Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K040512 - 379 pages
COMPANY:	WELL-LIFE HEALTHCARE, INC. (WELLLIFEHEALA)
PRODUCT:	STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF (GZJ)
SUMMARY:	Product: LIMITED FUNCTION WL/OTC-TENS DEVICE, MODEL WL-2103A, WL-2203A, WL-2203
DATE REQUESTED:	Jul 1, 2014
DATE PRINTED:	Jul 1, 2014

Note: Printed

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

MAY 27 2004

Grace Chang
Well-Life Healthcare, Inc.
1FL, No. 16, Lane 454
Jungjeng Rd., Yunghe City
Taipei County, Taiwan, R.O.C.

Re: K040512
Trade/Device Name: Models WL-2402, WL-2403 and WL-2401
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: May 11, 2004
Received: May 17, 2004

Dear Ms. Chang:

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

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Indications For Use

510(k) Number (if known): K040512

Device Name: Limited Function WL/OTC-TENS / Model: WL-2401, WL-2402, and WL-2403.

Indications For Use:

- The model WL-2402, WL-2403 TENS 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.
- The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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)

for Mark N Melkerson

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

510(k) Number K040512

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

MAY 27 2004

Grace Chang
Well-Life Healthcare, Inc.
1FL, No. 16, Lane 454
Jungjeng Rd., Yunghe City
Taipei County, Taiwan, R.O.C.

Re: K040512
Trade/Device Name: Models WL-2402, WL-2403 and WL-2401
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: May 11, 2004
Received: May 17, 2004

Dear Ms. Chang:

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

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

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Indications For Use

510(k) Number (if known): K040512

Device Name: Limited Function WL/OTC-TENS / Model: WL-2401, WL-2402, and WL-2403.

Indications For Use:

- The model WL-2402, WL-2403 TENS 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.
- The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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)

for Mark N Melkerson

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

510(k) Number K040512

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

May 07, 2004

WELL-LIFE HEALTHCARE, INC.
C/O THERATECH, INC.
1109 MYATT BLVD.
MADISON, TN 37115
ATTN: MIKE PRICE

510(k) Number: K040512
Product: LIMITED FUNCTION WL/OTC-TENS DEVICE, MODEL WL-2103A,

Extended Until: 28-JUN-2004

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

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Food and Drug Administration
9200 Corporate Boulevard, (HFZ-401)
Rockville, Maryland 20850
U.S.A.

Date: May 5, 2004

Dear Sirs:

Dear Mr. Shulman:

We have received your letter concerning our additional information provided for our 510(k) submission K040512. Thank you very much.

However, based on some information from our marketing department, we decided to make some further modification on our product so as to simplify the operation for OTC market.

This is also the main suggestion made on the review comment we received. Therefore, we sincerely request FDA to allow us to provide further revised additional information. As estimated, the revised information will be completed within 10 days. As soon as it is completed, we will send tem to you immediately.

Please kindly keep the reviewer informed about this request. For the providing of revised additional information, our US agent will contact with you so as to help the process of the review work of our submission.

The information of our US agent is:

Mr. mike price
THERATECH, INC.
1109 Myatt blvd., Madison, TN 37115
Phone: 615-865-4000
Fax: 800-485-2626
Email: mikeprice@stimsupply.com

FDA/CDRH/ODE/PMO
2004 MAY -7 A 9:53

Best regards,

Grace Chang

5K2

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 2004

Grace Chang
Well-Life Healthcare, Inc.
1FL, No. 16, Lane 454
Jungjeng Rd., Yunghe City
Taipei County, Taiwan, R.O.C.

Re: K040512/S1
Trade Name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS
Dated: Undated
Received: April 21, 2004

Dear Ms. Chang:

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 because you did not completely respond to the deficiencies listed in our March 12, 2004 letter. To complete the review of your submission, we require the following additional information:

1. Question number 10 of our March 12, 2004 letter to you requested that you include several warnings in your labeling for the models WL-2103A, WL-2203A and WL-2203B. Although you have included parts of each warning we believe the complete warnings are needed to ensure the safe use of your device. Therefore, please add the following warnings to your labeling or justify not doing so:

   a. (b)(4) Deficiencies-Comments [redacted]

   b. [redacted]

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

c. (b)(4) Deficiencies-Comments [redacted]

2. Please revise the following precaution, in your labeling for models WL-2103A, WL-2203A and WL-2203B, to be in bold faced font: "If your pain does not improve, becomes more than mild or if it continues for four to six days, stop using the device and consult your physician."

3. Question number 10 of our March 12, 2004 letter to you requested that you include several precautions in your labeling for models WL-2103A, WL-2203A and WL-2203B. We believe the following precaution is needed to ensure the safe use of your device: You should contact your physician prior to using the device following recent surgical procedures on your back (e.g., disc surgery, spinal cages inserted, etc.) because stimulation may disrupt the healing process. Therefore, please revise your labeling to include this precaution.

4. Please either (b)(4) Deficiencies-Comments [redacted]

5. Please revise the instruction manuals for models WL-2103A, WL-2203A and WL-2203B to (b)(4) Deficiencies-Comments [redacted].

6. Please revise (b)(4) Deficiencies-Comments [redacted]

7. Please revise (b)(4) Deficiencies-Comments [redacted]

8. Please revise (b)(4) Deficiencies-Comments [redacted].

9. Please revise (b)(4) Deficiencies-Comments [redacted]

10. Please revise the model WL-2103A, WL-2203A and WL-2203B instructions manuals to (b)(4) Deficiencies-Comments [redacted].

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

11. Please revise your instruction manual to include (b)(4) Deficiencies-Comments [redacted]

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Kristen A. Bowsher, Ph.D. at 301-594-1296. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer

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

Exemption 4 and 5 CCI and Internal Memoranda

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Grace Chang
Well-Life Healthcare, Inc.
1FL, No. 16, Lane 454
Jungjeng Rd., Yunghe City
Taipei County, Taiwan, R.O.C.

Re: K040512/S1
Trade Name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS
Dated: Undated
Received: April 21, 2004

Dear Ms. Chang:

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 because you did not completely respond to the deficiencies listed in our March 12, 2004 letter. To complete the review of your submission, we require the following additional information:

1. Question number 10 of our March 12, 2004 letter to you requested that you include several warnings in your labeling for the models WL-2103A, WL-2203A and WL-2203B. Although you have included parts of each warning we believe the complete warnings are needed to ensure the safe use of your device. Therefore, please add the following warnings to your labeling or justify not doing so:

    a. 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 effects on the heart rhythm or blood pressure.

    b. Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.

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

Exemption 4 and 5 CCI and Internal Memoranda

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Exemption 4 and 5 CCI and Internal Memoranda

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.

f/t:KXB:4-27-04

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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 AND HUMAN SERVICES Public Health Service

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

April 21, 2004

WELL-LIFE HEALTHCARE, INC.
1 FL.,NO. 16, LANE 454
JUNGJENG ROAD
YUNGHE CITY, TAIPEI COUNTY,
CHINA (TAIWAN) 234
ATTN: GRACE CHANG

510(k) Number: K040512
Product: LIMITED FUNCTION WL/OTC-TENS DEVICE, MODEL WL-2103A,

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

April 06, 2004

WELL-LIFE HEALTHCARE, INC.
1 FL.,NO. 16, LANE 454
JUNGJENG ROAD
YUNGHE CITY, TAIPEI COUNTY,
CHINA (TAIWAN) 234
ATTN: GRACE CHANG

510(k) Number: K040512
Product: LIMITED FUNCTION WL/OTC-TENS DEVICE, MODEL WL-2103A,

Extended Until: 11-MAY-2004

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

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

206

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

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

Re: K040512
Trade name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS

Dear Mr. Witten:

Thank you very much for the review comments of our 510(k) submission (K040512).

As requested in your review comments, we have to provide additional information so as to response to your comments within 30 days.

Because too much information is to be provided according to your comments, we are not able to complete our information with this time limit.

Therefore, we need more time to complete our information. Please kindly allow the extension of time, and give us the information when is the time limit for our additional information if our request for extension of time is allowed.

Sincerely yours,

Grace Chang
Well-Life Healthcare, Inc.
1FL, NO. 16, Lane 454
Jungjeng Rd., Yunghe City
Taipei County, Taiwan, R.O.C.

FDA/CDRH/ODE/PMO
2004 APR -6 A 9: 23
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SK18

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

Exemption 4 and 5 CCI and Internal Memoranda

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cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.

f/t:KXB:3-10-04

226

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

February 27, 2004

WELL-LIFE HEALTHCARE, INC.
1 FL.,NO. 16, LANE 454
JUNGJENG ROAD
YUNGHE CITY, TAIPEI COUNTY,
CHINA (TAIWAN) 234
ATTN: GRACE CHANG

510(k) Number: K040512
Received: 27-FEB-2004
Product: LIMITED FUNCTION WL/OTC-TENS DEVICE, MODEL WL-2103A, WL-2203A, WL-2203B

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

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

Sincerely yours,

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

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

K040512

5k15

Food and Drug Administration
9200 Corporate Boulevard, (HFZ-401)
Rockville, Maryland 20850
U.S.A.

Date: February 24, 2004

Dear Sir:

Enclosed with this mail, we would like to provided our 510(k) submission document as well as the payment information (User Fee Cover Sheet 012560-956733 and the payment check).

Please file our 510(k) submission and make it review as your normal review procedure.

If you have any question about this 510(k) submission, please contact us at the following address:

Company Name :	Well-Life Healthcare Inc.
Contact person:	Grace Chang
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 :	grace@welllifehealthcare.com.tw

Best regards,

Grace Chang
Sales Manager

NE
II

250

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

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510(k) Notification

Transcutaneous Electrical Nerve Stimulation Device,

Model: Limited Function WL/OTC-TENS series,

WL-2103A, WL-2203A, WL-2203B, and WL-2401 are included.

Presented by

Well-Life Healthcare Inc.

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

251

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Premarket Notification [510(k)] Submission

Date: January 08, 2004

Dear Sir:

This 510(k) submission is submitted for the legally marketing application of our TENS devices, the Limited Function WL/OTC-TENS series, model WL-2103A, WL-2203A, WL-2203B, and WL-2401. In general these four models are not complete new device. We developed these four device from our existing 510(k) cleared devices, WL-2103A (K002874), WL-2203A (K033857), WL-2203B (K030537), and WL-2401 (K020020).

For the development of these four models, the following three changed were made:
<1> Change the fixing device so as to limit the device being used on some specified area.
<2> Change the device label so as to state the limited use of the new devices.
<3> Based on <1> and <2> changed features as well as the clear information for OTC TENS on FDA web site, we are intended to change the indication for use from the general purpose physician TENS device to the limited function OTC device.

According to the rules set out on 510(k) Memorandum #K97-1 concerning the deciding when to submit a 510(k) for a change to an existing device, the new 510(k) submission shall be required for the change in the indication for use as above mention.

For this 510(k) submission, we compared our models to the following two FDA cleared OTC TENS device:
- K020180: Relief Band Device model, made by Woodside Biomedical, Inc.
- K013532: UltraStim Kit, made by Axelgaard Mfg Co., Ltd.

Since for the testing data and evaluation report about the electrical safety, EMC, performance as well as the software validation for our these four models have been provided and reviewed in our previous 510(k) submission and there is not any change in the electrical construction, we did not repeat the offer of those information on this new submission. If required, please refer to the information of our previous 510(k) submissions, K002874, K030537, K033857, and K020020,.

As general 510(k) submission document, we separate our submission into two parts:

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

And we also designate Wincent Consultant Company as our official correspondent to response for the action as defined in the regulation of CFR/Title 21. The following description is the information of this company.

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

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Company Name : Wincent Consultant Co., Ltd.
Contact person: Tony C. S. Chang
Address : No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd., Pei Tun Dist., Taichung, Taiwan, R.O.C.
TEL No. : 886-4-2297-2787
Fax No. : 886-4-2297-2476
E-mail address : wincent1@ms19.hinet.net

We included the designation document as attachment of this letter. Please contact this company for any problems of this submission. We sincerely send this submission with the whole package of document required to prove the substantial equivalence (SE) with the listing marketed device.

Hopefully, our submission could make you feel easy to sign the SE letter and allow our Limited Function TENS to distribute to USA.

Best Regards,

Grace Chang
Sales Manager of Well-Life

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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> Designation letter of Official Correspondent

The undersigned, Grace Chang, representing Well-Life Healthcare Inc. / 1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County Taiwan, R.O.C. to designate the following personnel as our official correspondent for the submission of 510(k) of Limited Function WL/OTC-TENS, models : WL-2103A, WL-2203A, WL-2203B, and WL-2401.

The detail information of the official correspondent:

Company Name :	Wincent Consultant Co., Ltd.
Contact person:	Tony C. S. Chang
Address :	No. 5, Alley 5, Lane Cheng Hsing, Chung Ching Rd., Pei Tun Dist., Taichung, Taiwan, R.O.C.
TEL No. :	886-4-2297-2787
Fax No. :	886-4-2297-2476
E-mail address :	wincent1@ms19.hinet.net

Submitter: Well-Life Healthcare Inc.

Qualification: Sales Manager.

Signature: _____.

Date: 19, 02, 2004.

