safety hazard has been provided.* | ***Pass*** |
| 44.2 | Overflow : Liquid overflowing from the reservoir or chamber shall not wet electrical safety insulation, nor shall a safety hazard be created. | *The function of water proof in this product has not been provided, but there is no safety hazard could be occurred in the event of liquid overflowing.* | *NC* |
| | No safety hazards shall develop if transportable equipment is tilted through an angle of 15°. | *There is no safety hazard is found even if the TENS has been titled through an angle of 15°.* | ***Pass*** |
| | Compliance is checked by test. | *The test has been carried out.* | ***Pass*** |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 44.3 | Equipment requiring the use of liquids in normal use shall be so constructed that spillage does not wet parts which may cause a safety hazard. | *No the situation of liquids use.* | *NA* |
| | Compliance is checked by test. | *Not applicable.* | *NA* |
| 44.4 | Liquid which might escape in a single fault condition shall not cause a safety hazard. | *There is no this situation.* | *NA* |
| | Compliance is checked by test. | *Not applicable.* | *NA* |
| 44.5 | Equipment shall be sufficiently proofed against the effects of humidity. | *Adequate prevision against the effects of humidity has been provided for the TENS.* | ***Pass*** |
| | Compliance is checked by test. | *The test has been carried out.* | ***Pass*** |
| 44.6 | Appropriate IP shall be provided according to IEC 529. | *Appropriate IP degree has been provided for the TENS.* | ***Pass*** |
| | Compliance is checked by tests. | *The test according to IEC 529 has not been done.* | *NC* |
| 44.7 | Cleaning, sterilization and disinfection. | | |
| | Equipment shall be capable of withstanding without damage or deterioration of safety provision the cleaning, sterilization, or disinfeation process. | *Keep the TENS clean is the only one thing specified by the manufacturer.* | ***Pass*** |
| | Should they are restricted to specific methods as a whole or for part of it, then only these specified method shall be applied. | *Not applicable.* | *NA* |
| | Compliance is checked by test. | *Not applicable.* | *NA* |
| **45.** | **PRESSURE VESSELS & PARTS SUBJECT TO PRESSURE.** | | |
| 45.1 | Not used. | | |
| 45.2 | If a pressure is not covered by a national regulation, and has a pressure x volume content greater than 200 kPa/L, and pressure greater than 50 kPa, it shall withstand the hydraulic test pressure. | *There is not any relevant pressure has been found.* | *NA* |
| | Compliance is checked by test. | *Not applicable.* | *NA* |
| 45.3 | The maximum pressure shall not exceed the maximum permissible working pressure of part. | *No any pressure is used for this device.* | *NA* |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | The appropriate consideration of maximum pressure. | *No any pressure is used for this device.* | *NA* |
| 45.4 | Not used. | - | - |
| 45.5 | Not used. | - | - |
| 45.6 | Not used. | - | - |
| 45.7 | Equipment shall incorporation pressure-relief device where excessive pressure could otherwise occur. | *There is no pressure-relief device.* | *NA* |
| | Pressure relief device shall comply with the following requirements : | - | - |
| a) | Be connected as close as possible to the pressure vessel. | *There is no pressure-relief device.* | *NA* |
| b) | Be readily accessible for inspection. | *There is no pressure-relief device.* | *NA* |
| c) | Not be capable of being adjusted or rendered inoperative without tools. | *There is no pressure-relief device.* | *NA* |
| d) | Discharge opening is not direct towards any persons. | *There is no pressure-relief device.* | *NA* |
| e) | Discharge opening shall not cause any safety hazards. | *There is no pressure-relief device.* | *NA* |
| f) | Adequate discharge capacity to ensure the pressure not exceeding the maximum permissible working pressure. | *There is no pressure-relief device.* | *NA* |
| g) | There shall be no shut-off valve between a pressure-relief device and the part that it is intended to protect. | *There is no pressure-relief device.* | *NA* |
| h) | The minimum number of cycles of operation shall be 100,000, except of bursting disks. | *There is no pressure-relief device.* | *NA* |
| 45.8 | Not used. | - | - |
| 45.9 | Not used. | - | - |
| 45.10 | Not used. | - | - |
| 46. | **HUMAN ERRORS : Not Used.** | - | - |
| 47. | **ELECTROSTATIC CHARGE : Not used.** | - | - |
| 48. | **MATERIAL IN APPLIED PARTS IN CONTACT WITH THE BODY OF PATIENT : Not used.** | - | - |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 49. | **INTERRUPTION OF POWER SUPPLY :** | - | - |
| 49.1 | Thermal cut-outs and over-current release with automatic resetting shall not be used if safety hazard will be caused. | *There is not any thermal cut-outs or over-current release device has been used.* | *NA* |
| 49.2 | Interruption & restoration of the power supply shall not result in a safety hazard. | *The interruption and restoration of the power supply for the TENS can't cause any safety hazard.* | *Pass* |
| 49.3 | Means shall be provided to allow the mechanical constraints on a patient to be removed in the event of failure of the supply mains. | *Not applicable.* | *NA* |
| 49.4 | Not used. | - | - |



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## SECTION 8 -ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| **50.** | **ACCURACY OF OPERATION DATA.** | - | - |
| 50.1 | Marking of control and instruments. | - | - |
| | Not used; See sub-clause 6.3. | - | - |
| 50.2 | Accuracy of control and instruments. | - | - |
| | Not used. | - | - |
| **51.** | **PROTECTION AGAINST HAZARDOUS OUTPUT.** | - | - |
| 51.1 | Intentional exceeding of safety limits. | - | - |
| | Means shall be provided which prevent hazardous setting or which indicate to the operator, if hazardous outputs exist. | *There is no this situation.* | *NA* |
| 51.2 | Indication of parameter relevant to safety. | - | - |
| | Any equipment delivering energy or substance to a patient shall indicate the possible hazardous output. ( This requirement shall apply only where Particular Standards specify it ) | *Not applicable.* | *NA* |
| 51.3 | Reliability of components : Not used. | - | - |
| 51.4 | Accidental selection of excessive output values. | - | - |
| | Appropriate steps shall be taken to minimise the possibility of a high intensity output accidentally. e.g. interlocks in order to achieve deliberate action, separated output terminals. | *There is no this situation.* | *NA* |

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## SECTION 9 -ABNORMAL OPERATION AND FAULT CONDITION; ENVIRONMENTAL TESTS

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 52. | **ABNORMAL OPERATION AND FAULT CONDITIONS.** | - | - |
| 52.1 | No safety hazard exists even in single fault condition. | *There is no safety hazard exists even in single fault condition.* | *Pass* |
| | The introduction of single fault (52.5) one at a time, No safety hazard (52.4) occur. | *No safety hazard occur.* | *Pass* |
| 52.2 | Not used. | - | - |
| 52.3 | Not used. | - | - |
| 52.4 | Safety hazard taken into consideration : | - | - |
| 52.4.1 | - Emission of flame, molten metal, poisonous or ignitable gas in hazardous quantities. | *There is no this situation.* | *NA* |
| | - Deformation to impair the compliance. | *There is no this situation.* | *NA* |
| | - Exceeding temperature rise. ( Temperature shall be measured according to clause 42.3.4) | *There is no this situation.* | *NA* |
| | For power dissipation in single fault under 15 W, the test is not required. | *There is no this situation.* | *NA* |
| | * Compliance is checked by tests of this clause. | *Not applicable.* | *NA* |
| 52.4.2 | - Exceeding of leakage current limits in single fault condition. | *There is no this situation.* | *NA* |
| | - Exceeding of voltage limits in case of a single fault condition. | *There is no this situation.* | *NA* |
| 52.4.3 | Starting, interruption, or locking of movements, particularity for equipment supporting, lifting or moving masses and suspension systems of masses in the vicinity of patients. | *There is no this situation.* | *NA* |
| 52.5 | Single fault conditions : | - | - |
| | During the insertion of single fault condition, air clearances & creepage distances which are specified in this standard but less than the specified value shall be short circuit. | *There is no this situation.* | *NA* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 52.5.1 | Overloading of main supply transformers in equipment. | *There is no transformer has been used.* | *NA* |
| 52.5.2 | Failure of thermostats. | *There is no thermostats has been used.* | *NA* |
| 52.5.3 | Short-circuiting of either constituent part of a double insulation. | *There is no this situation.* | *NA* |
| 52.5.4 | Interruption of the protective earth conductor. | *There is no protective earth conductor.* | *NA* |
| 52.5.5 | Impairment of cooling. | *The TENS doesn't need cooling.* | *NA* |
| 52.5.6 | Locking of moving parts. | *There is no moving part.* | *NA* |
| 52.5.7 | Interruption and short-circuiting of motor capacitors. | *No motor capacitor has been used.* | *NA* |
| 52.5.8 | Additional tests for motor operated equipment. | *Not a motor operated equipment.* | *NA* |
| 52.5.9 | Failure of components. | *The failure of components could not cause any safety hazard.* | *NA* |
| 52.5.10 | Overload. | | |
| a) | Compliance checking for equipment having heating elements. | *There is no heating element.* | *NA* |
| b) | Compliance checking for equipment having motor. | *There is no motor for this device.* | *NA* |
| c) | Compliance checking for equipment having heating elements but without adequate heat discharge. | *There is no heating element.* | *NA* |
| d) | Compliance checking for heating parts. | *There is no heating part.* | *NA* |
| e) | Additional compliance checking for equipment having heating parts. | *There is no heating part.* | *NA* |
| f) | Compliance checking for the motor running. | *There is no motor for this device.* | *NA* |