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

Medical Device User Fee Cover Sheet - FDA Form 3601

第 1 頁，共 1 頁

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

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

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

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment instructions at the following URL: http://www.fda.gov/cdrh/mdufma/fees.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

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

WELL-LIFE HEALTHCARE, INC.
1 FL., NO. 16, LANE 454, JUNGJENG RD.,
YUNGHE CITY, TAIPEI COUNTY, 234
TAIWAN, PROVINCE OF CHINA

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
JENNY HSIEH

2.1 E-MAIL ADDRESS
jenny@wellifehealthcare.com.tw

2.2 TELEPHONE NUMBER (Include Area Code)
886229282112

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
886229281880

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/cdrh/mdufma

Select an application type:

- [x] Premarket notification (510(k)): except for third party reviews
- [ ] Biologics License Application (BLA)
- [ ] Premarket Approval Application (PMA)
- [ ] Modular PMA
- [ ] Product Development Protocol (PDP)
- [ ] Premarket Report (PMR)

3.1 Select one of the types below:

- [x] Original Application

Supplement Types:

- [ ] Efficacy (BLA)
- [ ] Panel Track (PMA, PMR, PDP)
- [ ] Real-Time (PMA, PMR, PDP)
- [ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- [ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- [x] NO, I am not a small business

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

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- [ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- [ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- [ ] The sole purpose of the application is to support conditions of use for a pediatric population
- [ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

- [ ] YES
- [x] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b)(4) [redacted]

Form FDA 3601 (08/02)

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

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To = 嘉惠 From = 一 共7頁.

[redacted]

CHANG HWA COMMERCIAL BANK, LTD.
TAIWAN, REPUBLIC OF CHINA
彰化銀行

CHECK NO. 183823644
CLIENT NO. 85008

REF. NO: 4AQQH7000145
DATE : FEB. 09 2004
AMOUNT: (b)(4) [redacted]

PAY TO THE ORDER OF FOOD AND DRUG ADMINISTRATION

THE SUM OF USD THREE THOUSAND FOUR HUNDRED EIGHTY AND 00/100 ONLY

Payable through Citibank (New York State)
for Citibank, N.A.
ABA 0220 00868

FOR CHANG HWA COMMERCIAL BANK, LTD.

BY AUTHORIZED SIGNATURE BY AUTHORIZED SIGNATURE

⑈183823644⑈ ⑆022000868⑆ 99⑈85008

256

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

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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 I. Documentation for the 510(k) Submission

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

0. Introduction to this 510(k) submission

As mentioned on the 510(k) submission letter, this 510(k) submission was prepared for the change of indication for use from prescription medical device to OTC device for the models WL-2103A, WL-2203A, WL-2203B, and WL-2104. For the models of this 510(k) submission we give them the title "Limited Function WL/OTC-TENS" so as to separate them from the existing cleared devices.

Basically these four models are not complete new device. We developed these four device from our existing 510(k) cleared devices, WL-2103A (K002874), WL-2203A (K033857), WL-2203B (K030537), and WL-2401 (K020020). Need new name as they are different! OK?

For the development of these four models, the following three changed were made:
<1> Change the fixing device so as to limit the device being used on some specified area.
<2> Change the device label so as to state the limited use of the new devices.
<3> Based on <1> and <2> changed features as well as the clear information for OTC TENS on FDA web site, we are intended to change the indication for use from the general purpose physician TENS device to the limited function OTC device.

According to the rules set out on 510(k) Memorandum #K97-1 concerning the deciding when to submit a 510(k) for a change to an existing device, the new 510(k) submission shall be required for the change in the indication for use as above mention.

For this 510(k) submission, we compared our models to the following two FDA cleared OTC TENS device:
- K020180: Relief Band Device model, made by Woodside Biomedical, Inc.
- K013532: UltraStim Kit, made by Axelgaard Mfg Co., Ltd.

Since for the testing data and evaluation report about the electrical safety, EMC, performance as well as the software validation for our these four models have been provided and reviewed in our previous 510(k) submission and there is not any change in the electrical construction, we did not repeat the offer of those information on this new submission. If required, please refer to the information of our previous 510(k) submissions, K002874, K030537, K033857, and K020020,.

Need to provide in this 510(k).

As general 510(k) submission document, we separate our submission into two parts:

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

In part I, the following detail information were provided:
- Clause 1. Truthful and Accurate Statement
- Clause 2. Device Name
- Clause 3. Registration Number
- Clause 4. Classification
- Clause 5. Performance Standards
- Clause 6. Intended use, contraindications, and specification
- Clause 7. Design information
- Clause 8. Substantial Equivalence Comparison
- Clause 9. Test report for the bio-compatibility
- Clause 10. 510(k) Statement

For the details of this 510(k) submission, please see the followings:

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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. Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As required by CFR/Title 21, Part 807.87]

I declare, upon my honour and to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Submitter: Grace Chang.

Qualification: Sales Manager.

Signature: .

Date: 19, 02, 2005.

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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. Device Name

Trade name : Limited Function WL/OTC-TENS Device, model WL-2103A, WL-2203A, WL-2203B, and WL-2401.

Common name : Transcutaneous Electrical Nerve

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

3. Registration Number

The owner/operator number of Well-Life is 9042951.

4. Classification

Regulation Number : 882.5890
Medical Specialty : Neurology
Product Code : GZJ
Device Class : II
Tier : II

5. Performance Standards

Limited Function TENS Device is designed to comply with the following standards:

* EN 60601-1; EN 60601-1-1 : General safety requirement for medical devices
* EN 60601-1-2 : EMC requirement for medical devices
* ANSI/AAMI NS4-1985 : American National Standard for Transcutaneous Electrical Nerve Stimulators

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

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6. Intended use, contraindications, and specification.

6.1. Indication for use.

Basically the indication for use was defined clearly on some page of each manual. Due to the different operation functions for these four models, the different indication for use may be stated for different models as the description of the following table.

Model Name	Statement of "indication for use"	Intended for
WL-2103A WL-2203A WL-2203B	The models WL-2103A, WL-2203A, and WL-2203B 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.	OTC
WL-2401	The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.	OTC

Regarding the FDA format 'Indication for use', please see the following pages.

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

510(k) Number (if known): _____

Device Name: Limited Function WL/OTC-TENS / Model: WL-2103A, WL-2203A, WL-2203B, and WL-2401

Indications For Use:

- The model WL-2103A, WL-2203A, WL-2203B TENS 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.
- The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use √

(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 2013-4395; Released by CDRH on 12/31/2014

6.2. Specification of Limited Function TENS series.

Features	*New models*			
	WL-2103A	*WL-2203A*	*WL-2203B*	*WL-2401*
510(k) Number	K002874	K0033857	K030537	K010010
Manufacturer	Well-Life	Well-Life	Well-Life	Well-Life
Classification	Class II	Class II	Class II	Class II
Basic Specification Comparison				
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual	Dual	Single
Power supply	9 volt battery	9 volt battery	9 volt battery	3 volt battery
Circuit designed	Analog	Digital	Digital	Analog
Software	Yes	Yes	Yes	Yes
Amplitude (mA)	0-80	0-80	0-80	0-50
Pulse rate (Hz)	2-150	1-150	1-160	30 fixed
Width (μs)	30-260	30-260	50-260	250 fixed
Power ON indicator	LED	LCD	LCD	LED
Timer (min)	60	15-60	15-60	15
Weight (grams) (batt. Include)	135	142	142	19
Size (mm)	92×62×25	110×62×27	110×62×27	60×47.3×14.6
Prescription or OTC	OTC	OTC	OTC	OTC
Indication for use	All models as above mentioned 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.			All models as above mentioned are intended for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.
Output Specification Comparison				
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square	Square	Square
Maximum Output Voltage (V) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	 40 68 92	 40 68 92	 40 68 92	 25 68 92
Maximum Output Current (mA) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	 80 68 46	 80 68 46	 80 68 46	 50 68 46
Pulse Width (μS)	30-260	30-260	50-260	250 fixed
Frequency (Hz)	2-150	1-150	1-160	30 fixed
Maximum Phase charge (μC) @500Ω	20.8	20.8	20.8	7.0
Maximum Current Density (A/cm^2) @500Ω	3.5×10^{-5}	3.5×10^{-5}	3.7×10^{-5}	13.4×10^{-5}

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

7. Design information.

7.0. General.

As stated on the 510(k) submission letter at the beginning of this 510(k) submission, the electrical and mechanical construction for the main stimulation unit covered by this submission was not changed while compared with our previous cleared models. We do not intended to include the electric related information for these four models. If required, you may check the information provided in our previous submission document K020020, K002874, K030537, and K033857.

For this submission, we would like to provide the following additional information for the description about the actual change of the new models.

The basic information includes:

7.1. The identification & overall drawing.
7.2. The information of packing and labeling.
7.3. Operation instruction.
7.4. Overall comparison between the new models and existing Well-life cleared mode.

Upon going through the information provided in this clause, we hope you have a very clear view for our products.

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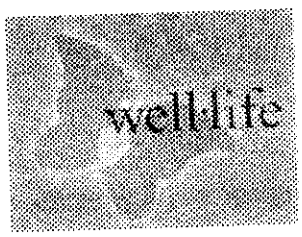
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

7.1. The identification & overall drawing.

Brand Name (logo).



Overall drawing.

Please see the following drawing and photos.

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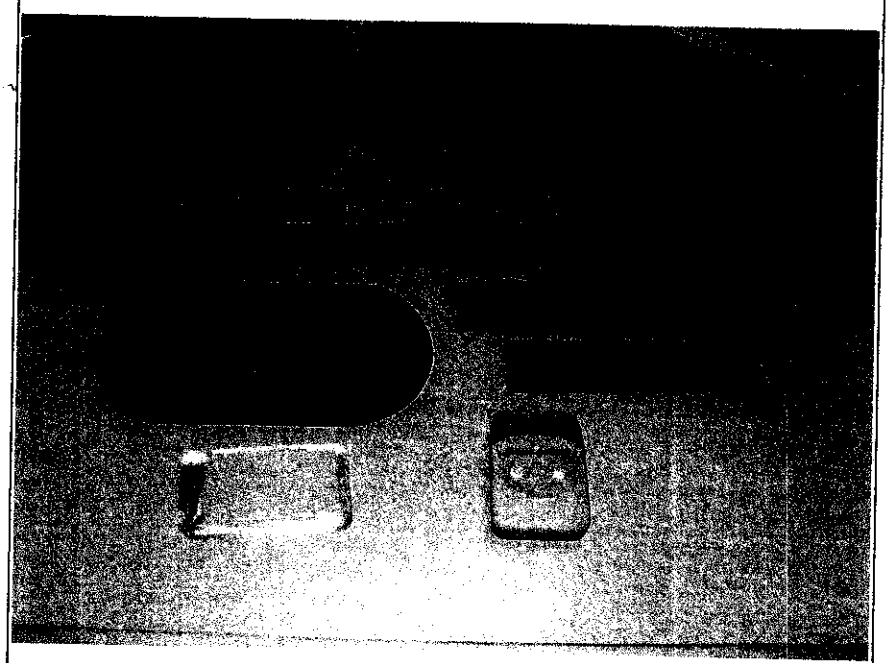
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

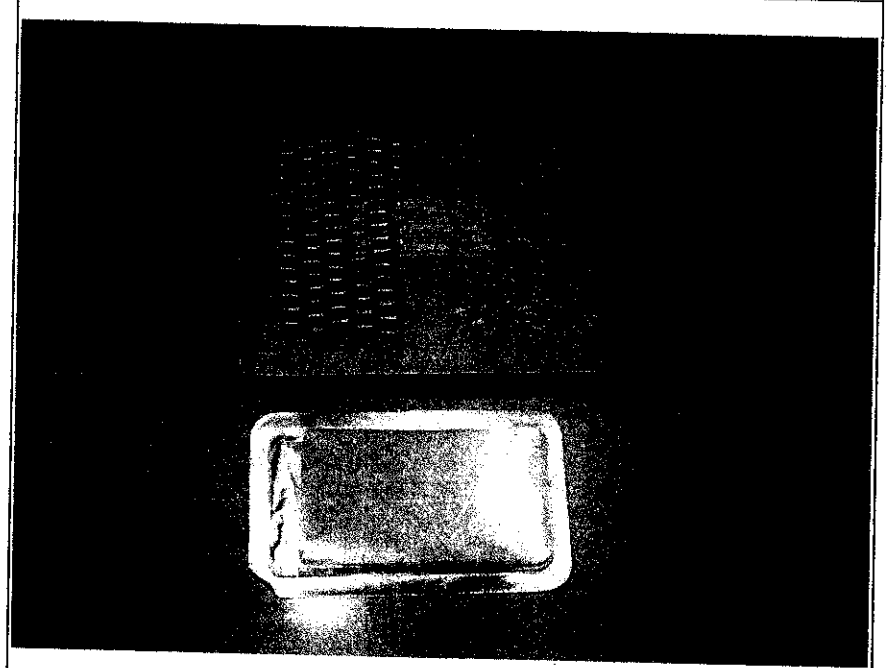
Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Photos of Low Back OTC-TENS
(Models: WL-2103A, WL-2203A, WL-2203B)

122-1. Overall combination of low back TENS device.



122-2. Electrode combination of low back TENS device.