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## SECTION 10 - CONSTRUCTIONAL REQUIREMENTS.

| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| g) | Compliance checking for equipment of short-time or intermittent operation. | *The TENS is not used for short-time or intermittent operation.* | *NA* |
| h) | Compliance checking for the equipment with three phase motors. | *No three phase motor.* | *NA* |
| **53.** | **ENVIRONMENTAL TESTS.** | - | - |
| | See Sub-clause 4.10 & clause 10. | - | - |
| **54.** | **GENERAL.** | - | - |
| 54.1 | Arrangement of function : Not used. | - | - |
| 54.2 | Serviceability : Not used. | - | - |
| 54.3 | Inadvertent Change of settings : Not used. | - | - |
| **55.** | **ENCLOSURE AND COVERS : Not used. (See clause 16, 21, and 24)** | - | - |
| 55.1 | Material : Not used. | - | - |
| 55.2 | Mechanical Strength : Not used. | - | - |
| 55.3 | Access Covers : Not used. | - | - |
| 55.4 | Grips and other handling device : Not used. ( See clause 21 c) & 24.6 ) | - | - |
| **56.** | **COMPONENTS & GENERAL ASSEMBLY.** | - | - |
| 56.1 -a) | Not used. | - | - |
| b) | - Rating shall not conflict with the use condition of equipment.<br>- All component shall be marked or identified so that the rating could be ascertained.<br>- Marking shall be integral with the parts or by reference to drawing, part list, or in accompany documents.<br>- Inspect the rating to ascertain that no conflict exist with the use condition of equipment. | *All the relevant requirements specified in this clause have been complied with.* | *Pass* |
| c) | Supporting : Not used. | - | - |

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| | Clause | Requirement - test | Result | Verdict |
|---|---|---|---|---|
| | d) | Component fixing :<br>- Unwanted movement which could result in a safety hazard shall be prevented. | *There is no this situation.* | *NA* |
| | e) | Resistance of component to vibration : Not used. | - | - |
| | f) | Fixing of wiring<br>- Conductor and connection shall be secured and/or insulation to prevent safety hazard.<br>- Consideration of breaking free at joint ? | *Any connection for the TENS could not cause safety hazard.* | *NA* |
| | 56.2 | Screw and nuts : Not used. | - | - |
| | 56.3 | Connections - General | - | - |
| | | Connection & connector of main parts : See clause 57.2 & 57.5. | - | - |
| | a) | - Where safety hazard may be caused, the incorrect connection & removable w/o tools shall be prevented.<br>- Connector shall comply with 17 g)<br>- Plugs of patient circuit shall not capable of being connect to the socket of other function.<br>- Medical gas connections for different gas shall not be interchangeable. | *No any safety hazard will be occurred while the TENS has incorrect connection.* | *Pass* |
| | b) | Connections of different parts : See clause 58.<br>- Accessible metal part shall not become live while connection is loosen or broken due to disengagement for the connection between different parts.<br>- Compliance is checked and inspected. | *Even the connection is loosen, there is not any safety hazard could be occurred.* | *NA* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 56.4 | Connections of capacitors<br>- Capacitor shall not be connected between live parts and non-protective earthed accessible metal parts.<br>- Capacitor connected between main parts and protectively earthed accessible parts shall comply with IEC 384-14.<br>- The enclosure of capacitor shall not be secured directly to non-protectively earthed accessible metal parts.<br>- Capacitors or other spark-suppression device shall not be connected between the contacts of thermal cut-out. | *There is not any capacitor has been used.* | *NA* |
| 56.5 | Protective devices. (PD)<br>- PD which would cause disconnection by producing a short-circuit which results in operation of an over-current device shall not be fitted with equipment. | *No protective device.* | *NA* |
| 56.6 | Temperature & overload control devices.<br>- Thermal cot-outs, reset by soldering operation shall not be fitted with equipment.<br>- Thermal safety device shall be provided where necessary.<br>- Where safety hazard caused by a failure of a thermostat, the additional thermal cut-out shall be provided.<br>- Where loss of function caused by operation of thermal cut-out present a safety hazard, an audible warning shall be provided.<br>- Compliance is checked by inspection. | *No temperature or overload control device.* | *NA* |
| | - Equipment incorporated with a fluid filled container having heating facilities shall be provided with a safety device to safeguard against overheating.<br>- Compliance is checked by test. | *No any fluid filled container was used for this device.* | *NA* |
| b) | Temperature settings :<br>- For varying temperature setting, the temperature range shall not exceed that of proper function.<br>- The operating temperature of thermal cut-outs shall be clearly indicated. | *No temperature setting was used for this device.* | *NA* |

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| | Clause | Requirement - test | Result | Verdict |
|---|---|---|---|---|
| | 56.7 -a) | Batteries<br>- Housings containing batteries from which gases can escape during charging or discharging shall be ventilated to minimise the risk of accumulation and ignition.<br>- The risk of accidentally short circuiting the battery shall be prevented where the safety hazard would occur. | *It is in accordance with the requirements specified in this clause.* | **Pass** |
| | b) | - Means to prevent incorrect polarity of battery shall be provided, where safety hazard might develop by the incorrect connection. | *The markings "+" and "-" have been provided for the operator to install the battery.* | **Pass** |
| | 56.8 | Indicators : Unless indication is otherwise apparent to the operator, indicator light shall be provided<br>- Indication of energized.<br>- To indicate that the heaters are operative if a safety hazard could result.<br>- To indicate that an output exist where an inadvertent or prolonged operation of output could constitute a safety hazard. | *Appropriate indications have been provided for the operator.* | **Pass** |
| | | - Appropriate colours : See clause 6.7<br>- Charging mode of internal power source shall be indicated. | *Appropriate colours have been provided on the TENS.* | **Pass** |
| | 56.9 | Pre-set controls : Not used. | - | - |
| | 56.10 | Actuation parts of controls | - | - |
| | a) | Protection against electric shock.<br>- Accessible parts shall comply with 16c) | *Please see clause 16c).* | **Pass** |
| | b) | Fixing; prevention of maladjustment :<br>- Actuating parts / can not be pulled off or work loose.<br>- Indication of any scale shall always corresponds with the position of the control.<br>- Incorrect connection of the indicating shall be prevented.<br>- Torque test for rotating controls ? | *It is in compliance with these requirements.* | **Pass** |
| | c) | Limitation of movement.<br>- Stops of adequate mechanical strength shall be provided on rotating or movable parts to prevent an unexpected change from max. to min.<br>- Compliance is checked by inspection & manual test. | *All the rotating adjustment switch on the TENS will not cause any safety hazard.* | **NA** |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 56.11 | Cord-connected hand-held and foot-operated control devices. | *There is no cord-connected hand-held and foot-operated control device.* | *NA* |
| a) | Limitation of operation voltage.<br>- Those devices shall contain only conductors and components operating at voltage not exceeding 25V a.c. or 60V d.c. | *Not applicable.* | *NA* |
| b) | Mechanical strength.<br>- Hand-held control shall comply with the requirement & test of 21.5.<br>- Foot-operated control devices shall be able to support the weight of an adult human being. | *Not applicable.* | *NA* |
| c) | Inadvertent operation.<br>- Control setting shall not bechanged when inadvertently placed in an abnormal position.<br>- Compliance is checked by testing. | *Not applicable.* | *NA* |
| d) | Entry of liquids.<br>- Foot-operated control shall be drip-proof.<br>- Electrical switching parts of foot-operated control shall be of watertight construction. | *Not applicable.* | *NA* |
| e) | Connection cords.<br>- The connection and anchorage for the cords of those device shall comply with the requirement of 57.4. | *Not applicable.* | *NA* |
| 57. | **MAIN PARTS, COMPONENTS, & LAYOUT.** | - | |
| 57.1 | Isolation from the supply mains. | - | |
| a) | Isolation<br>- Means to isolate circuit from supply mains on all poles simultaneously ?<br>- Isolation shall either be incorporated in equipment or be specified on document. | *Appropriate insulation method has been provided for TENS.* | *Pass* |
| b) | Not used. | - | |
| c) | Not used. (See 57.1a) | - | |
| d) | Switch shall comply with the Creepage distance & Air clearance (IEC-328). | *It is in conformity with the relevant requirements.* | *Pass* |
| e) | Not used. | - | |
| f) | Main switch shall not beincorporated in a power supply cord or external flexible lead. | *The main switch is fixed on the TENS.* | *Pass* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| g) | Directions of movement for actuator of switch shall comply with IEC 447. | *There is no direction of movement for actuator of switch.* | *NA* |
| h) | Suitable plug is considered as complying with 57.1a. | *No plug was used.* | *NA* |
| j) | Not used. | - | - |
| k) | Not used. | - | - |
| l) | Not used. | - | - |
| m) | Fuse & semiconductor devices shall not be used as isolating devices. | *No fuse and semiconductor device was used for this device.* | *NA* |
| 57.2 | Main connector, Appliance inlets & the like. | - | - |
| a) | Not used. | - | - |
| b) | Not used. | - | - |
| c) | Not used. | - | - |
| d) | Not used. | - | |
| e) | Auxiliary mains socket outlets shall be of a type that can not accept a main plug. | | |
| f) | Not used. | - | - |
| 57.3 | Power supply cords. | - | - |
| a) | Application<br>- Equipment shall not be provided with more than one connection to supply.<br>- No safety hazard shall occur when more than one connection is made simultaneously.<br>- Main plug shall not be fitted with more than one power supply cord.<br>- Power supply cord or an appliance inlet shall be provided with equipment which is not permanently connected to a fixed wiring. | *All the relevant requirements specified in this clause have been complied with.* | *Pass* |
| b) | Type<br>- Power supply cords shall be not less than H05-RNF or H05-VVF.<br>- VVF shall not be used for equipment having external metal parts with a temperature exceeding 75°C. | *Because the power supply for the TENS is a D.C. battery, there is not any power supply cord or similar component for this device.* | *NA* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| c) | Cross-sectional area:<br>- Not less than that shown in Table XV. | *Not applicable.* | *NA* |
| d) | Preparation of Conductor :<br>- Stranded conductors shall not be soldered if fixed by any clamping means. | *Not applicable.* | *NA* |
| 57.4 | Connection of Power supply cords. | - | - |
| a) | Cord anchorage :<br>- Cord anchorage to relieve conductor from strain for equipment with power supply cord. | *No cord anchorage has been used.* | *NA* |
| | - Cord anchorage shall be made of the following material :<br>1) Insulation material.<br>2) Metal insulated from NPE conductive accessible parts.<br>3) Metal provided with an insulating lining. | *No cord anchorage has been used.* | *NA* |
| | - Cord is not clamped by a screw which bears directly on the cord insulation. | *No cord anchorage was used for this device.* | *NA* |
| | - Screws shall not serve to fix any component other than parts of the cord anchorage. | *No cord anchorage was used for this device.* | *NA* |
| | - Conductor of power supply cord shall be so arrange that the earth conductor is not subject to strain if cord anchorage fail. | *No cord anchorage was used for this device.* | *NA* |
| | - Compliance is checked by testing. | *Not applicable.* | *NA* |
| b) | Cord guard :<br>- Cord guard to protect cord against excessive bending at inlet opening of equipment. | *No cord guard was used for this device.* | *NA* |
| | - Compliance is checked by testing. | *Not applicable.* | *NA* |
| c) | Accessibility of connection :<br>- Adequate space inside equipment ? | *Adequate space for all components inside the TENS has been provided.* | *Pass* |
| 57.5 | Main terminal devices & wiring of main parts. | - | |
| a) | General requirement :<br>Main terminal devices shall be provided for the following cases :<br>- Connect to fixed wiring.<br>- Connect by rewirable non-detachable power supply cord. | *There is no terminal used for this device.* | *NA* |



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| | Clause | Requirement - test | Result | Verdict |
|---|---|---|---|---|
| | | Reliance shall not be placed upon the terminals alone, unless ... (one situation of conductor break , about CD & AD). | *There is no any terminal used for this device.* | *NA* |
| | | Terminals of components may be used as terminal for external conductor, if comply with 6.2 h), j), & k). | *There is no any terminal used for this device.* | *NA* |
| | | Screw for external conductors shall not serve to fix any other component, except that they are unlikely to be displaced when fitting the supply conductors. | *There is not any external conductor used for this device.* | *NA* |
| | b) | Arrangement of mains terminal : Terminals for external cords or flexible supply cords, & any protective terminal shall be closely grouped. | *There is no any terminal used for this device.* | *NA* |
| | | See clause 58 about the connection of protective earth conductor. | *There is not any connection of protective earth conductor.* | *NA* |
| | | See clause 6.2 about the marking of main terminal device. | *There is no terminal has been used.* | *NA* |
| | | Main terminal device shall not be accessible without tools, even if their live part are not accessible. | *There is no any terminal used for this device.* | *NA* |
| | | Appropriately located & shielded - There shall be no risk of accidental contact, should a wire of stranded conductor escape. - Compliance is checked by inspection or test in case of doubt. | *There is no any terminal used for this device.* | *NA* |
| | c) | Fixing of mains terminals: -Internal wiring are not subjected to stress & creepage distance & air clearance comply with 57.10. -Compliance is checked by testing. | *There is no any terminal used for this device.* | *NA* |
| | d) | Connections to mains terminals: - The cord terminals shall not require special preparation while connection, and shall be so placed that the conductor is not damaged and can not slip out when the clamping screws or nut are tightened. | *There is no any terminal used for this device.* | *NA* |
| | | See clause 57.3 for further requirements. | *Not applicable.* | *NA* |
| | e) | Fixing of wiring : See 56.1. | *Please make reference to clause 56.1.* | *Pass* |
| | 57.6 | Main fuse & over-current releases: | - | |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | Fuse or over-current release shall be provided in each supply lead for :<br>- Class I device; and<br>- Class II device having functional earth. | *No fuse or over-current was used for this device.* | *NA* |
| | Appropriate current rating :<br>- Reliably carry the normal operation current.<br>- Shall not greater than the rating of any component in main circuit. | *No fuse or over-current was used for this device.* | *NA* |
| | Protective earth conductor shall not be fused. | *No protective earth conductor was used for this device.* | *NA* |
| | Neutral conductor shall not be fused. | *No neutral conductor was used for this device.* | *NA* |
| 57.7 | Location of interference suppressors in the mains part. : Not used. | - | - |
| 57.8 | Wiring of main parts : | - | - |
| a) | Insulation :<br>- If the individual conductor is not equivalent to that of IEC-227 or 245, it is considered as a bare conductor. | *Not applicable.* | *NA* |
| b) | Cross-section :<br>- Internal wiring of a main part shall have a cross-sectional area not less than that of power supply cord specified in 57.3. | *Not applicable.* | *NA* |
| | Cross-sectional for the others & the sizes of tracks on printed wiring shall be sufficient to prevent the fire hazards. | *Appropriate cross-section has been provided for the wiring On printed wiring.* | *Pass* |
| 57.9 | Main supply transformers. | - | - |
| 57.9.1 | Overheating<br>- Main supply transformers shall be protected against overheating in event of short-circuit or overload on any output winding.<br>- Compliance is checked by the tests of 57.9.1a & 57.9.1b. | *No main supply transformer was used for this device.* | *NA* |
| | Protection device shall be connected in such a way that failure of any component can not renderthe protective device inoperative.<br>- Compliance is checked by inspection. | *No main supply transformer was used for this device.* | *NA* |
| 57.9.1 a) | Short-circuit test :<br>- Tested under conditions specified in clause 42. | *No main supply transformer was used for this device.* | *NA* |