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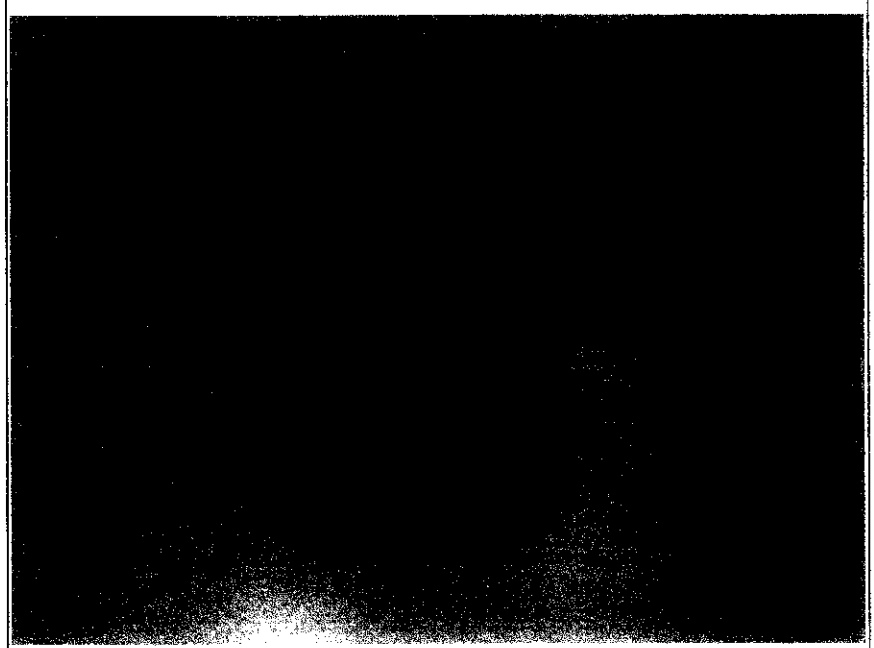
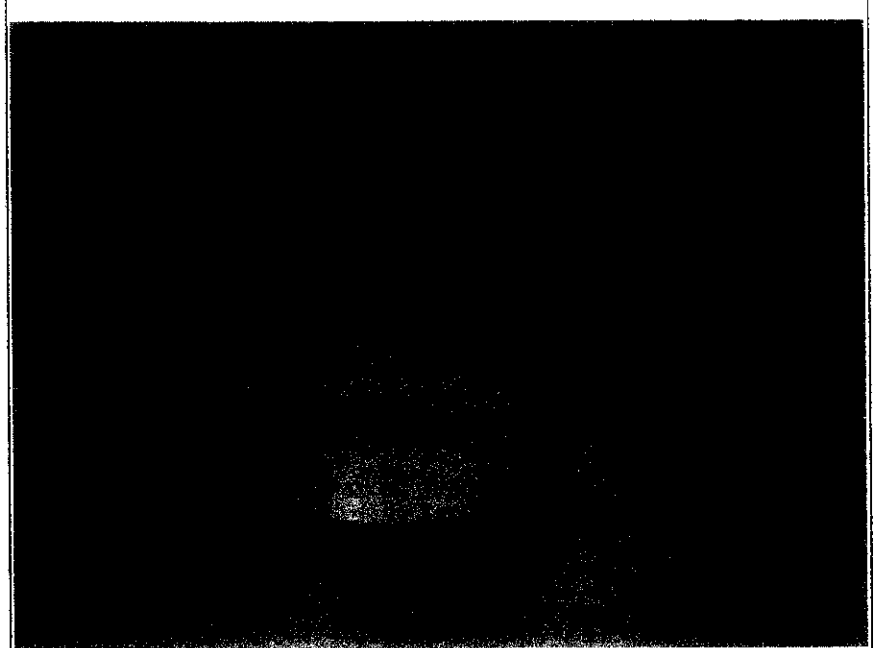
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

139-1. WL-2203A TENS Unit.



139-2. WL-2203B TENS 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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140-5. WL-2103A TENS Unit.

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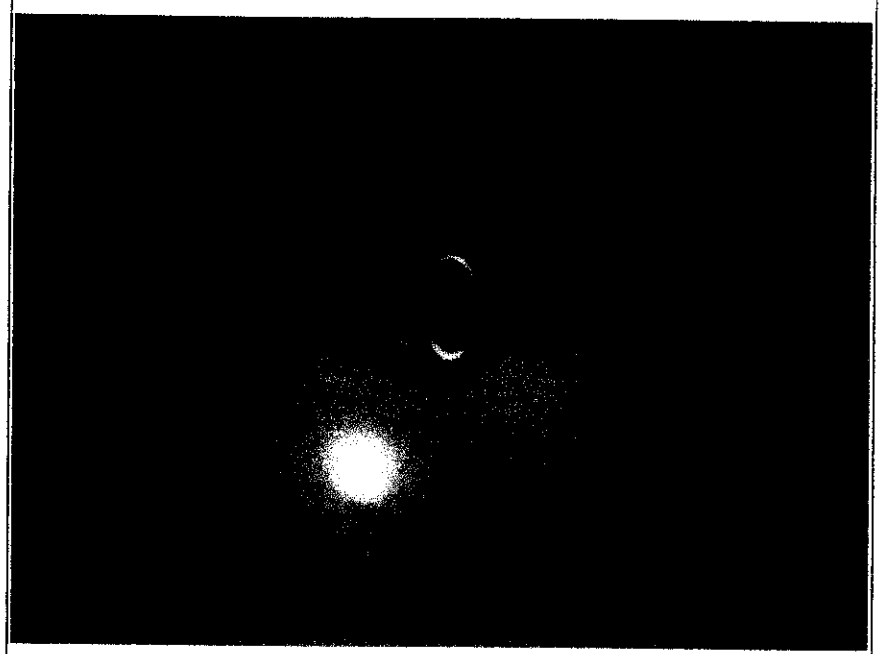
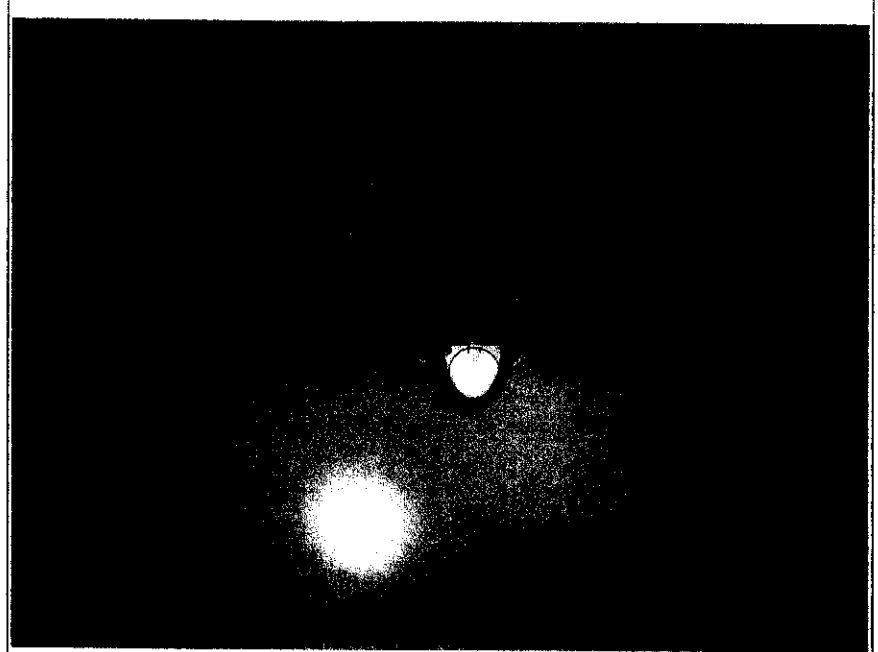
Photos of model WL-2401

140-3. Front Side of WL-2401.



140-4. Back Side of WL-2401.



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

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7.2. The information of packing and labeling.

See the following photos & indications of labeling.

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Photo for the packing of WL-2103A, WL-2203A, and WL-2203B.

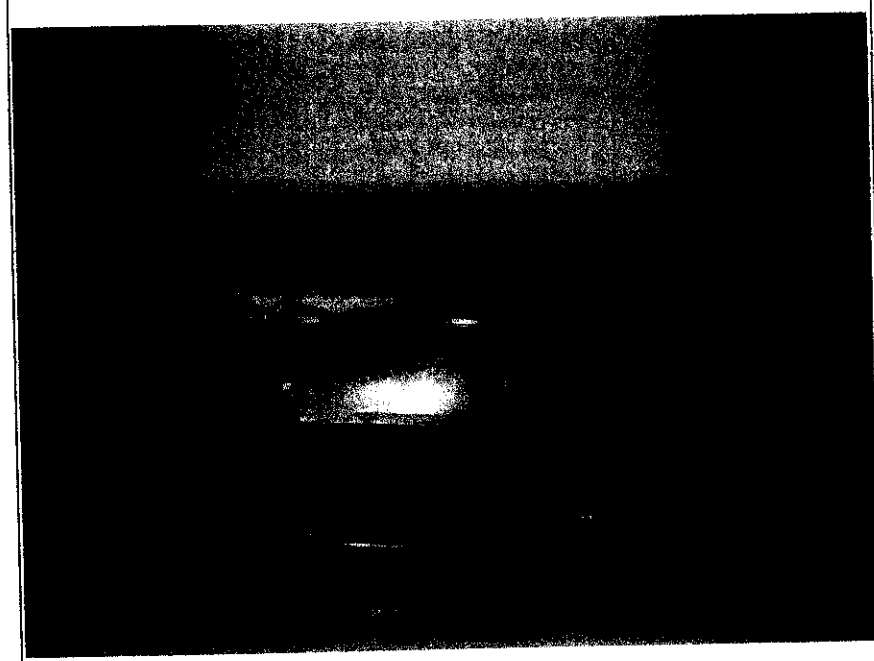

Photo for the packing of WL-2401.

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

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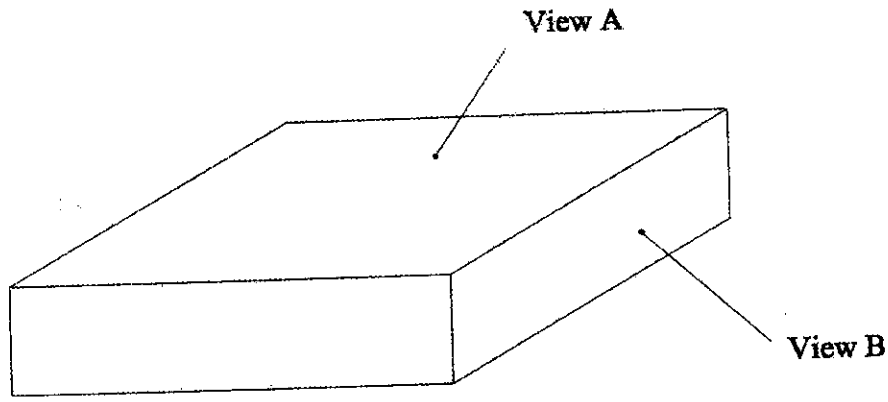
Labeling Indication for WL-2103A, WL-2203A, and WL-2203B



View A Labeling

Indication for Use

This WL/OTC-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.

High Quality production incontestable usefulness

The production of WL/OTC-TENS fulfills norms, requirements of ISO 9001/ISO 13485 norms, WL/OTC-TENS satisfies the CE mark according to the 93/42/EEC European directive for medical device

CE 0434

View B Labeling

Company: Well-Life Healthcare Inc.
Address: 1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County Taiwan
IDT FRANCE.IDT IBERICA.WELL LIFE

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

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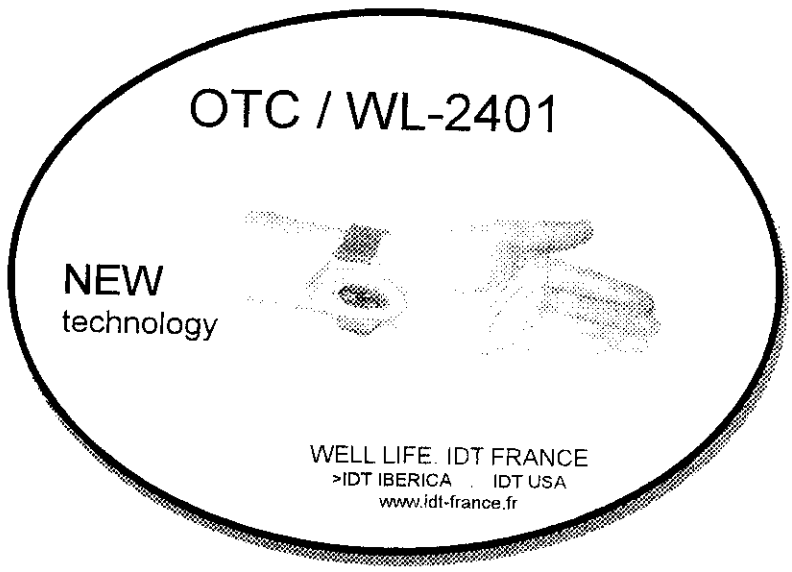
Labeling Indication for WL-2401

LABELING ON VIEW A



Labeling on view B

Indication for use

The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

Labeling on view C

High Quality production incontestable usefulness

The production of OTC-TENS fulfills the requirements of ISO9001 / ISO13485 norms, OTC-TENS satisfies the CE mark according to the 93/42/EEC European directive for medical device

> two colors available CE 0434

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7.3. Operation instruction.

For the manual of WL-2103, WL-2203A, and WL-2203B, please see attachment 1, and for WL-2104, please see attachment 2.

Need separate manual for each model

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

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ATTACHMENT

Operation Manual

For OTC Use

Indication For Use

This WL/OTC-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.

CE 0434

Well-Life Healthcare Inc.

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

European Representative:

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

Description Of WL/OTC-TENS Device

The WL/OTC-TENS gives you powerful, personalized relief with a proven, widely used medical technology known as TENS (transcutaneous electrical nerve stimulation). Doctors in the U.S. and around the world have been using TENS technology for more than 30 years to help millions of people with their lower back pain.

The WL/OTC-TENS is the TENS device to meet all FDA requirements for use without a prescription. You can use it home to relieve your pain, quickly and effectively, wherever and whenever you need it.

Indications For Use

This WL/OTC-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.

Parts Of WL/OTC-TENS Device

WL/OTC-TENS System includes

1 Well-Life Support Belt

1 Well-Life TENS Stimnlator

1 package of four Well-Life self-adhesive pads Replacement?

1 set of plastic Storage Liners (not shown)

1 pair of Snap Cables

1 Well-Life System User Manual (not shown)

1 9-volt Alkaline Battery

PICTURES

Safety Information

Warnings:

- The device must be kept out of reach of childre.
- The safety of device for use during pregnancu or delivery has not been established.
- Do not place electrodes on front of the throal. This may result is soasms of the laryngeal and pharyngeal muscles.
- Do not place the electrodes over the carotid nerve.
- Avoid adjusting controls while operating machinery or vehicles.
- The device may interfere with electric monitoring equipment (such as ECG monitors and ECG alarms).
- Electrodes should not be placed over the eyes, in the mouth, or internally.
- The device has no curative value.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.

Contraindications?

* Plain language
* Spelling

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

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Safety Information (continued)

Precautions/adverse Reactions:

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Stimulation should be stopped and electrides removed until the cause of the irritation can be determined.
- If the device treatment becomes ineffective or unpleasant, should be discontinued. ???
- Always turn the device off before applying or removing electrodes

Use canution and consult your Phsician before using the WL/OTC-TENS System if any of the following statements apply to you:

- If you have suspected or diagnosed heart problems.
- If you have suspected or diagnosed epilepsy.
- If you have a tendency to bleed internally following an injury.
- If you recently has 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 WL/OTC-TENS System 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.

How To Use WL/OTC-TENS Device

It is very easy to use WL/OTC-TENS device, whenever you need it. You will feel very confortable for your low back just following a very simple step as the followings:

PICTURES ?

- Put on the plush, supportive belt. How ?
- Clip on the stimulation module and turn it on. How ?
- Select a stimulation pattern. How to choose ?
- Adjust the intensity level. How ? To what level ?
- Enjoy the quick, targeted relief. ???
- Get back into life again.
- Minor redness is a normal skin reaction to electrical stimulation. The redness normally disappear within 30 minutes after you have stopped using the stimulator. This is different from skin irritation. Skin irritation may feel itchy or may develop an area where the redness does not disappear 30 minutes after using the stimulator. If the skin under one or more pads feels irritated or itchy, or the redness does not disappear 30 minutes after use, you must not use the stimulator again until after the skin irritation or excessive redness has disppeared.
- Turn off the stimulator if the stimulation feels unpleasant or does not pain relief.
- Turn off the stimulator if the stimulation feels unpleasant or does not provide pain relief.
- Keep your WL/OTC-TENS System out of the reach of children.
- Use your stimulator only with the pads, snap cables and accessories recommended by the manufacturer.
- Do not use the WL/OTC-TENS System when driving, operating machinery or when swimming.
- To avoid unpleasant stimulation, always turn OFF both power knobs before removing the belt or pads.
- **If your pain does not improve, becomes more than mild or if it continues for four to six days, stop using the WL/OTC-TENS Device System and consult your Physician.**

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

Questions? Contact FDA/CDRH/OCE/DID at 301-796-5704 or CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

About The WL/OTC-TENS Device

Your device offers two controllable output channels. This device creates electrical impulses whose amplitude, duration, and modulation can be altered with the controls or buttons. The device controls are very easy to use and the side cover protects accidental changes in settings.

How to choose?

About The Device Controls

PICTURES / DIAGRAMS

For WL-2203A / WL-2203B

Panel cover

A cover conceals the controls for Mode, Time, Width▲▼, Rate▲▼. Press the top side of the cover and pull down in order to open the cover.

Intensity

The intensity knobs located on the top of the unit for the strength adjustment of the stimulation and also function as ON/OFF controls.

Mode → what does all this mean to OTC user?

The Mode key is used to select / set the type of treatment utilized. The seven modes are Burst (B), Normal (N), Modulation (M), Modulation with Rate (MR), Modulation with Rate / width (MRW), Strength-Duration and Rate modulation (SDR), Strength Duration and Width modulation (SDW).

TIME → How Determine

Treatment Time of device can be pre-select / set with Time key. There are six programs fixed duration of 10, 20, 30, 40, 50, 60 minutes. Press the key until engaged in position desired.

Note: For X=3~5, only 15,30, and 60 are available for time setting.

WIDTH ▲▼ ???

The pulse Width key regulates the pulse width for both channels.

RATE ▲▼

The pulse Rate key regulates the number of pulse per second for both channels.

For WL-2103A

You may adjust the output of stimulation by the following adjustment switches: When & how do you know what settings?

Pulse width: Select the pulse width from 30μs to 200μs.

Mode: Select "B", "C", and "M" operation mode.

Timer: Select "C" for continuous operation, and "30", "60" for setting operation time.

Pulse rate: Select pulse rate from 2Hz to 150Hz.

Amplitude: Switch the intensity knobs located on the top of unit, you may adjust the amplitude and the ON/OFF controls.

Attaching The Lead Wires

— PICTURES

The lead wires provided with the device insert into the lack sockets located on top of the unit. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks. After connecting the wires to the stimulator, attach each wire to an electrode. HOW?

Lead wires provided with the device are compliant with mandatory compliance standards set for the by FDA.

??

Note: Use carefully when you plug and unplug the wires. Pulling on the lead wire instead of its insulated connector may cause wire breakage.

Caution: Never insert the plug of the lead wire into an AC power supply socket.

criteria for adjustment

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ATTACHMENT I

Tips For Skin Care

Good skin care is important for comfortable use of your device.

- Always clean the electrode site with mild soap and water solution, rinse well, and blot dry thoroughly prior to any electrode application.
- Any excess hair should be clipped, not shoved, to ensure good electrode contact with the skin.
- You may choose to use a skin treatment or preparation that is recommended by your physician. Apply, let dry, and apply electrode as directed. This will both reduce the chance of skin irritation and extend the life of your electrodes.
- Avoid excessive stretching of the skin when applying electrodes, this is best accomplished by applying the electrode and smoothly pressing it in place from the center outward.
- When removing electrodes, always remove by pulling in the direction of hair growth.
- It may be helpful to rub skin lotion on electrode placement area when wearing electrodes.

Connecting the Device

??? OTC ? Bell ?

1. Prepare the Skin

Prepare the skin as previously discussed and according to instructions provided with your electrodes. Before attaching the electrodes, identify the area in which your physician/practitioner has recommended for electrode placement.

2. Connect lead wires to the electrodes

Connect the lead wires to the electrodes before applying the electrodes to the skin.
Note: Be sure both intensity controls for Channel 1 and 2 are turned to the "OFF" position.

3. Place Electrodes on Skin

Place the electrodes on the skin as recommended by your clinician.

4. Insert Lead Wire Connector to device

Plug end of lead wire into the channel output receptacle to be used, pushing plug in as far as it will go.

5. Select Treatment Settings

Check and be sure your unit is still set to the proper settings recommended by your physician/practitioner.

6. Adjusting Channel Intensity Control

Locate the intensity control knob at the top of the unit. Slowly turn the intensity control knob for Channel 1 clockwise until you reach the intensity recommended by your medical professional. Always start with the lowest step and increase slowly. Repeat the same process for Channel 2.

If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level or cease stimulation and contact your physician/practitioner if problems persist.

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

A 9-volt disposable alkaline battery is provided with your unit. When the low battery mark light on the LCD the battery has become too weak to power the unit and it is time to change the battery. At this point, the unit will shot off until a fresh battery is inserted.

Changing The Battery

When the low battery mark light is on the LCD panel, the battery should be replaced with a fresh battery.

1. Remove the Panel Cover by pressing the top and sliding down until is completely removed from the unit this will reveal the battery compartment.
2. remove the discharged battery from the device.
3. place new battery in compartment. Note the proper polarity alignment indicated on the battery and the compartment.

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

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Cleaning For Your Device

Your device may be cleaned by wiping gently with a damp cloth moistened with mild soap and water. Never immerse the device in water or other liquids.

Wipe lead wires with a damp cloth as above if they become soiled.

To properly store the device extended period of time, remove the battery from the unit. Put the unit and accessories in the carrying case and store in a cool dry location.

Troubleshooting

If the device does not function properly:

1. Make sure the battery is properly installed or replace battery. Be sure to observe proper polarity markings when replacing the battery. If the low battery mark light is on the LCD pane when the unit is turned on, replace the battery and check again.
2. If the intensity has been adjusted and there is no stimulation, check that the leas wires are properly connected and the electrodes are in place. If the unit appears to be functioning and no stimulation, the lead wires or electrodes may need to be replaced.
3. If the battery appears to be charged and the unit is not functioning, turn both intensity Control Knobs to the OFF position (counter clockwise). Then gradually turn the intensity Control Knob to the on position.

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User Assistance Information

If you have any questions about how to use the Well-Life Device Model WL/OTC-TENS please call Well-Life Healthcare Inc. 1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City, Taipei County Taiwan, R.O.C. TEL: +886-2-2928-2112, FAX: +886-2- 2928-1880

Maintenance Information

Cleaning:

Keep the electrode area clean. A moist cloth may be used to remove gel buid-up, which may decrease stimlation. Avoid immersion of the device in water.

To purcjase additional WL/OTC-TENS Device or accessory items, including conductivity gel, call Well-Life.

Storage Information

Remove batteries if the device is going to be stored. See Environmental Conditions Section for additional information.

Disposal Information

The product and batteries do not contain any environmentally hazardous substances and can be disposed of normally. The batteries used in this device may explode if mistreated. Do not recharge, disassemble or dispose of them if fire. Dispose of the old batteries normally after changing batteries.

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

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Technical Information

The WL/OTC-TENS Device complies with IEC 601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, including Am. No.1 (1991) and Am. No.2 (1995), and EN 60601-1.

The WL/OTC-TENS Device has been verified to meet the requirements of the following Electromagnetic Compatibility standards, EN 55011 (CISPR II) Radiated Emissions, EN 61000-4-2 Electrostatic Discharge Immunity, EN 61000-4-3 Radiated Electromagnetic Field Immunity.

The WL/OTC-TENS Device is classified as TYPE B equipment.

Attention, the WL/OTC-TENS Device produces physiological effects as described in this guide.

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ATTACHMENT 1

Technical Specifications

Differences?

Features	WL-2103A	WL-2203A	WL-2203B
510(k) Number	K002874	K0033857	K030537
Manufacturer	Well-Life	Well-Life	Well-Life
Classification	Class II	Class II	Class II
Basic Specification Comparison			
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual	Dual
Power supply	9 volt battery	9 volt battery	9 volt battery
Circuit designed	Analog	Digital	Digital
Software	Yes	Yes	Yes
Amplitude (mA)	0-80	0-80	0-80
Pulse rate (Hz)	2-150	1-150	1-160
Width (μs)	30-260	30-260	50-260
Power ON indicator	LED	LCD	LCD
Timer (min)	60	15-60	15-60
Weight (grams) (batt. Include)	135	142	142
Size (mm)	92×62×25	110×62×27	110×62×27
Prescription or OTC	OTC	OTC	OTC
Indication for use	All models as above mentioned 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.		

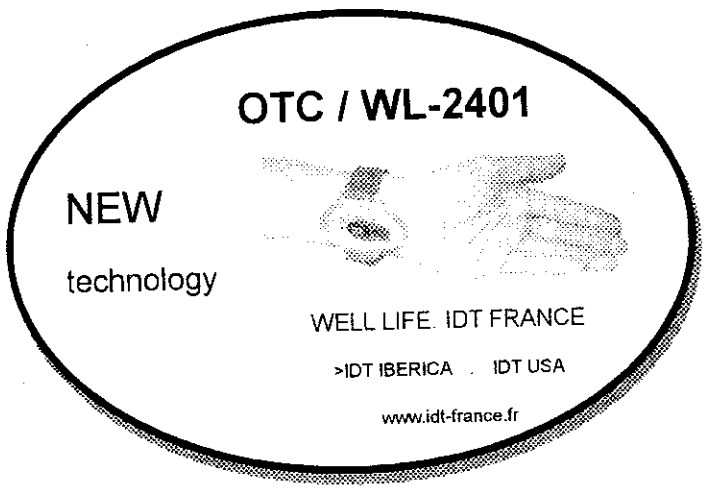
Output Specification Comparison

Features	WL-2103A	WL-2203A	WL-2203B
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square	Square
Maximum Output Voltage (V) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	40 68 92	40 68 92	40 68 92
Maximum Output Current (mA) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	80 68 46	80 68 46	80 68 46
Pulse Width (μS)	30-260	30-260	50-260
Frequency (Hz)	2-150	1-150	1-160
Maximum Phase charge (μC) @500Ω	20.8	20.8	20.8
Maximum Current Density (A/cm^2) @500Ω	3.5×10^{-5}	3.5×10^{-5}	3.7×10^{-5}

Questions? Contact FDA/CDRH/OCE/DID at 2-5 CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Operation Manual

For OTC Use



CE 0434

Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

European Representative:

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Description Of WL-2401 Device

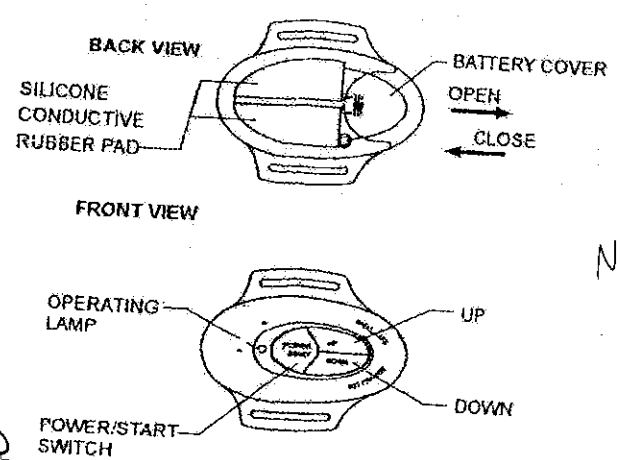
The WL-2401 Device is a small, medical device incorporated into a wristband worn on the underside of the wrist. It provides relief from nausea and vomiting due to motion sickness by gentle electrical stimulation of the nerves in your wrist. Batteries will last about 150 hours of total use at middle power level. Batteries are user replaceable. Replace batteries in unit when they become drained.

pregnancy
⇓
Additional warning

Indications For Use

The WL-2401 Device is indicated for use in the relief of nausea and vomiting (NV) due to motion sickness.