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| | Clause | Requirement - test | Result | Verdict |
|---|---|---|---|---|
| | 57.9.1 b) | Overload tests: - Tested under conditions specified in clause 42. | *No main supply transformer was used for this device.* | *NA* |
| | 57.9.2 | Dielectric strength : - Tested between turns and layers of the primary and secondary windings of a main supply transformer after humidity treatment shall pass the followings. | *No main supply transformer was used for this device.* | *NA* |
| | 57.9.3 | Housing : Not used. | - | - |
| | 57.9.4 | Construction : | - | - |
| | a) | Appropriate separation of primary & secondary winding by one of the following methods : - Wound on separate bobbins or former. -...with an imperforate insulating partition between winding. -....with concentric windings & .... - Concentrically wound on one bobbin with winding separated by double or reinforced insulation. | *No main supply transformer was used for this device.* | *NA* |
| | b) | Not used. | - | - |
| | c) | Means shall be provided to prevent displacement of end turns beyond the interwinding insulation. | *No main supply transformer was used for this device.* | *NA* |
| | d) | The insulated overlap of not less than 3 mm for the protective earthed screen having only one turn. | *No main supply transformer was used for this device.* | *NA* |
| | e) | Appropriate construction for the transformer with reinforced insulation or double insulation ? | *No main supply transformer was used for this device.* | *NA* |
| | f) | Appropriate creepage distance for transformer complying with 57.9.4a) ? | *No main supply transformer was used for this device.* | *NA* |
| | g) | Double sleeving, having a total wall thickness of at least 0.3 mm, extending at least 20 mm outside the winding shall be provided for the exit of the wires from the internal windings of toroidal transformer. | *No main supply transformer was used for this device.* | *NA* |
| | 57.10 | Creepage Distance & Air Clearance. | - | - |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| a) | Values :<br>- Comply with table XVI.<br>- Comply with table XVI by making reference of 20.3.<br>- For slot insulation of motors, a reduction to 50% of the value oftable is allowed. | *Basically the TENS is actuated by a D.C. battery power supply the creepage distance and air clearance are not an important factor in the design of the TENS.* | *NA* |
| b) | Application :<br>- CD & AC are not required for the insulation between parts of opposite polarity if short circuit of each single one of CD & AC in turn does not produce a safety hazard. | *Not applicable.* | *NA* |
| | - The contribution to the CD of any groove or air gap less than 1 mm. wide shall be limited to its width. | *Not applicable.* | *NA* |
| | - The effect of insulating lining of metal enclosure or cover shall be taken into consideration. | *Not applicable.* | *NA* |
| | - AC alone is only acceptable for insulation between Live parts & applied part and accessible parts not protectively earthed, If ..... | *Not applicable.* | *NA* |
| c) | Not used. | - | - |
| d) | Measurement of CD & AC :<br>- Compliance by measurement taking into account the rulesin Fig.39 through Fig.47. | *The measurement has not been carried out.* | *NA* |
| **58.** | **PROTECTIVE EARTHING - TERMINALS & CONNECTIONS.** | - | - |
| 58.1 | Clamping means of protective earth terminal shall comply with 57.5c). It shall not be possible to loosen it without tool. | *There is no protective earth terminal.* | *NA* |
| | Screws for internal protective earthing connections shall be completely covered or protected against inadvertent loosening from the outside of equipment. | *There is no internal protective earthing connection.* | *NA* |
| 58.2 | For internal protective earthing connections, clamping by means of screw, soldering, crimping, wrapping, welding or a reliable pressure contact are allowed. | *There is no internal protective earthing connection.* | *NA* |
| 58.3 | Not used. See 57.5b) | - | - |
| 58.4 | Not used. | - | - |



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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| 58.5 | Not used. | - | - |
| 58.6 | Not used. | - | - |
| 58.7 | Where an appliance inlet from the supply connection to equipment, the earth pin of the appliance inlet shall be regarded as the protective earth terminal. | *No appliance inlet from the supply connection to equipment.* | *NA* |
| 58.8 | The protective earth terminal shall not be used for the mechanical connection. | *There is no protective earth terminal.* | *NA* |
| 58.9 | The protective earth connection shall be made before and interrupted after the supply connection are made or interrupted for plug /socket device and also interchangeable parts connected to protective earth. | *There is no protective earth connection.* | *NA* |
| **59.** | **CONSTRUCTION & LAYOUT.** | - | - |
| 59.1 | Internal wiring : | - | - |
| | For fixing of wiring in the applied part & main part, see 57.5. | *Please see clause 57.5.* | *Pass* |
| a) | Mechanical protection : | - | - |
| | Cable & wiring shall be adequate protected against contact with moving part or from friction at edge or sharp corner. | *Adequate protection has been provided for wiring.* | *Pass* |
| | Wiring having only basic insulation shall be protected by additional fixed sleeving or the similar. | *Adequate protection has been provided for wiring.* | *Pass* |
| | Wiring, cord forms or components shall not likely to be damaged in the normal process of assembly or replacement of cover or opening or closing of inspection doors. | *There is not any similar damage found in the relevant conditions specified in this clause.* | *Pass* |
| b) | Bending : ( For guiding roller of leads ) | - | - |
| | Movable leads in normal use are not bent round a radius of less than 5 times the outer of the lead concerned. | *No guiding roller of leads.* | *NA* |
| c) | Insulation : | - | - |
| | The insulating sleeving shall be adequate secured, whenever used. | *All relevant insulation protections have been secured adequate.* | *Pass* |

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| Clause | Requirement - test | Result | Verdict |
|---|---|---|---|
| | Inside equipment the sheath of a flexible cord shall be used as supplementary insulation only where it is not subject to undue mechanical stress and if its insulation properties are not less than IEC-227 & IEC-245. | *No sheath of a flexible cord was used for this device.* | *NA* |
| | Insulated conductors which in normal use are subject to temperature exceeding 75°C shall have an insulation of heat-resistant material. | *No this situation.* | *NA* |
| d) | Material : | - | - |
| | Aluminium wires of less than 16 $mm^2$ cross-section shall not be used. | *No aluminium wire was used for this device.* | *NA* |
| e) | Separation of circuits : Not used. See clause 17. | - | - |
| f) | Applicable requirements : | - | - |
| | Connection cords between equipment part shall be considered as belonging to the equipment and not be subject to requirements for wiring of electrical installation. | *Appropriate connection has been provided for the wiring inside the TENS.* | *Pass* |
| 59.2 | Insulation : | - | - |
| | This sub-clause refers to parts of equipment other than insulation which is covered in sub-clause 59.1c). | - | - |
| a) | Fixing : Not used. | - | - |
| b) | Mechanical strength & resistance to heat and fire. | - | - |
| | The insulation, mechanical strength & resistance to heat shall be retained.<br>- Compliance is checked by inspection and in conjunction with tests, if required. | *Appropriate insulation, mechanical strength and resistance to heat has been retained.* | *Pass* |
| | Resistance to heat is established by the tests which need not be performed if satisfactory evidence of compliance is provided.<br>- Test requirements 1) & 2). | *The TENS is designed and constructed with appropriate protection.* | *Pass* |
| c) | Protection. | - | - |

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| Clause | Requirement - test | Result | Verdict | |
|---|---|---|---|---|
| | Insulation shall be not likely to be impaired by deposition of dirt or by dust resulting wear of parts to the extent that CD & AV are reduce below the values specified in 57.10. | *Appropriate insulation protection has been provided.* | *Pass* | |
| | Ceramic material not tightly sintered, and the like, and beads, shall not be used as supplementary or reinforce insulation. | *There is no similar material used as supplementary or reinforced insulation.* | *Pass* | |
| | Parts of natural or synthetic rubber used as insulation shall be resistant to ageing and be so arranged and dimensions that CD satisfy 57.10. | *No natural or synthetic rubber was used.* | *NA* | |
| | Insulating material in which heating conductors are embedded shall be considered as basic insulation and shall not used as reinforced insulation. | *No this situation.* | *NA* | |
| | Compliance is checked by inspection. | *The relevant requirements have been checked by inspection.* | *Pass* | |
| 59.3 | Excessive current and voltage protection : | - 59.3 Excessive current and voltage protection | - | |
| | See Sub-clause 57.6. | - See Sub-clause 57.6 | - | |
| | An internal electrical power source in equipment shall be provided with an appropriate rated device for protection against fire hazard, if fire hazard may be given rise to in case of short circuit. | *No hazard was found in case of short circuit.* | *Pass* | |
| | Fuse elements replaceable without opening enclosure shall be fully enclosed in a fuseholder. | *No fuse has been used.* | *NA* | |
| | Protective devices connected between an F-type applied part and enclosure shall not operate below 500 V r.m.s. | *No protective device connected between an F-Type applied part and enclosure.* | *NA* | |
| | For thermal cut-outs and over-current release: See sub-clause 56.6. | *No this situation.* | *NA* | |
| 59.4 | Oil Containers | - | - | |
| | Oil containers in portable equipment shall be adequate sealed to prevent loss of oil in any position. The design of container shall allow for the expansion of the oil. | *There is no oil container.* | *NA* | |



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

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| Clause | Requirement - test | | Result | Verdict |
|---|---|---|---|---|
| | Oil containers in mobile equipment shall be sealed to prevent loss of oil during transport, but may be fitted with a pressure-release device which can operate during normal use. | *There is no oil container.* | Oil containers in mobile equipment shall be sealed to prevent loss of oil during transport, but may be fitted with a pressure-release device which can operate during normal use. | *NA* |
| | Partially sealed oil-filled equipment or equipment parts shall be provided with means for checking the oil level. | *There is no oil container.* | Partially sealed oil-filled equipment or equipment parts shall be provided with means for checking the oil level. | *NA* |

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# Attachment 10.



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# Third Party Test Report

# No. WELL LIFE-06002

**According to ANSI/AAMI NS4**

Device Name: OTC TENS

Model Name: WL- 2407

Manufactured by:

Well-Life Healthcare Limited.

1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Tested by:

Wincent Consultant Co., Ltd.

No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd.,

Pei Tun Dist., Taichung, Taiwan, R.O.C.

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# Test Content of NS4 Testing

**Report No: WL-06002**

1. Clause 4.1 Compliance with the Labeling Requirements
2. Clause 4.2.1 Electrical Safety.
3. Clause 4.2.2 Output Characteristics.
4. Clause 4.2.3 Functional Controls.
5. Clause 4.2.4 Open/Short Circuit Performance.
6. Clause 4.2.5 Incorrect Battery Installation.
7. Clause 4.2.6.1 Temperature (Operating).
8. Clause 4.2.6.2 Humidity (Endurance).
9. Clause 4.2.6.3 Water Immersion.
10. Clause 4.2.6.4 Solvent Resistance.
11. Clause 4.2.6.5 Vibration (Operating).
12. Clause 4.2.6.6 Mechanical Shock (Non-Operating).

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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.1 | Labeling Requirement | | |
| Type/Model | | WL- 2407 | Serial No. | - |
| Test requirement | | 4.1.1. Device Markings. Compliance with the requirements of 3.1.1 can be verified by visual inspection.<br>4.1.2. Clinician Information. Compliance with the requirements of 3.1.2 cab be verified by visual inspection, except for the electrical performance specifications required in 3.1.2.1 (8). The test circuit of Figure 1 can be used to measure the output characteristics to be reported in the clinician information accompanying the stimulus the stimulus generator.<br>4.1.3. Patient Information. Compliance with the requirements of 3.1.3 can be verified by visual inspection. | | |
| Test Procedures | | Visual inspection. | | |
| Test Equipments | | No particular equipment. | | |

Test Results: As the following records.
<1> The device marking has been verified by visual inspection.
<2> The clinician information has been verified by output wave form.
<3> The patient information has been verified by visual inspection.

| | | | |
|---|---|---|---|
| Conclusion | Test results indicated the chosen samples complying with the relevant requirement of ANSI/AAMI NS 4. | | |
| Refer to | <1> Labeling information.<br><3> User manual. | <2> Wave form information.<br><4> ANSI/AAMI NS4 inspection. | |
| Attachment | No particular attachment | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd.,
Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.1 | Electrical Safety. | | |
| Type/Model | | WL-2407 | Serial No. | |
| Test requirement | | 4.2.1. Electrical Safety. Test methods for verifying compliance with Applicable Document 2.1 are provided in that standard. | | |
| Test Procedures | | <1> One sample was submitted for the leakage current test according to the detail requirement of EN 60601-1. | | |
| Test Equipments | | <1> Leakage current meter.<br><2> Humidity chamber. | | |

Test Results: For the leakage current, see the following table.

| | | | | |
|---|---|---|---|---|
| A2 | APPENDIX 2(19.4.g) Measurement of the enclosure leakage current | | | P |
| | | Before moisture treatment | After moisture treatment | |
| | From surface to surface | 0μA at normal condition | 0μA at normal condition | P |
| | From surface to surface | 0μA with AP connected to ground | 0μA with AP connected to ground | P |

| | | | |
|---|---|---|---|
| A3 | APPENDIX 3(19.2.c) | | |
| | Measurement of the enclosure leakage current with 110% mains voltage on any signal input or signal output part. | No signal connection | N |

| | | | | |
|---|---|---|---|---|
| A4 | APPENDIX 4(19.4.h) Measurement of the patient leakage current | | | P |
| | | Before humidity treatment | After humidity treatment | P |
| | From AP to enclosure | 0μA at normal condition | 0μA at normal condition | P |

| | | | | |
|---|---|---|---|---|
| A5 | APPENDIX 5(19.4.h.2) Measurement of the patient leakage current with 250Vac voltage on the F type isolated (floating) applied part | | | P |
| | | Before humidity treatment | After humidity treatment | P |
| | From AP to ground | 4μA at condition Line to AP | 4μA at condition Line to AP | P |
| | | 0μA at connected Neutral to AP | 0μA at connected Neutral to AP | P |

| | | | |
|---|---|---|---|
| A6 | APPENDIX 6(19.4.h.3) | | |
| | Measurement of the patient leakage current with 110% mains voltage on a signal input or signal output part | No signal connection | N |

| | | | |
|---|---|---|---|
| A7 | APPENDIX 7(19.4.j) | | |
| | Measurement of the patient auxiliary current | No signal connection | N |

| | | | |
|---|---|---|---|
| Conclusion | Test results indicated the chosen samples complying with the relevant requirement of ANSI/AAMI NS 4. | | |
| Attachment | No particular attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C.S. Chang |



No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd.,
Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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# ANSI / AAMI NS4 Test Report

| | | | |
|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | |
| | Clause 4.2.2 | Output Characteristics. | |
| Type/Model | | WL-2407 | Serial No. |
| Test requirement | | 4.2.2. Output Characteristics. To determine compliance with the limits on output characteristics specified in 3.2.2, a 500-ohm purely resistive load is used in the test setup of Figure 1 (i.e., R1=500 ohms, and R2 and C are short-circuited). | |
| Test Procedures | | <1> Measure the output wave form for single pulse by using pure load 500Ω.<br><2> Calculate the output characteristics, and check the conformity of 3.2.2.2 | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | |

Test Results:

Calculation of output characteristics:

<1> Maximum output charge per pulse

The maximum output charge per pulse = 0.26msx80mA = 20.8μc

<2> Maximum charge per pulse

According to the formular of 3.2.2.2, the maximum charge per pulse Q

Q = 20μc+(0.8) (35t); where t = pulse width measured at 50 percent amplitude

So, Q = 20μc+(0.8) (35x0.26) = 27.0μc

<3> Maximum average current

Maximum average current = maximum output charge per pulse x No. of pulse per sec

= 20.8μcx120 = 2496μA = 2.496mA

<4> Maximum output power

Maximum output power = maximum average current (I) x maximum voltage (V)

= 2.486mAx40V = 99.84 mAV = 0.09984W

<5> Current and power density

Since the cross-section area of electrode is 16cm$^2$, the current and power density could be calculated as the followings:

Average current density = 2.496mA/16cm$^2$ = 0.156mA/cm$^2$

Average power density = 0.09984W/16cm$^2$ = 0.00624W/cm$^2$

| | | | |
|---|---|---|---|
| Conclusion | Test results indicated the chosen samples complying with the relevant requirement of ANSI/AAMI NS 4. | | |
| Attachment (Reference) | | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



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Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.3 | Functional Controls | | |
| Type/Model | | WL-2407 | Serial No. | |
| Test requirement | | 4.2.3.1. The design and construction of the devices shall be inspected to evaluate whether appropriate consideration has been given to the safety requirement of 3.2.3.1.<br>4.2.3.2. The test setup of 4.2.1, Figure 1, with R1=500 ohms, shall be used for the measurements needed to determine compliance with 3.2.3.2. | | |
| Test Procedures | | <1> Operation for each function of control in every possible operation condition, and monitor the output wave from of device.<br><2> Monitor the wave from of single pulse at 500Ω load for single and twin output, and compare the output wave form. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | | |

Test Results:

<1> Through operation for each function of device in any condition, the output of each control was not changed through inadvertent contact with the controls.

<2> The Wave form comparison between single output and twin output are as the following table:

| | Output | | |
|---|---|---|---|
| | Amplitude | Width | Frequency |
| Single output | 78 mA | 260 | 120 Hz |
| Twin output | 76 mA | 255 | 118 Hz |
| Difference | 2.5% | 1.9% | 1.6% |

| | | | |
|---|---|---|---|
| Conclusion | This testing item was not carried out, because it is a single channel device. | | |
| Attachment (Reference) | No particular attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



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Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.4 | Open/Short Circuit Performance. | | |
| Type/Model | | WL-2407 | Serial No: | |
| Test requirement | | The stimulus generator shall conform to the electrical performance specifications provided in the labeling, after operating for a minimum of 15 minutes under any combination of open- and short- circuited conditions. See also 3.2.4. | | |
| Test Procedures | | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Make the combination of open/short circuit for 15 minutes.<br><5> Recover the circuit of device, and repeat the test of <1> and <2>. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006<br><3> 500Ω pure load. | | |

Test Results:

After carrying out the testing as mentioned above, the output waveform of measuring are indicated as the following comparison table.

| | Frequency | Pulse amplitude | Current |
|---|---|---|---|
| Before treatment | 120 Hz | 38V | 76 mA |
| After treatment | 116 Hz | 37V | 74 mA |

| | |
|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After 15 min operation of abnormal situation of open/short circuit combination as indicated in this report, the device could be operated normally without any unacceptable change.<br><2> The waveform before and after abnormal operation is almost identical.<br><3> The testing requirement set out on clause 3.2.4. is completely fulfilled. |
| Attachment (Reference) | No particular attachment. |

| | | | |
|---|---|---|---|
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



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Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net



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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.5 | Incorrect Battery Installation. | | |
| Type/Model | | WL-2407 | Serial No. | - |
| Test requirement | | The stimulus generator shall conform to the electrical performance specifications provided in the labeling after a minimum use time of one half hour in the "on" condition and one half hour in the "off" condition, with the batteries installed such that the supply voltage polarity is reversed from the normal operating polarity. See also 3.2.5. | | |
| Test Procedures | | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Install the battery with reverse polarity.<br><5> Repeat the test of <1>, <2> and <3>. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | | |

Test Results:

After carrying out the testing as mentioned above, the output waveform of measuring are indicated as the following comparison table.