Parts Of WL-2401



NOT clear

Safety Information

Warnings:

- Nauea and vomiting may be signs of a serious health problem. Contact a doctor if your nausea and vomiting seem to be lasting a long time.
- Do not use the WL-2401 Device when the cause of nausea and vomiting symptoms is undiagnosed because those symptoms might be an important indication of more severe health problems.
- The WL-2401 Device should only be used on the wrist. Do not use it on any other areas of the body because the device might cause undesirable effects such as tingling, muscle twitching or skin irritation.
- The WL-2401 Device does not cure the underlying causes of nausea and vomiting. The relief you get may vary depending on your body's individual characteristics and any medications that you may be taking that coulf cause your body to respond differently.
- The WL-2401 Devices should be kept out of reach of young children. The battery door, battery tray or batteries may become a choking hazard if removed.
- Pacemaker users – Use this device only as directed on the wrist to prevent possible interference with your pacemaker. Avoid placing the electrodes directly on your chest or near the pacemaker.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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ATTACHMENT 2

Safety Information (continued)

Caution:

- The WL-2401 Device is water-resistant. This product is resistant to splashing water (rain, waves, eyc). Do not immerse WL-2401 Device in water. The WL-2401 Device is also shock resistant.
- The elastic strap contains natural rubber latex which may cause allergic reactions.

Side Effects:

- For some people, skin irritation may occur beneath or around the gold plates on the back of the device (electrodes). If skin irriation occurs beneath or around the electrode sites, move the device to the other erist. If irritation does not disappear within 24 hours, stop using the device and consult your doctor or pharmacist. Continued use of the device on irritated skin injuary.

When To Use WL-2401 Device

You can use your WL-2401 Device either before or after your motion sickness starts, and leave it on for as long as your symptoms last. If you are highly susceptible to motion sickness, apply the WL-2401 Device one half hour before a motion sickness event.

What Comes With Your WL-2401 Device?

Please check your package and be sure all of the items listed below are included. Refer to this Instruction for User Manual for details on how to use your WL-2401 Devuce.

Included in this package are all of the following:

- WL-2401 Device**
- Instruction for Use
- Conductivity Gel (10ml/.34fl.oz)

**Batteries have been pre-installed for customer convenience.

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

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How To Use Well-Life WL-2401 Device

Find the Starting Location:

1) On the underside of either wrist, measure down two finger widrhs from the first crease below the hand (see figure 1). This is the location where the stimulation is to be placed.

device should be centered?

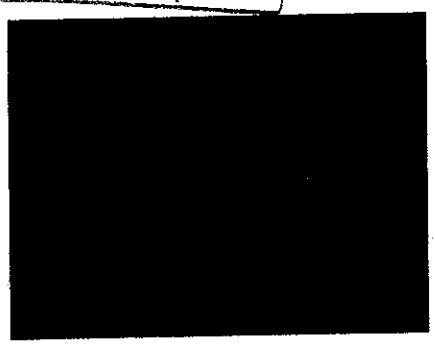

Figure 1. Finding the starting loaction on your wrist for the device.

2) Apply the Fel: Place a very small drop of conducyivity gel on the rubber part of the button side of WL-2401 (see figure 2).

Figure 2

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3) Attach the WL-2401 onto the wrist: Attach the device WL-2401 onto the placement as measured in step 1). The appropriate attachment of WL-2401 is as the indication of figure 3.

Figuer 3.

How To Turn On The WL-2401 Device

Activate the device by pressing the "Power start" button once. This will activate the unit at the lowest level. The green light will begin to flash indicating the unit is on. It also lets you know whether the device is operated.

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

ATTACHMENT 2

Adjusting Strap and Stimulation Level

1) Without moving the device from the stimulation point, tighten strap until it fits snugly but comfortably. (It may be necessary to reposition the device after the strap is tightened.)

How?

2) Adjust the power level for your optimum balance of stimulation and comfort. Set the power level to the highest comfortable setting for maximum relief. The stimulation will cycle every four seconds.

REMEMBER: If you do not feel the tingling in your hand, you will not be getting the relief the WL-2401 Device is capable of providing. Adjust location and power setting to the highest comfortable level to get maximum relief.

How To Turn Off WL-2401 Device

To turn off the WL-2401 Device, press and hold down thw "Power start" button for 3 seconds.

Usage Tips

1) Try the WL-2401 Device on each wrish and use it on the wrist where the greatest tingling is felt at the lowest setting.
2) For some people, applying and rubbing in the gel rwicw assists in nerve stimulation.
3) Gel should be re-applied every 6-8 hours, any time after washing, or if stimulation decreases.
4) While still on the wrist, turn the WL-2401 Device off periodically to determine if motion sickness symptoms are present. If they are, turn it back on immediately.
5) When finished using the WL-2401 Device, take it off your wrist and remove the gel from your wrist and the device with a tissue.
6) When not using the WL-2401 Device, be sure to turn the power off to extend battery life.
7) Store the WL-2401 Device a safe, dry place. Keep it away from young children.

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

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ATTACHMENT

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

Changing The Battery

1) Peel back the rubberized battery door at end marked OPEN HERE ▶ (see figure 4) and pull out the red colored tray.
2) Remove used batteries and then replace them with two fresh batteries (3V, CR2025 Lithium coin cells only) available at grocery or drug stores.
3) IMPORTANT: Make sure the new batteries are ubserted in the correct direction (+ side down – see figure 4), the battery tray is inserted correctly, and the door is closed. Be sure door is replaced with the OPEN HERE ▶ facing in original position and there are no gaps in the seal (gaps decrease water resistance). Be sure the WL-2401 Device is dry before changing the batteries.

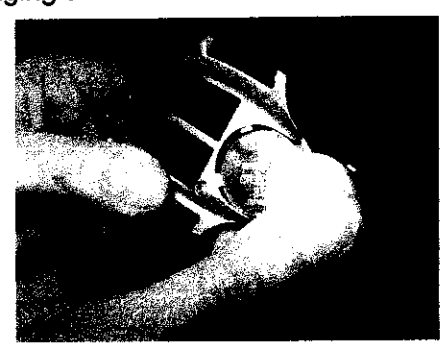

Figure 4.

*NOTE: Battery tray only fits in one waty. Always insert into WL-2401 Device with arrows up, as shoen above.

Environmental Conditions That Can Affect Use

The WL-2401 Device is water-resistant. This product is resistant to splashing water (rain, waves, etc). Do not immerse WL-2401 Device in water or wear while bathing. The device is also shock-resistant.
The WL-2401 Device should only be used within the temperature range of 10°C to 45°C (50°F to 113°F), and a relative humidity range of 20% to 90% (non-condensing). If the product has been stored or transported in conditions outside these ranges, keep it within the normal ranges for at least 30 minutes before using.

The product can be stored and transported in the temperature range of 0°C to 50°C (32°F to 122°F), and a relative humidity range of 20% to 90% (non-condensing). The device may not operate if stored in conditions outside of this range.

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ATTACHMENT 2

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Questions and Answers

How can I be sire I have found the area for maximum stimulation?

- After the device is turned on, move it slightly up or down, and side to side on the wrist until the maximum "tingling" feeking is felt. You will feel a tingling sensation in your palm and/or middle fingers when the WL-2401 Device is in the proper wrist location. Stimulation will cycle every four seconds.
- If little or no tingling is felt aftre moving it around, increase the power level.
- Try the band on the opposite wrist. Use it on the wrist where you feel the most tingling. Increase the power setting to the highest comfortable setting for maximum relief.

On which wrist should I wear the WL-2401 Device?

- On the wrist that gives you the greatest tingling in the hand at the lowest stimulation level.

Questions and Answers (continued)

Is dry or sensitive skin a problem?

- For dry skin, the gel may be lightly more often.
- If you have especially sensitive skin, seitch wrists every 2-3 hours. Be sure to re-apply gel as directed.

How long will the batteries last?

- The batteries should last for about 150 hours of total use at middle, power level, less time at higher power levels. Battery life depends on individual usage of product.

How do I know when the batteries are getting low?

- The kow battery light on the display will flash slowly to let you know when the batteries are low.
  At this time, about 10 hours of use remain depending on the power level used and how long you have used the device.
- Once the battery light goes out, the batteries need to be replaced. It is a good idea to carry an extra set of batteries with you.

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

ATTACHMENT 2

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Troubleshooting

The WL-2401 Device has been designed to provide feedback to ensure propwe usage to relieve the symptoms of motion sickness. The Troubleshooting Chart velow will help to assist you in handling situations that may aries while you use the product.

Situation	Recommended Solution
Green light flashing (No stimulation is felt)	Move the WL-2401 Device around the underside of the wrist. Check for proper placement Increase the power setting. Re-apply a small amount of gel. Be sure gel is rubbed in to a sheen. The area should appear shiny. Be sure the strap is secure around wrist. Be sure green light is flashing at one of the 5 power settings.
No lights flashing	Check that device is on. You should see green flashing light at one of the 5 power setting (1-5). Turn device OFF and reactivate. Batteries may be drained (*see Disposal Information section*).
Low battery light flashing	The red light indicates a low battery. Restart unit to see if power remains. Set the unit at a lower setting. Of red light continues to flash, the batteries are running out of power.

User Assistance Information

If you have any questions about how to use the Well-Life Device Model WL-2401 please call Well-Life Healthcare Inc. Room 6C01, No. 5, Sec. 5, Hsin Yi Rd., Taipei, Taiwan, R.O.C. TEL: +886-2-2928-2112, FAX: +886-2-2928-1880

Maintenance Information

Cleaning:

Keep the electrode area clean. A moist cloth may be used to remove gel buid-up, which may decrease stimlation. Avoid immersion of the device in water.

To purcjase additional WL-2401 Device or accessory items, including conductivity gel, call Well-Life.

Storage Information

Remove batteries if the device is going to be stored. See Environmental Conditions Section for additional information.

Disposal Information

The product and batteries do not contain any environmentally hazardous substances and can be disposed of normally. The batteries used in this device may explode if mistreated. Do not recharge, disassemble or dispose of them if fire. Dispose of the old batteries normally after changing batteries.

ATTACHMENT 1

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

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ATTACHMENT

Technical Information

The WL-2401 Device complies with IEC 601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, including Am. No.1 (1991) and Am. No.2 (1995), and EN 60601-1.

The WL-2401 Device has been verified to meet the requirements of the following Electromagnetic Compatibility standards, EN 55011 (CISPR II) Radiated Emissions, EN 61000-4-2 Electrostatic Discharge Immunity, EN 61000-4-3 Radiated Electromagnetic Field Immunity.

The WL-2401 Device is classified as TYPE B equipment.

Attention, the WL-2401 Device produces physiological effects as described in this guide.

Technical Specifications

Channel	Single channel
Output Volt.	0-140 volt (open circuits)
On function	Power ON and intensity setting (up 10 levels)
Off function	Power OFF and intensity setting (down)
Pulse amplitude	Adjustable, 0-50mA peak into 500Ω load.

Mode	Pulse rate	Pulse width	Interval	Duration
A	30Hz	250μs	ON: 3sec, OFF: 5sec	continuous

Power source	1xDC 3V Lithium battery (CR2032)
Dmensions	60(L) × 47.3(W) × 14.6(H) mm
Weight	Approx 19 grams (include battery)

* The allowable variation in supply voltage is 70% for 3V battery.

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

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7.4. Overall comparison between the new models and existing Well-life cleared models.

Based on the information provided in 7.0 ~ 7.3, we would like to draw the summary for the conclusion of overall comparison between our new development models and existing Well-life clear models as the following two table.

For WL-2103A, WL-2203A, and WL-2203B

Compared features	Well-life existing cleared model	New development model
Electrical construction	The electrical construction for the new models are completely identical to that of existing models.	
Fixing construction	No particular fixing device	A support belt was provided to position the stimulation on low back for the specified indication for use.
Indication for use	As general TENS device (prescription use)	OTC use for Limited TENS operation function
Labeling	Description for the general purpose TENS use	See information in 7.0 ~ 7.3.
Application	This device could be used for any part of patient under the prescription of physician except the contraindication indicated on product labeling.	This device is limited for the pain relief on the low back of patient without prescription of physician.

For WL-2401

Compared features	Well-life existing cleared model	New development model
Electrical construction	The electrical construction for the new model is completely identical to that of existing model.	
Fixing construction	The fixing construction for the new model is completely identical to that of existing model.	
Indication for use	As general TENS device (prescription use)	OTC use for Limited TENS operation function
Labeling	Description for the general purpose TENS use	Description for the special limited TENS operation use
Application	This device could be used on wrist of patient under the prescription of physician except the contraindication indicated on product labeling.	This device could be used on wrist for use in for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy without the prescription of physician.

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8. Substantial Equivalence Comparison.

8.0. General.

As statement above mention, the main intended purpose for this 510(k) submission is to change the indication for use from prescription device to OTC device for existing 510(k) cleared device WL-2103A, WL-2203A, WL-2203B, and WL-2401.

For the change of indication for use, we choosed UltraStim Kit (K013532) and Relief Band Device (K020180) for the 510(k) cleared comparison models, because that our development models have the same 'indication for use' as these two chosen models.

As the information of indication for use for both the chosen comparison models and our new development models, please see the description of the following table.

Model Name		Description the 'indication for use' of new model and clear model
New model	Clear model	
WL-2103A WL-2203A WL-2203B	UltraStim Kit (K013532)	The models WL-2103A, WL-2203A, and WL-2203B TENS 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.
WL-2401	Relief Band Device (K020180)	The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

For the detail information of chosen 510(k) cleared model, UltraStim Kit (K013532) and Relief Band Device (K020180), please see in detail the attachment 1 and attachment of this clause.