| | Frequency | Pulse amplitude | Current |
|---|---|---|---|
| Before treatment | 120 Hz | 38 V | 76 mA |
| After treatment | 116 Hz | 37.5V | 75 mA |

| | | | |
|---|---|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After incorrect battery installation as indicated in this report, the device could be operated normally without any unacceptable change.<br><2> The waveform before and after incorrect battery installation is almost identical.<br><3> The testing requirement set out on clause 4.2.5. is completely fulfilled. | | |
| Attachment (Reference) | No particular attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd.,
Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.6.1 | Temperature (Operating). | | |
| Type/Model | | WL-2407 | Serial No. | - |
| Test requirement | | The following test shall be performed, both with output parameters set at the midpoint of their specified ranges and with output parameters set at their full maximum values: two full-temperature cycles shall be made between 0°C and +50°C, with a soak time of at least one hour at the temperature extremes. The device shall be operating continuously throughout this test, and the current output, voltage output, and pulse rate and duration monitored using the test setup of 4.1.2 with R, set at 500 ohms. Throughout the test, these parameters shall not differ by more than ±20 percent from their values at room temperature, unless otherwise specified in the labeling. | | |
| Test Procedures | | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Place the device in the specified environments as indicated in the following descriptions:<br>① 0°C for 1 hour.<br>② 50°C for 1 hour.<br>③ 0°C for 1 hour.<br>④ 50°C for 1 hour.<br><5> Remove the device from the environment chamber.<br><6> Repeat the test of <1> and <2>. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | | |

Test Results:
After carrying out the testing as mentioned above, the output waveform of measuring are indicated as the following comparison table.

| | Frequency | Pulse amplitude | Current |
|---|---|---|---|
| Before treatment | 120 Hz | 37.5 V | 75 mA |
| After treatment | 117 Hz | 37 V | 74 mA |

| | |
|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After temperature treatment as indicated in this report, the device could be operated normally without any unacceptable change.<br><2> The waveform before and after temperature treatment is almost identical.<br><3> The testing requirement set out on clause 4.2.6.1 is completely fulfilled. |
| Attachment (Reference) | No particular attachment. |

| | | | |
|---|---|---|---|
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. C |



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Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net



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# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.6.2 | Humidity (Endurance). | | |
| Type/Model | | WL-2407 | Serial No. | - |
| Test requirement | | The device shall be exposed to a temperature of at least 40°C and a relative humidity of 90 to 95 percent for 21 days. Batteries may be left in the unit with the unit turned off. Fresh batteries may be installed and any condense in the circuitry removed after humidity exposure and before testing final electrical performance. The device shall conform to the electrical performance specifications provided in the labeling. Labels shall be legible and firmly attached after exposure. | | |
| Test Procedures | | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Place the device into the humidity with 90 to 95%, 40°C for 21 days.<br><5> Remove the device from the humidity chamber.<br><6> Repeat the test of <1>, <2> and <3>. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load.<br><4> Humidity chamber. | | |

Test Results:

After carrying out the testing as mentioned above, the output waveform of measuring are indicated as the following comparison table:

| | Frequency | Pulse amplitude | Current |
|---|---|---|---|
| Before treatment | 120 Hz | 37.5 V | 75 mA |
| After treatment | 114 Hz | 36.5V | 73 mA |

| | | | |
|---|---|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After humidity treatment as indicated in this report, the device could be operated normally without any unacceptable change.<br><2> The waveform before and after humidity treatment is almost identical.<br><3> The testing requirement set out on clause 4.2.6.2. is completely fulfilled. | | |
| Attachment (Reference) | No additional attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



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Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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# ANSI / AAMI NS4 Test Report

| | | | |
|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | |
| | Clause 4.2.6.3 | Water Immersion. | |
| Type/Model | WL-2407 | Serial No. | - |
| Test requirement | The device, while operating with all parameters at maximum value, shall be immersed in distilled water for three minutes. The output shall be monitored and must not increase above the maximum output of 75 μC or 10 mA into a 500-ohm load (as specified in 3.2.2.2). | | |
| Test Procedures | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Immerse device into water for 3 mins.<br><5> Remove the device from the water and dry it.<br><6> Repeat the test of <1>, <2> and <3>. | | |
| Test Equipments | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | | |

Test Results:

After immersing the device to water for three minutes, the device can be switched on only for very few seconds. After the device was switched on, the output does not exceed the value of normal operation, and then was reduced to zero very soon.

So, it is "Fail to safe" operation.

| | | | |
|---|---|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After 3 min water immersion as indicated in this report, the device could be operated for some seconds, then it was shut down.<br><2> The waveform before and after water immersion does not exceed the value of normal operation.<br><3> The testing requirement set out on clause 4.2.6.3 is completely fulfilled. | | |
| Attachment (Reference) | No particular attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. C |



No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd.,
Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.6.4 | Solvent Resistance. | | |
| Type/Model | | WL-2407 | Serial No. | - |
| Test requirement | | The exterior of the device shall be wiped or painted with the following common substances: 70 percent isopropyl alcohol, dish soaps and detergents, electrode gels. After a 1-minute period of exposure to these substances, labels shall be legible and firmly attached. | | |
| Test Procedures | | <1> Apply the solvent to every labels of device for at least 1minute.<br><2> Visual inspection for the labeling. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | | |

Test Results:

After applying the solvent to the labels of device for at least 1 minutes, every labels on device are legible and firmly attached.

| | | | |
|---|---|---|---|
| Conclusion | This result complies with the requirement of clause 4.2.6.4 of NS4 standard. | | |
| Attachment (Reference) | No particular attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C. S. Chang |



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Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015



# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.6.5 | Vibration (Operating). | | |
| Type/Model | | WL-2407 | Serial No. | - |
| Test requirement | | The device, while operating, shall be subjected to three sinusoidal vibration sweeps from 50 to 500 Hz in each of the three orthogonal axes at a level of 2.5 g peak. Each sweep shall be 15 minutes in duration. The electrical output shall be monitored before and after the sweeps. The stimulus generator shall perform within the electrical performance specifications provided in the labeling. | | |
| Test Procedures | | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Fix device onto vibration testing machine as indicated on the following drawing.<br><5> Remove device from vibration machine.<br><6> Repeat the test of <1>, <2> and <3>. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load.<br><4> Vibration simulator. | | |

Test Results:

After carrying out the testing as mentioned above, the output waveform of measuring are indicated as the following comparison table.

| | Frequency | Pulse amplitude | Current |
|---|---|---|---|
| Before treatment | 120 Hz | 37.5 V | 75 mA |
| After treatment | 116 Hz | 36.5 V | 73 mA |

| | | | |
|---|---|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After vibration as indicated in this report, the device could be operated normally without any unacceptable change.<br><2> The waveform before and after vibration is almost identical.<br><3> The testing requirement set out on clause 4.2.6.5. is completely fulfilled. | | |
| Attachment (Reference) | No particular attachment. | | |
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C.S.C |



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Pei Tun Dist., Taichung, Taiwan, R.O.C. (406)
Tel: +886-4-2297-2787 Fax: +886-4-2297-2476
E-mail: wincent1@ms19.hinet.net

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

Records Processed under FOIA Request #.2015-813; Released by CDRH on 9-10-2015



# ANSI / AAMI NS4 Test Report

| | | | | |
|---|---|---|---|---|
| According to | NS4 | American National Standard for Transcutaneous Electrical Nerve Stimulators | | |
| | Clause 4.2.6.6 | Mechanical Shock (Non-Operating). | | |
| Type/Model | | WL-2407 | Serial No. | - |
| Test requirement | | The device shall be subjected to a half-sine shock of 850-g peak and 0.8-millisecond duration, in each of six orthogonal directions. The output characteristics of the device shall then be measured and shall conform to the electrical performance specifications provided in the labeling. | | |
| Test Procedures | | <1> Set the pulse rate, pulse amplitude, and pulse width at maximum setting value.<br><2> Connect the device with the "Test setup circuit" as indicated in Figure 1 of NS4.1985 with load 500Ω.<br><3> Switch on the device, measure the output and print out the output waveform of measuring.<br><4> Drop device onto ground for each of six orthogonal direction from 1 meter high.<br><5> Recover the circuit of device, and repeat the test of <1>, <2> and <3>. | | |
| Test Equipments | | <1> Oscilloscope; type Pitek, calibrated at August 18, 2006.<br><2> Frequency counter, type Lock, calibrated at August 18, 2006.<br><3> 500Ω pure load. | | |

Test Results:

After carrying out the testing as mentioned above, the output waveform of measuring are indicated as the following comparison table.

| | Frequency | Pulse amplitude | Current |
|---|---|---|---|
| Before treatment | 120 Hz | 38 V | 76 mA |
| After treatment | 117 Hz | 37 V | 74 mA |

| | |
|---|---|
| Conclusion | According to the test result as mentioned above, the following conclusion could be drawn:<br><1> After dropping as indicated in this report, the device could be operated normally without any unacceptable change.<br><2> The waveform before and after dropping is almost identical.<br><3> The testing requirement set out on clause 4.2.6.6. is completely fulfilled. |
| Attachment (Reference) | No particular attachment. |

| | | | |
|---|---|---|---|
| Tested by Joan Chen | Joan Chen | Approved by C. S. Chang | C.S.C |



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E-mail: wincent1@ms19.hinet.net

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

# Attachment 11.



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

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**Appendix 1. FDA Form-3514.**



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

Records Processed under FOIA Request # 2015-813; 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)* |
|---|---|---|
| 06/10/2009 | (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: Well-Life Healthcare Limited | Establishment Registration Number *(if known)*: |
| Division Name *(if applicable)*: | Phone Number *(including area code)*: ( ) 886-2-29282112 |
| Street Address: 1F, No.16, Lane 454, Jungjeng Road | FAX Number *(including area code)*: ( ) 886-2-29281880 |
| City: Yunghe City, Taipei County | State / Province: ; ZIP/Postal Code: 234 ; Country: Taiwan |
| Contact Name: Chin-Chih Hsieh | |
| Contact Title: Official Correspondent | Contact E-mail Address: jenny@welllifehealthcare.com.tw |

## 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: |



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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 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

Records Processed under FOIA Request # 2015-813; 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 | K060846 | 2 | K033122 | 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 | K060846 | 1 | Endurance T1040 | 1 | Endurance Therapeutics |
| 2 | K033122 | 2 | Prizm 5000-Z system | 2 | Prizm Medical, 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

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|---|---|---|
| 1 | OTC TENS for Arm & Leg Pain Relief | 1 | WL-2407 |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

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

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

Data Included in Submission

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

## SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

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

Classification Panel

Division of General Restorative and Neurological Devices

Indications *(from labeling)*

The OTC TENS for Arm & Leg Pain Relief; Model:WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.



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

| | | | | |
|---|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifer (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ 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 | |

| | | | | |
|---|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifer (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ 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

Records Processed under FOIA Request # 2015-813; 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 | EN/IEC 60601-1 | IEC | Medical Electrical Equipment - Part 1: General requirements for safety | 1990 + A1/A2/A13: 1996 | |
| 2 | EN/IEC 60601-1-2 | IEC | Medical Electrical Equipment - Part 1-2: General requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests | 2001 | |
| 3 | ANSI/AAMI NS4 | ANSI | American National Standard for Transcutaneous Electrical Nerve Stimulators | 1985 | |
| 4 | | | | | |
| 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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

**Appendix 2. FDA Form-3654.**





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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI NS4, American National Standard for Transcutaneous Electrical Nerve Stimulators, 1985

| *Please answer the following questions* | *Yes* | *No* |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☐ | ☑ |
| FDA Recognition number [3] # | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☑ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☑ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☑ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☑ | ☐ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☑ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☑ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☑ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☑ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☑ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☑ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html



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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED* | | |
| DESCRIPTION. | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED* | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED* | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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



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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirments for Safety, 1990+A1/A2/A13:1996

| *Please answer the following questions* | *Yes* | *No* |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☑ | ☐ |
| FDA Recognition number [3] # 5-4 | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☑ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☑ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☑ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☑ | ☐ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☑ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☑ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☑ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☑ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☑ |
| If yes, was the guidance document followed in preparation of this 510k? | | ✓ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html



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

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS***

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED* | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED* | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? ☐ Yes ☐ No ☐ N/A |
|---|---|---|
| TYPE OF DEVIATION OR OPTION SELECTED* | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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



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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-1-2, Medical Electrical Equipment - Part 1-2: General Repuirments for Safety - collateral Standard,2001

| *Please answer the following questions* | *Yes* | *No* |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☑ | ☐ |
| FDA Recognition number [3] # 5-34 | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☑ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? | ☑ | ☐ |
| If no, complete a summary report table. | | |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☑ | ☐ |
| Does this standard include acceptance criteria? | ☑ | ☐ |
| If no, include the results of testing in the 510(k). | | |
| Does this standard include more than one option or selection of tests? | ☐ | ☑ |
| If yes, report options selected in the summary report table. | | |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☑ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? | ☐ | ☑ |
| If yes, report these deviations or adaptations in the summary report table. | | |
| Were there any exclusions from the standard? | ☐ | ☑ |
| If yes, report these exclusions in the summary report table. | | |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☑ |
| If yes, was the guidance document followed in preparation of this 510k? | | ☑ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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SECTION NUMBER

TYPE OF DEVIATION

DESCRIPTION

JUSTIFICATION

## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

SECTION NUMBER | CONFORMANCE?

**CONFORMANCE WITH STANDARD SECTIONS*** ☐ Yes ☐ No ☐ N/A

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 17, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757

Product: OTC TENS FOR ARM AND LEG PAIN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



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

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

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(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

(b) (4), (b) (5) Predecisional Reviewer Correspondence and Test Reports

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**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 15, 2009

WELL-LIFE HEALTHCARE LIMITED
1FL, NO.16, LANE 454 JUNGJENG RD.
YUNGHE CITY, TAIPEI COUNTY
CHINA (TAIWAN) 234
ATTN: JENNY HSIEH

510k Number: K091757

Product: OTC TENS FOR ARM AND LEG PAIN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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Sincerely,

510(k) Staff



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

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K091757/S3

# Response Report for K091757/S2

Device Name: OTC TENS For Arm & Leg Pain Relief

Model Number: WL - 2407

*Presented by*

FDA CDRH DMC
DEC 11 2009
Received

**Well Life Healthcare Limited**

1Fl., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C

**Date: December 10, 2009**

21

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

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

To: Rahul K. Ram **Date : Dec. 10, 2009**
Lead Reviewer, K091757/S2
Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Center for Devices and Radiological Health

From: Well Life Healthcare Ltd.
c/o Ms. Jenny Hsieh
1 FL, No. 16, Lane 454 Jungjeng Rd.
Yunghe City, Taipei County
China (Taiwan) 234

Re: K091757/S2
Trade Name: OTC TENS for arm and leg pain relief, model WL-2407
Dated: November 13,2009
Received: November, 16, 2009

Dear Dr. Ram :

According to comments on K091757 /S2 received by e-mail on November 17, 2009 , we would like to response further each in the followings :

| Comment No.1 |
|---|
| In response to deficiency 1, you identify another garment electrode / TENS device combination predicate (K033122, "5000Z System") and provide a comparison of overall impedance between the TheraKnit electrodes and the electrodes of the 5000Z system. Based upon this comparison, you reason that the TheraKnit garment electrode can be used with the WL-2407 stimulator. Because the TheraKnit device intended is for prescription use only, it is inappropriate to package or sell the TheraKnit with your device, as your device is for over-the-counter use. Therefore, please confirm that your device is not packaged or sold with the TheraKnit device (instead, it is only indicated to be used with the TheraKnit device). Furthermore, please revise your "Operation Manual" to include the following warning: "The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider." Alternatively, please remove all references to the TheraKnit Garment Electrodes from your submission and labeling. |

<Response>

For this comment, we provided a declaration and revised 510(K) summary so as to clearly indicate that our device is not packaged and sold with the TheraKnit device.

**The declaration is as attached 1-a , and the revised 510(K) summary is as attachment 2.**



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

In addition, we also revised our instruction manual new revision ( IM-24-006 RevB09) on the pages (P10 &P14) concerning the use of garment electrode to include the recommended warning as mentioned in this comment.

**For this revised page ( P 10 & P 14) & Manufacturer statement , please see attachment 1-b.**

| Comment No.2 |
| --- |
| In response to deficiency 2, you provide testing and calculations in Attachment 2 of the submission. The testing shows that the output power and power density is roughly half of the corresponding values for your predicate device. You claim that this is due to the fact that "the 5000Z is a high voltage stimulator, whilst WL-2407 is a typically asymmetrical biphasic TENS device." However, you have not stated why this does not significantly diminish the effectiveness of your device. Therefore, please revise your 510(k) summary to include the following:<br>a. The results of all comparison testing noted in Attachment 2, and;<br>b. An acknowledgement of the lower output power and power density of your device and a scientific rationale for how effectiveness is equivalent.<br>This information is important to ensure that your device is equivalent to your predicate devices. |

<Response>

According to this review comment, we revised our 510(K) summary so as to include the comparison testing result (a) and the acknowledgement (b) as required by this comment. In addition, we also added the statement that our device is not packaged and sold with the TheraKnit device.

**For the revised 510(K) summary, please see attachment 2.**

| Comment No.3 |
| --- |
| In response to deficiencies 2 and 3, you have provided electrical performance testing. However, you have not provided dispersion testing for any of the electrodes. Please provide dispersion testing to ensure that current traveling through the electrodes does not congregate in "hot spots." This is important to ensure that your device is reasonably safe for its indicated use. |

<Response>

The Dispersion Testing Report for Adhesive Electrode has been clearly included on the response report of K082065. **The test report for adhesive electrode is as attachment 3-a .**

For this comment, we conduct and complete **the dispersion test for the silicon pad additionally as attachment 3-b.**

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Based on this testing result as attachment 3, the maximum deviation of current distribution for every quarter is not more than 5%. We concluded that current distribution for our adhesive and silicone pad electrode are within the acceptable deviation specification of the device, and ***the risk of unintended focal stimulation does not occur for our electrodes***. Also, the material of Adhesive Electrode and Silicone Pad used for our electrode are ***appropriate and properly constructed for the intended use as claimed in submission.***

**These are for K091757/S2 responses for your review ~~ thank you !**

**Yours truly,**

**Jenny Hsieh/ Official Correspondent**



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

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# Attachment 1-a

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

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威 立 德 有 限 公司
永和市中正路 454 巷 16 號 1 樓
1F., No. 16, Lane 454, Jungjeng Road,
Yunghe City, Taipei County 23455, Taiwan ROC

# Manufacturer Statement

Date: Dec.10,2009

Subject: 510(k): K091757/S2
Trade Name: OTC TENS for Arm and Leg Pain Relief, Model WL-2407

With reference to review comment by Dr. Rahul K. Ram , 510(k): K091757/S2 , dated on November 17,2009, **this is to further confirm that** *Well-Life OTC TENS, Model WL-2407 stimulator , intended for Arm and Leg Pain Relief* , **will not packed or sold with the TheraKnit device without prescription .**

We shall include the warning in the operation manual -

***"The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."***

Your Faithfully,

Jenny Hsieh
Official correspondent
Well-Life Healthcare Ltd.