Regarding the substantial equivalence comparison for the models and chosen 510(k) clear model, please see the further assessment of clause 8.1 ~ clause 8.4.

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

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Attachment 1. Detail Information for UltraStim Kit (K013532)

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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

MAY 28 2003

Dan Jeffery
Axelgaard Mfg. Co., Ltd.
1667 S. Mission Road
Fallbrook, California 92028-4115

Re: K013532
Trade/Device Name: UltraStim Kit
Regulation Number: 21 CFR 882.5890, 21 CFR 882.1320 and 21 CFR 890.3490
Regulation Name: Transcutaneous Electrical Nerve Stimulator, Cutaneous Electrode and Truncal Orthosis
Regulatory Class: Class II
Product Code: GZJ, GXY and IQE
Dated: May 28, 2002
Received: June 6, 2002

Dear Mr. Jeffery:

This letter corrects our substantially equivalent letter of August 22, 2002 to clarify the over-the-counter (OTC) status of your device.

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 (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.

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

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

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OTC INDICATIONS FOR USE

510(k) Number: K020180 (To Be Assigned By FDA)

Device Name: ReliefBand® Device Models RB-DL, RB-EL, and RB-RL

Indications For Use: The ReliefBand® device is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number K020180

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

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Attachment 2. Detail Information for Relief Band Device (K020180)

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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

MAR 21 2002

Woodside Biomedical,Inc.
C/O Carol L. Patterson
Patterson Consulting Group
21911 Erie Lane
Lake Forest, California 92630

Re: K020180
Trade/Device Name: ReliefBand® Device Models RB-DL, RB-EL and RB-RL
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: January 17, 2002
Received: January 18, 2002

Dear Ms. Patterson:

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

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

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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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

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Indications for Use

510(k) Number (if known): K013532

Device Name: UltraStim Kit

Indications for Use:

The UltraStim Kit 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ Over-the-Counter (OTC) Use X

for Mark N Melkerson

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

510(k) Number K013532

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

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MAR 21 2002

510(k) SUMMARY
Woodside Biomedical Inc. ReliefBand® Device
Models RB-DL, RB-EL, and RB-RL

SUBMITTER INFORMATION

A.	Company Name:	Woodside Biomedical, Inc.
B.	Company Address:	1915 Aston Avenue Carlsbad, CA 92008
C.	Company Phone: Company Fax:	(760) 804-6900 (760) 804-6925
D.	Contact Person:	Tom Grey Vice-President of Product Development Woodside Biomedical, Inc.
E.	Date Summary Prepared:	January 16, 2002

DEVICE IDENTIFICATION

A.	Classification Name:	Transcutaneous Nerve Stimulator
B.	Trade/Proprietary Name:	ReliefBand® Device
C.	Classification:	Class II (21 CFR 882.5890)
D.	Product Code:	GZJ

IDENTIFICATION OF PREDICATE DEVICE

The Woodside Biomedical, Inc. ReliefBand® device Models RB-DL, RB-EL, and RB-RL are of comparable type and are substantially equivalent to the following predicate devices:

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

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Predicate Device	Manufacturer	510(k) No.	Date Cleared
ReliefBand® Device Models RB-2, RB-6, and RB-R (OTC)	Woodside Biomedical, Inc.	K982967	February 23, 1999
ReliefBand® Device Models WB-2L, WB-6L, and WB-RL (Rx)	Woodside Biomedical, Inc.	K994387	March 16, 2000

DEVICE DESCRIPTION

The ReliefBand® Device Models RB-DL, RB-EL, and RB-RL are non-invasive devices which are indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy. The devices are contained within a wristband, and provide relief through electrical stimulation of the nerves in the patient's wrist.

The devices can be worn on the ventral or palmar (i.e., inside) surface of either or both wrists, approximately 2 fingers breadth above the distal skin crease of the wrist joint, between the tendons of the palmaris longus and flexor carpi radialis muscles.

The ReliefBand® device Model RB-xL family has a user display that incorporates five blinking LEDs which are used to identify the intensity level (5 discrete LEDs, one for each intensity level), so that the patient can easily select the desired stimulation. Selection of the intensity level is performed via a pushbutton located on the user display, which controls the peak pulse amplitude of the electrical impulse and thereby determines the intensity of the stimulation. A sixth blinking LED is used to display the low battery indicator.

The ReliefBand® device Model RB-xL family is powered by two 3V lithium batteries. The batteries are not user replaceable in the disposable device model RB-DL, but are user

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replaceable in the reusable device models RB-EL and RB-RL. The battery life for all models is specified to be 150 hours when used at setting 3.

INDICATIONS FOR USE

The ReliefBand® Devices are indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ReliefBand® Device and the predicate device has been performed. The results of this comparison demonstrate that the ReliefBand® Device is equivalent to the marketed predicate device. The differences between the ReliefBand® Device Models RB-DL, RB-EL, and RB-RL and the predicate models are insignificant and do not affect the safety or effectiveness of the device.

PERFORMANCE DATA

The performance data indicate that the ReliefBand® Device Models RB-DL, RB-EL, and RB-RL are substantially equivalent to the predicate ReliefBand® Devices distributed under K982967 and K994387.

CONCLUSIONS

Woodside Biomedical, Inc. has demonstrated through its evaluation of the ReliefBand® Device Models RB-DL, RB-EL, and RB-RL that the devices are equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

1-16-02

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8.1. Substantial Equivalent comparison for WL-2103A, WL-2203A, and WL-2203B (Group 1 model).

8.1.1. Table of comparison.

Basically, the main comparison between the models WL-2103A, WL2203A, and WL-2203B as well as their 510(k) cleared device is listed as the following table:

Features	*New models*			*510(k) cleared device*
	WL-2103A	*WL-2203A*	*WL-2203B*	*Ultra Stim Kit*
510(k) Number	K002874	K0033857	K030537	K013532
Manufacturer	Well-Life	Well-Life	Well-Life	Axelgaard Mfg. Co., Ltd.
Classification	Class II	Class II	Class II	Class II
Basic Specification Comparison				
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual	Dual	Dual
Power supply	9 volt battery	9 volt battery	9 volt battery	9 volt battery
Circuit designed	Analog	Digital	Digital	Analog
Software	Yes	Yes	Yes	Yes
Amplitude (mA)	0-80	0-80	0-80	0-80
Pulse rate (Hz)	2-150	1-150	1-160	3-100
Width (μs)	30-260	30-260	50-260	72-260
Power ON indicator	LED	LCD	LCD	LCD
Timer (min)	60	15-60	15-60	NIL
Weight (grams) (batt. Include)	135	142	142	120
Size (mm)	92×62×25	110×62×27	110×62×27	100×60×21
Prescription or OTC	OTC	OTC	OTC	OTC
Indication for use	All models as above mentioned 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.			
Output Specification Comparison				
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square	Square	Square
Maximum Output Voltage (V) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	40 68 92	40 68 92	40 68 92	40 68 92
Maximum Output Current (mA) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	80 68 46	80 68 46	80 68 46	80 68 46
Pulse Width (μS)	30-260	30-260	50-260	72-260
Frequency (Hz)	2-150	1-150	1-160	3-100
Maximum Phase charge (μC) @500Ω	20.8	20.8	20.8	20.8
Maximum Current Density (A/cm^2) @500Ω	3.5×10^{-5}	3.5×10^{-5}	3.7×10^{-5}	2.3×10^{-5}

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8.1.2. Discussion of comparison for group 1 models.

For both the chosen 510(k) cleared device and our new device provided the following accessories to attach the stimulation unit on abdominal area for the specified indication for use of device:

1 Support Belt
1 TENS Stimulator
1 package of self-adhesive pads
1 set of plastic Storage Liners (not shown)
1 pair of Snap Cable
1 User Manual (not shown)
1 9-volt Alkaline Battery

The main difference exists in the stimulation output. This difference may cause some impact on the performance and safety. The possible impact was evaluated hereafter.

As information from the manufacturer of UltraStim Lit, the stimulation specification is as the indication of the following table.

Program	Max. Amplitude	Phase duration	Rate	Cycle Time
1	80mA	200μs	50Hz	10 Seconds
2	80mA	200μs	60-100Hz	10 Seconds
3	80mA	120-72μs	80Hz	10 Seconds
4	80mA	260-78μs	100Hz	15 Seconds
5	80mA	260μs	3-5Hz	15 Seconds

For our new device, the stimulation specification is as the indication of the following table.

Need description of each mode output (p.21)

Model	Max. Amplitude	Phase duration	Rate	Cycle Time
WL-2103A	80mA	30-260μs	2-150Hz	60 minutes
WL-2203A	80mA	50-260μs	1-160Hz	15-60 minutes
WL-2203B	80mA	30-260μs	1-150Hz	15-60 minutes

Based on the information as above mentioned, the safety for the stimulation output may be calculated as the following details.

For the UltraStim Kit (K013532)

<1> Maximum phase charge = 0.26 ms × 80mA = 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)x(35x0.26) = 27.28μc

<3> Maximum average current (measured at program 4/80mA; 260μs; and 100Hz)
= maximum charge per pulse × No. of pulse per second
= 20.8μc × 100 = 2080μA = 2.08mA

<4> Maximum Current Density (A/cm^2) @ 500Ω
= maximum average current / cross-sectional area
= 20.8mA / (9x5x2) = 0.023mA/cm^2 = 2.3×10^{-5} A/cm^2

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For WL-2103A, and WL-2203A (New Device)

<1> Maximum phase charge = 0.26 ms × 80mA = 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)x(35x0.26) = 27.28μc

<3> Maximum average current (measured at 80mA; 260μs; and 150Hz)

= maximum charge per pulse × No. of pulse per second

= 20.8μc × 150 = 3120μA = 3.12mA

<4> Maximum Current Density (A/cm^2) @ 500Ω

= maximum average current / cross-sectional area

= 3.12mA / (9x5x2) = $0.035mA/cm^2 = 3.5x10^{-5}A/cm^2$

For WL-2203B (New Device)

<1> Maximum phase charge = 0.26 ms × 80mA = 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)x(35x0.26) = 27.28μc

<3> Maximum average current (measured at 80mA; 260μs; and 150Hz)

= maximum charge per pulse × No. of pulse per second

= 20.8μc × 160 = 3328μA = 3.328mA

<4> Maximum Current Density (A/cm^2) @ 500Ω

= maximum average current / cross-sectional area

= 3.328mA / (9x5x2) = $0.037mA/cm^2 = 3.7x10^{-5}A/cm^2$

Summary for the safety comparison of stimulation output

Based on the calculation information as above mentioned, the main stimulation output characteristics may be listed as the following table.

Characteristic	Max. phase charge		Max. charge per pulse		Max. average current	
Limited value acc. to NS4	25μc		75μc		10mA	
Calculated value	K013532	New device	K013532	New device	K013532	New device
	20.8μc	20.8μc	27.28μc	27.28μc	2.08mA	3.12mA/3.328mA
Verdict	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Conclusions of group 1 comparison

For the comparison information provided in this clause, it is very clear that the following comparison conclusions could be made:

1> Both the chosen 510(k) clear model and our new device have the similar fixing device to provide the application of the similar stimulation position. So it is very reasonable that all the devices have the similar "indication for use".

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2> The stimulation output may have some difference in output characteristics. However, all of the output characteristics are within the acceptable limits of ANSI/AAMI, NS4 standard. So they could be considered as appropriate stimulation output according to ANSI/AAMI NS4 standard.

3> Even though the stimulation output has different level, it does not effect the indication for use as well as the safety of operation. Therefore, the stimulation strength for both 510(k) cleared device and our new devices could adjusted by the patient or user without the involvement of physician.

Based on this reason, we would like to claim that our devices are also capable of being sold as OTC device as that chosen of 510(k) cleared device, UltraStim Kit (K013532).

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Ultrastim Comp...

8.2. Substantial Equipment comparison for WL-2401. (Group 2 model)

8.2.1. Table of comparison.

Basically, the main comparison between the models WL-2401 well as their 510(k) cleared device is listed as the following table:

Features	*New models* WL-2401	*510(k) cleared device* Relief Band Device
510(k) Number	K010010 ?	K020180
Manufacturer	Well-Life	Woodside Biomedical, INC.
Classification	Class II	Class II
Basic Specification Comparison		
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Single	Single
Power supply	3 volt battery	3 volt battery
Circuit designed	Analog	Analog
Software	Yes	Yes
Amplitude (mA)	0-50	0-35
Pulse rate (Hz)	30 fixed	135 fixed
Width (μs)	250 fixed	200 fixed
Power ON indicator	LED	LED
Timer (min)	15	NIL
Weight (grams) (batt. Include)	19	34
Size (mm)	60×47.3×14.6	1.5" ×2" ×0.45"
Prescription or OTC	OTC	OTC
Indication for use	All models as above mentioned are intended for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.	
Output Specification Comparison		
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square
Maximum Output Voltage (V) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	25 68 92	17.5 - -
Maximum Output Current (mA) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	50 68 46	35 - -
Pulse Width (μS)	250 fixed	350 ~~200~~ fixed
Frequency (Hz)	30 fixed	31 ~~135 fixed~~
Maximum Phase charge (μC) @500Ω	7.0	6.1 12.5
Maximum Current Density (A/cm^2) @500Ω	13.4×10^{-5}	6.25×10^{-5}

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8.2.2. Discussion of comparison for group 2 model.

For the accessories provided in this group of models, both the chosen 510(k) cleared device and our new device have included the accessories to place the stimulation device on wrist for stimulation treatment.

The main difference exists in the stimulation output. This difference may cause some impact on the performance and safety. The possible impact was evaluated hereafter.