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

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Attachment 1-b

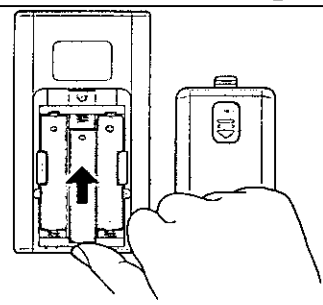
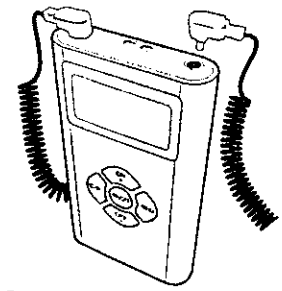
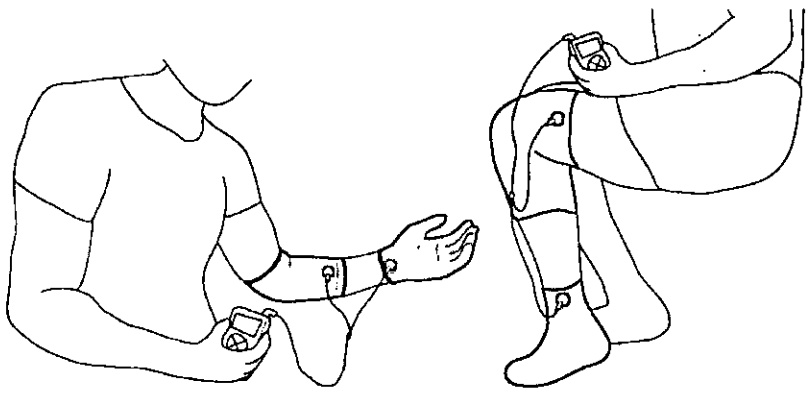
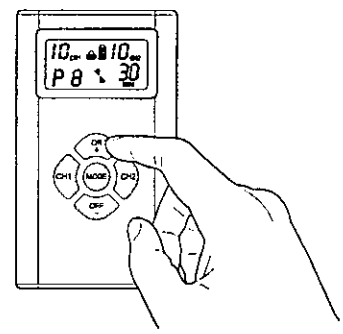


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

## Quick reference Guide

### i. How to attach conductive mesh garment electrode (Glove, Sock, Elbow/Knee )

| | |
|---|---|
|  <br>Step 1:<br>Insert 3AAA batteries, taking care to match up the symbols (+/-). |  <br>Step 2:<br>Connecting the cable to the device. |
|  |  |
| Step 3: Preparing treatment site and accessories,<br>Putting cable on the garment | Step 4:<br>Power On / Select Program / Timer / Intensity Level |

"The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."



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

## Replacement Parts

Be sure to use only WELL LIFE Arm & Leg Pain Management System parts originally supplied . The following replacement parts can be ordered for replacement purpose :

a. Conductive Mesh Garment Electrode ( 510k cleared no. K053214 TheraKnit Garment Electrodes) :

| | |
|---|---|
| **Socks**<br><br>Theraknit Part no, measured by shoe size. | Small # 3005: 6~9 shoe size<br>Medium #3006 : 10~13 shoe size<br>Large # 3007 : Over 14 shoe size |
| **(Gloves)**<br><br>Theraknit Part no, Measured by Palm Width . | Small # 3001: up to 8 cm<br>Medium #3002 : 8~9 cm<br>Large # 3003 : 9~10 cm<br>X-Large #3004: Over 10cm |
| **Elbow Sleeve**<br><br>Theraknit Part no, measured by elbow circumference | Small # 3008: 15~23 cm<br>Medium #3009 :25~30 cm<br>Large # 3010: over 30 cm |
| **Knee Sleeve**<br><br>Theraknit Part no, measured by Knee circumference. | Small # 3011: 30~36 cm<br>Medium #3012 : 38~46 cm<br>Large # 3013 : Over 46 cm |

"The TheraKnit Garment Electrodes are for prescription use only, therefore use of these accessories can only be sanctioned by a licensed healthcare provider."

b. Self-Adhesive Electrodes ( 510k cleared no. K082065 Well Life Self Adhesive Electrodes ) :

| | |
|---|---|
| **Self -adhesive Pads (set of 4)**<br><br>Well-Life Part no . measured by length and width of electrode size | CM5050 , size 50x50 mm , snap type<br>CM50100, size 50x100 mm , snap type |

Records Processed under FOIA Request # 2015-813; Released by CDRH on 9-10-2015

Attachment 2



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

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# 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091757 .

1. Submitter's Identifications:
   Well Life Healthcare Limited
   1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 23455,
   Taiwan, ROC

   Contact: Jenny Hsieh

   Date of Summary Preparation: December 08, 2009

2. Name of the Device:

   OTC TENS for Arm & Leg Pain Relief / Model: WL-2407.

3. Information of the 510(k) Cleared Device (Predicate Device):
   1> The Prizm 5000-Z system (K033122)
   2> Endurance Therapeutics T1040 (K060846).

4. Device Description:

   The Well Life TENS devices, WL-2407 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. Basically the stimulation model WL-2407 is completely identical to that of model as mentioned in the Well-Life K063660- 510(K) cleared device. To change the indication for use for the treatment location as the chosen predicate devices, Well-Life change the design of electrode.

   For the device included in this submission, we use the following third party 510(K) legally marketed predicate components:
   <1>K022494, the Home Care Jelly.

   WL-2407 is a selectable dual channel, 4.5V (3xAAA/Alkaline battery) operated TENS device with the following features:

   <1> The operation function is dual channels completely identical to the model being modified, WL-2407 for low back pain relief(K063660).
   <2> For the stimulation electrode, Well-Life uses upper arm belt as well as snap type adhesive electrode as standard accessories.
   <3> The output waveform is selectable pre-programming change among P1~P8.
   <4> The output strength is adjustable at 0~80 mA, with setting time 21 minutes counting from switching ON.
   <5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.



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

5. Intended Use:

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

The standard format for the statement of indications and contraindication for use are provided hereafter.

6. Power level testing comparison and acknowledge of comparison result with Prizm 5000Z system:

For the substantial equivalent comparison, the power level testing comparison with the chosen 510(K) cleared device, Prizm 5000-Z system was conducted via using 1K ohm loading resistance for the garment electrodes. The comparison result is as the following table:

Current comparison:

| Electrode Type | Glove | Sleeve& Knee | Sock | Silicone Pad |
|---|---|---|---|---|
| Well-life WL-2407 | 0.00337 | 0.00386 | 0.00271 | 0.11728 |
| Prizm 5000-Z | 0.00340 | 0.00385 | 0.00274 | 0.11817 |

Power Density Comparison :

| Electrode Type | Glove | Sleeve & Knee | Sock | Silicone Pad |
|---|---|---|---|---|
| Well-life WL-2407 | 0.00032 | 0.00036 | 0.00025 | 0.01098 |
| Prizm 5000-Z | 0.00064 | 0.00072 | 0.00051 | 0.02222 |

Based on this comparison result, we made a acknowledge that the model WL-2407 has a lower output power and power density than that of Prizm 5000-Z system while using the same electrode, and that the garment electrode for prescription use will not be packed or sold with WL-2407 model. In case the garment electrode is to be used with WL-2407 model , the effectiveness is to be determined by the physician who prescribes the use of that electrode.

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 60601-1-2 requirement.



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8. Conclusions

The OTC TENS for Arm & Leg Pain Relief / model WL-2407 has the same intended use and the similar technological characteristics as the cleared device of Prizm 5000-Z system (K033122) and Endurance Therapeutics T1040 (K060846). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.



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# Indications For Use

510(k) Number (if known):

Device Name: OTC TENS For Arm & Leg Pain Relief / Model WL-2407.

Indications For Use:

- The OTC TENS for Arm & Leg Pain Relief / model WL-2407 are intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

Prescription Use ____ OR Over-The-Counter Use __√__
(Part 21 CFR 801 Subpart D) (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)



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Attachment 3-a



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(b) (4) Dispersion Test Reports and Results for Electrode

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