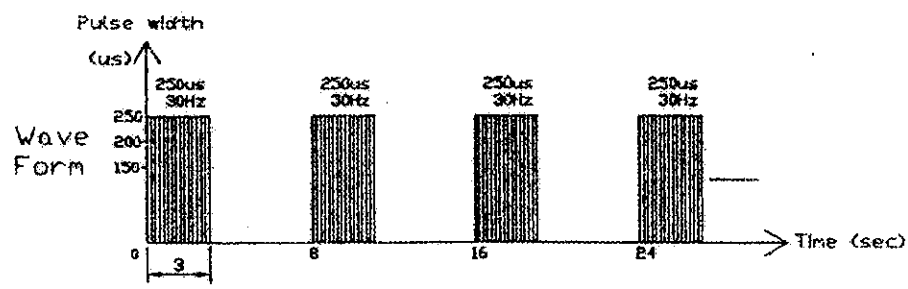
As information from the manufacturer of Relief Band, the stimulation specification is as the indication of the following table.

Program	Max. Amplitude	Phase duration	Rate	Cycle Time
1	10.5mA @500Ω	200μs	135Hz	No timer control
2	17.5mA @500Ω	200μs	135Hz	No timer control
3	24.5mA @500Ω	200μs	135Hz	No timer control
4	31.5mA @500Ω	200μs	135Hz	No timer control
5	35mA @500Ω	200μs	135Hz	No timer control

For our new device, the stimulation specification is as the indication of the following table.

Model	Outlook	Time for each operation cycle	Combination of wave form	Wave form information			
				Type	Pulse rate (Hz)	Pulse width (μs)	Time duration
Mini- TENS WL-2401	Type A	15 minutes	Single wave form (A)	A	30	250	3s/ON, 5s/OFF

The type A wave form is as the indication of the following drawing:



Based on the information as above mentioned, the safety for the stimulation output may be calculated as the following details.

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For the Relief Band (K020180)

<1> Maximum phase charge = 0.20 ms × 35mA = 7.0μc

<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)x(35x0.20) = 25.6μc

<3> Maximum average current (measured at program 35mA; 200μs; and 135Hz)

= maximum charge per pulse × No. of pulse per second

= 7.0μc × 135 = 945μA = 0.945mA

<4> Maximum Current Density (A/cm^2) @ 500Ω

= maximum average current / cross-sectional area

= 0.945mA / (2x1.5x1.5) = 0.134mA/cm^2 = 1.34×10^{-4}A/cm^2

For WL-2401 (New Device)

<1> Maximum phase charge = 0.25 ms × 50mA = 12.5μc

<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)x(35x0.25) = 27μc

<3> Maximum average current (measured at 50mA; 250μs; and 300Hz)

= maximum charge per pulse × No. of pulse per second

= 12.5μc × 30 = 375μA = 0.375mA

<4> Maximum Current Density (A/cm^2) @ 500Ω

= maximum average current / cross-sectional area

= 0.375mA / (2x3) = 0.0625mA/cm^2 = 6.25×10^{-5}A/cm^2

Summary for the safety comparison of stimulation output

Based on the calculation information as above mentioned, the main stimulation output characteristics may be listed as the following table.

Characteristic	Max. phase charge		Max. charge per pulse		Max. average current	
Limited value acc. to NS4	25μc		75μc		10mA	
Calculated value	K020180	New device	K020180	New device	K020180	New device
	7.0μc	12.5μc	25.6μc	27μc	0.945mA	0.375mA
Verdict	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

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Conclusions of group 2 comparison

For the comparison information provided in this clause, it is very clear that the following comparison conclusions could be made:

1> Both the chosen 510(k) clear model and our new device have the similar fixing device to provide the application of the similar stimulation position. So it is very reasonable that this two devices have the similar "indication for use".

2> The stimulation output may have some difference in output characteristics. However, all of the output characteristics are within the acceptable limits of ANSI/AAMI, NS4 standard. So they could be considered as appropriate stimulation output according to ANSI/AAMI NS4 standard.

3> Even though the stimulation output has different level, it does not effect the indication for use as well as the safety of operation. Therefore, the stimulation strength for both 510(k) cleared device and our new device could adjusted by the patient or user without the involvement of physician.

Based on this reason, we would like to claim that our device is also capable of being sold as OTC device as that chosen of 510(k) cleared device, Relief Band (K020180).

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8.3. What we did to prove "Substantial Equivalent"

Based on the detail comparison as provided in clause 8.1 and clause 8.2, our new devices are substantial equipment to the chosen cleared device Ultra Kit (K013532) and Relief Band (K020180) from the specification and operation function point of view.

In addition to the specification and operation function comparison, we need the performance and safety test report according to some appropriate standards to prove that our device is safe and effective.

Since our new devices were developed from our previous 510(k) cleared models to change the intended use from prescription device to OTC device, the re-testing of electrical safety, EMC and operational performance are not required.

If you have to check the testing report, please refer to our previous 510(k) submission document as the following indication:

Model Name	Relevant K-number	Testing reports included:
WL-2103A	K002874	① Electrical safety according to EN 60601-1 and EN 60601-1-1. ② EMC according to EN 60601-1-2. ③ Performance according to ANSI/AAMI NS4.
WL-2203A	K0033857	
WL-2203B	K030537	
WL-2401	K010010	

In addition to the existing test report provided in our previous 510(k) submission, we have also completed a bio-compatibility for the "Neoprene Conductive Belt", which is for the placement of the models WL-2103A, WL-2203A, and WL-2203B. this report was provided in clause 9.

For the modification of labeling, including user manual and device packaging, please see the information provided in clause 7.1 ~ 7.3.

Finally, we have draw up the 510(k) statement in clause 10, and 510(k) summary in part II of this 510(k) submission document.

Based on the information and testing reports as above mentioned, we strongly believe that the change of the intended use for our new application meet the FDA regulation requirement for the OTC 510(k) application.

Therefore, we wish the SE letter for this 510(k) submission could be issued from FDA.

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9. Test report for the bio-compatibility.

9.1. General bio-compatibility requirement

Basically the bio-compatibility testing was conducted according to ISO 10993-1. the following table indicate the required testing items for different products.

(b)(4)

[redacted]

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Description for the bio-compatibility testing condition.

(b)(4)

[redacted]

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SGS

TEST REPORT

BIOCOMPATIBILITY

Test of: Neoprene conductive belt

SGS Reference: DUR 24310-5/R/AC/03

Applicant: Well - Life Healthcare Inc.

Address: 1 Fl. No. 16, Lane 454, Jungjeng Rd. Yunghe City, Taipei County, Taiwan 234 R.O.C.

Test Specification: EN 30993-1: 1994

Date of receipt: 17th July 2002

Date of Tests: 5th August – 20th September 2002

Date of Issue: 21st July 2003

Conclusion:

Cytotoxicity:	Negative
Skin Sensitization:	Negative
Acute Cutaneous Irritation:	Negative

This report refers only to the samples submitted for test

See attached SGS Lab Simon Test Reports refs:
101054 (3 pages), **S102727** (21 pages) and **S102728** (26 pages)

Signature

A Clifford ***Authorised Signatory***

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9.3. Bio-compatibility test report.

As assessment listed in 9.2, the following three report are attached hereafter:

- Attachment 1: Report No. 101054
- Attachment 2: Report No. S10272
- Attachment 3: Report No. S102728

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

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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ATTACHMENT 2

SGS Lab. Simon reference : S102727

DETERMINATION OF ACUTE DERMAL IRRITATION OF VARIOUS COMPONENTS OF AN ELECTRODE

SEPTEMBER 2002
STUDY REPORT
FINAL VERSION

僅供參考

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ATTACHMENT 2

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APPENDIX : study plan

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ATTACHMENT 2

STUDY DIRECTOR STATEMENT

I, the undersigned, hereby declare that :

The study described in this analytical report no S102727 entitled "Determination of acute dermal irritation of various components of an electrode" was performed by myself under my responsibility as study director in the Toxicology department of SGS Lab Simon S.A., Vieux Chemin du Poëte 10, B-1301 Wavre (Belgium), from 28 August 2002 to 02 September 2002.

The present report provides a true and accurate record of the study and the data generated.

The experimental work was conducted according to the principles of the current OECD principles of Good Laboratory Practice, and following the Standard Operating Procedures currently in use in the Toxicology department of SGS Lab Simon S.A. There were no significant deviations which affecetd the quality or integrity of the study.

I consider the data as valid.

V. Thisse, D.V.M.,
Study Director

03 September 2002
Date

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MANAGEMENT STATEMENT

At the request of SGS U.K., we have appointed V. Thisse, D.V.M. as study director for the conduct of the study no S102727 entitled "Determination of acute dermal irritation of various components of an electrode".

V. Thisse is included on our company's study director list.

All arrangements have been taken to ensure the proper conduct of the present study according to the current OECD principles of Good Laboratory Practice.

To the best of our knowledge the study was conducted according to these principles and applicable Standard Operating Procedures of SGS Lab Simon S.A. without any undocumented deviation.

P.O. J.M. GHYSEL, Ind. Pharm.
Pharmacist Director

03 September 2002
Date

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1. INTRODUCTION

The acute dermal irritation test of the components of the electrode was performed by a protocol based on the norm ISO 10993-10 : Biological evaluation of medical devices – part 10 : Tests for irritation and sensitization and the norm ISO 10993-12 : Biological evaluation of medical devices – part 12 : Sample preparation and reference materials (1992).

2. MATERIALS AND METHODS

2.1. TEST ARTICLE

2.1.1. Description of the test article

[redacted]

2.1.2. Composition

(b)(4)

[redacted]

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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ATTACHMENT 2

With such observations, the primary irritation index is equal to 0 what is corresponding to an absence of skin irritation.

5. CONCLUSION

In the study conditions and according to the norm ISO 10993-10, the test article " Components of an electrode" (without batch number) was not irritating for the skin.

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APPENDIX - STUDY PLAN (11 PAGES including this one)

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ATTACHMENT

COMPONENTS OF AN ELECTRODE

Determination of acute dermal irritation of various components of an electrode

SGS LAB SIMON S.A.
TOXICITY STUDY PLAN S102727
Final version

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The information contained within this study plan is confidential and must not be disclosed without written authorisation from SGS U.K. Ltd, South Industrial Estate, Bowburn, Durham DH6 5AD (United Kingdom). SGS Lab Simon S.A. undertakes not to disclose any of the results, work practices or functions of SGS UK conveyed to them during the course of this work.

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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11. CONFIDENTIALITY

The information contained in this study plan and the experimental data pertaining to the study must be considered as strictly confidential, and will not be disclosed to others without written permission of the sponsor, except to the staff involved in the study.

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12. APPROVALS

ATTACHMENT

This study plan has been read and accepted by the sponsor :

Mr. Andy Clifford
Sponsor Representative

30/8/02
Date

This study plan has been read and approved by the investigators :

V. Thisse, D.V.M.
Study Director

26 August 2002
Date

J.M. Ghysel, Ind. Pharm.
Pharmacist Director

20.08.2002
Date

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

SGS Lab.Simon reference : S102728

ATTACHMENT 3

DETERMINATION OF THE SKIN SENSITIZATION OF VARIOUS COMPONENTS OF AN ELECTRODE

AUGUST 2002
STUDY REPORT
FINAL VERSION

僅供參考

This confidential report contains 25 pages. It is the property of SGS U.K. Ltd, South Industrial Estate, Bowburn, Durham DH6 5AD (United Kingdom). It may not be reproduced nor transmitted by any means, in whole or in part, without written permission from the owner. Citations are allowed with mention of SGS Lab Simon S.A.

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大匯工業有限公司 文管中心 92.10.24 發行章

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

(b)(4) Testing

(b)(4) Testing

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ATTACHMENT 3

MANAGEMENT STATEMENT

At the request of SGS U.K., we have appointed V. Thisse, D.V.M. as study director for the conduct of the study no S102728 entitled " Determination of the skin sensitization of various components of an electrode".

V. Thisse is included on our company's study director list.

All arrangements have been taken to ensure the proper conduct of the present study according to the current OECD principles of Good Laboratory Practice.

To the best of our knowledge the study was conducted according to these principles and applicable Standard Operating Procedures of SGS Lab Simon S.A. without any undocumented deviation.

08/10/02

p° J.M. GHYSEL, Ind. Pharm.
Pharmacist Director

Date

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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ATTACHMENT 3

4. CONCLUSION

In the limits of the study, the test article "Components of an electrode" (no batch number communicated by the sponsor) did not produce any dermal reaction. The weights of treated animals had the same increasing as the control animals.

This test article must thus be considered as having no delayed contact dermatitis (Type IV sensitization) when tested according to a method based on the norm ISO 100993-10 and ISO 10993-12.

僅供參考

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大進工業有限公司
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92.10.24
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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 : STUDY PLAN (12 pages including this one)

ATTACHMENT 3

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ATTACHMENT 3

COMPONENTS OF A MEDICAL DEVICE

Determination of the skin sensitization of various components of an electrode

SGS LAB SIMON S.A.
TOXICITY STUDY PLAN S102728
Final version

僅供參考

The information contained within this study plan is confidential and must not be disclosed without written authorisation from SGS U.K. Ltd, South Industrial Estate, Bowburn, Durham DH6 5AD (United Kingdom). SGS Lab Simon S.A. undertakes not to disclose any of the results, work practices or functions of SGS UK conveyed to them during the course of this work.

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92. 10. 24
發行章

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

(b)(4) Testing

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ATTACHMENT 3

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文管中心
92.10.24
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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12. APPROVALS

ATTACHMENT 3

This study plan has been read and accepted by the sponsor :

Mr Andy Clifford
Sponsor Representative

30/8/02
Date

This study plan has been read and approved by the investigators :

V. Thisse, D.V.M.
Study Director

26 August 2002
Date

J.M Ghysel, Ind. Pharm.
Pharmacist Director

20
Date

僅供參考

管制文件
不得影印

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

10. 510(k) Statement

510(k) STATEMENT
(As required by 21 CFR 807.93)

I certify that, in my capacity as the sales manager of Well-Life Healthcare Inc. I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature of certifier)

19, 02, 2004
(Dated)

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

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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

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

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

   Contact:
   Ms. Jenny Hsieh
   Sales Manager

   Date of Summary Preparation: February 09, 2004.

2. Device Identification:
   Classification Name: Transcutaneous Nerve Stimulator.

   Trade/Proprietary Name: Limited Function device, model WL-2103A, WL-2203A, WL-2203B, and WL-2401.

   Classification: Class II (21 CFR 882.5890)

   Product Code: GZJ

3. Identification of predicate device
   The Well-Life models WL-2103A, WL-2203A, WL-2203B, and WL-2401 are of comparable type and are substantially equivalent to the following predicate devices:

New Device Model	Predicate Device	Manufacturer	510(k) No.	Date Cleared
WL-2401	ReliefBand Device Models	Woodside Biomedical, Inc.	K020180	January 17, 2002
WL-2103A, WL-2203A, WL-2203B	Ultra Stim Kit	Axelgaard Mfg. Co., Ltd.	K013532	June, 6, 2002

4. Device Description:

   For WL-2103A, WL-2203A, and WL-2203B
   The Well-life models WL-2103A, WL-2203A, and WL-2203B are non-invasive devices which are intended for over the counter use in temporary relied of pain associated with sore and aching muscles in the lower back due to stain from exercise or normal household and work activities.
   T
   he devices contain the following main parts: TENS stimulation unit, Support Belt, Self-adhesive pads, and Snap Cable.

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

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The device can be worn on the low back part of user so as to place the stimulation pads on the treatment location of low back.

The main stimulation function is achieved through the stimulation unit of WL-2103A, WL-2203A, or WL-2203B. those stimulation units have been cleared for 510(k) before being submitted on this new submission for OTC application. The K-number for these three models are K002874, K003857, and K030537.

For the detail description of these three stimulation models, please refer to the information provided in K002874, K003857, and K030537.

For WL-2401
The Well-Life model WL-2401 is a non-invasive device which is indicated for over the counter use in the relief nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy. This device is contained within a wristband, and provide relief through electrical stimulation of the nerves in the patient's wrist.

The device can be worn on the ventral or palmar (i.e., inside) surface of either or both wrists, approximately 2 fingers breadth above the distal skin crease of the wrist joint, between the tendons of the palmaris longus and flexor carpi radialis muscles.

WL-2401 device is equipped with three operation keys to control the ON/OFF operation and amplitude of stimulation. The stimulation is fixed at certain wave form. The output amplitude may be adjusted up to 50mA via "up" and "down" control key.

The Well-Life model WL-2401 is powered by one 3V lithium battery. This battery may be replaced by user while the battery power becomes low.

5. Intended Use:

For WL-2103A, WL-2203A, and WL-2203B
The models WL-2103A, WL-2203A, and WL-2203B are indicated for over the counter use in the temporary relief of pain associated with sore and aching muscles in the low back due to stain from exercise or normal household and work activities.

Foe WL-2401
The WL-2401 is indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

6. Technological characteristics:

A comparison of the technological characteristics of the Well-Life models WL-2103A, WL-2203A, WL-2203B, and WL-2401 and the predicate device has been performed. The results of this demonstrate that the Well-Life model WL-2103A, WL-2203A, WL-2203B, and WL-2401 are equivalent to the marketed predicate device. The differences between the Well-Life models WL-2103A, WL-2203A, WL-2203B, and WL-2401 and the predicate models are insignificant and do not affect the safety or effectiveness of the device.

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

7. Performance data:
Since there is not any significant change in the construction specification for the main stimulation unit WL-2103A, WL-2203A, WL-2203B, and WL-2401, the performance testing reports according to ANSI/AAMI NS4, and the safety testing reports according to EN 60601-1, EN 60601-1-1, and EN 60601-1-2 as mentioned in the previous 510(k) submission documents are still available for this submission.

For the additional fixing part, the neoprene conductive belt, the bio-compatibility testing report done according to ISO 10993-1 as well as the relevant standards are included in this submission.

8. Conclusions
Well-Life Healthcare Inc, has demonstrated through its evaluation of the Well-Life models WL-2103A, WL-2203A, WL-2203B, and WL-2401 that the devices are equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) KRISTEN BOWSHER

Subject: 510(k) Number K040512/S2

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☐ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☐ A 510(k) summary OR ☒ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ N

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90

Predicate Product Code with class: Class II, GZJ

Additional Product Code(s) with panel (optional):

Review: (Branch Chief) (Branch Code) REDB (Date) 5/27/04

Final Review: (Division Director) (Date) 5/27/04

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

Revised:4/2/03

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

510(k) MEMO

DATE: 5-19-04

FROM: Kristen A. Bowsher, Ph.D., Biomedical and Electrical Engineer, KAB
ODE/DGRND/REDB

SUBJECTS: Well-Life Healthcare, Inc. - Models WL-2402, WL-2403 and Model WL-2401 Limited Function OTC TENS

TO: K040512/S2

Background

This application was put on hold with a letter, dated March 12, 2004, requesting additional information and then again on April 29, 2004. This supplement is in response to the April 29, 2004 letter.

Response

In response to our concerns and concerns from the sponsor's marketing department the sponsor has made the following changes to the device:

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

The sponsor has also revised the user manuals adequately in response to the additional information requested in our April 29, 2004 letter.

RECOMMENDATION

I recommend that the ReliefBand Models WL-2402, WL-2403 and WL-2401 Limited Function OTC TENS be found substantially equivalent to legally-marketed TENS devices (21 CFR 882.5890, Class II).

TENS ProCode: GZJ

6

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Bowsher, Kristen

From: Bowsher, Kristen
Sent: Wednesday, May 19, 2004 11:44 AM
To: 'grace@welllifehealthcare.com.tw'
Cc: Bowsher, Kristen
Subject: K040512

Dear Ms. Chang:

I have reviewed your responses to our request for additional information. Everything is adequate. However, since you have revised model numbers, please provide a revised Indications for Use form and 510(k) Summary that reflect these changes and contain the appropriate indications for use for each model number. You may email them or fax them to 301-594-2358.

Please let me know that you have received this email and will respond to the request.

Kristen A. Bowsher, Ph.D.
FDA

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Bowsher, Kristen

rom: Grace(welllifehealthcare) [grace@welllifehealthcare.com.tw]
Sent: Wednesday, May 26, 2004 10:32 PM
To: Bowsher, Kristen
Subject: Fw: K040512

Dear Dr.Bowsher,

Good day!

Regarding to your furthermore question, I supposed that you are asking if we would like to put 510(K) Summary on 510(K) database?

If this is correct, we prefer to put Statement Only.

Thanks very much for your attention.

With my best regards,
Grace Chang
Well Life Healthcare

----- Original Message -----
From: Bowsher, Kristen
To: 'Grace(welllifehealthcare)'
Sent: Tuesday, May 25, 2004 7:21 PM
ıbject: RE: K040512

510(k) Summary?

-----Original Message-----
From: Grace(welllifehealthcare) [mailto:grace@welllifehealthcare.com.tw]
Sent: Sunday, May 23, 2004 9:50 PM
To: Bowsher, Kristen
Subject: Re: K040512

Dear Dr. Bowsher,

Firstly, I owe you my deeply apology to reply your e-mail till now.

Thanks very much for your review to our revised report.

Here enclosed with this mail, we would like to provide the revised Indication For Use.

Hopefully our additional information could help you complete your review work.

Best regards,
Grace Chang
Well LIfe Healthcare

----- Original Message -----
From: Bowsher, Kristen

8

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

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To: 'grace@welllifehealthcare.com.tw'
Cc: Bowsher, Kristen
Sent: Wednesday, May 19, 2004 11:44 PM
Subject: K040512

Dear Ms. Chang:

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Please let me know that you have received this email and will respond to the request.

Kristen A. Bowsher, Ph.D.
FDA

9

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Indications For Use

510(k) Number (if known): K040512

Device Name: Limited Function WL/OTC-TENS / Model: WL-2401, WL-2402, and WL-2403.

Indications For Use:

- The model WL-2402, WL-2403 TENS 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.
- The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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)

10

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Kristen Bowsher

Subject: 510(k) Number K040512/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☐ A 510(k) summary OR ☒ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ N

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: [signature] (Branch Chief) K&DB (Branch Code) 4/28/04 (Date)

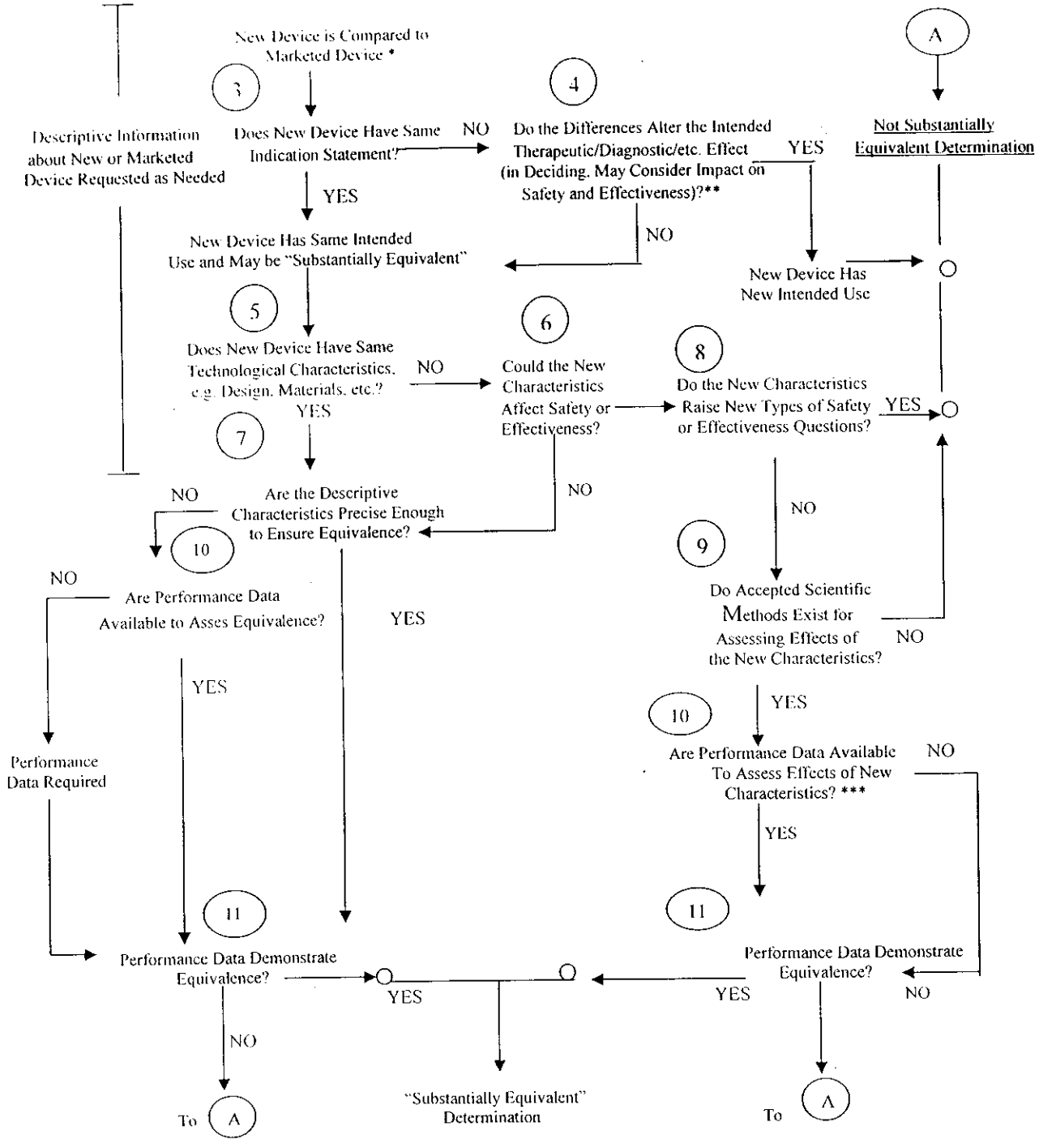
Final Review: (Division Director) (Date) 90

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

Revised:4/2/03

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

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

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

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

510(k) MEMO

DATE: 4-27-04

FROM: Kristen A. Bowsher, Ph.D., Biomedical and Electrical Engineer KAB
ODE/DGRND/REDB

SUBJECTS: Well-Life Healthcare, Inc. - Models WL-2103A, WL-2203A and WL-2203B and Model WL-2401 Limited Function OTC TENS

TO: K040512/S1

Background

A letter requesting additional information was sent to the sponsor on March 12, 2004. This supplement is in response to that letter.

This 510(k) contains two completely separate devices for two completely separate indications. However, both devices are classified as TENS devices. The question as to whether the two devices could be "bundled" in the same submission was raised to Bob Gatling and Heather Rosecrans of 510(k) Staff. It was determined that "bundling" was appropriate in this case.

Responses to Deficiencies

(b)(4)

[redacted]

93

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

(b)(4)

[redacted]

9H

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

Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) KRISTEN BOWSHER

Subject: 510(k) Number K 040512

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☐ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☐ A 510(k) summary OR ☐ A 510(k) statement Both

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 d

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: (Branch Chief) (Branch Code) 3/11/04 (Date)

Final Review: (Division Director) Mark N Melkerson 3/12/04 (Date) 227

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

Revised:4/2/03

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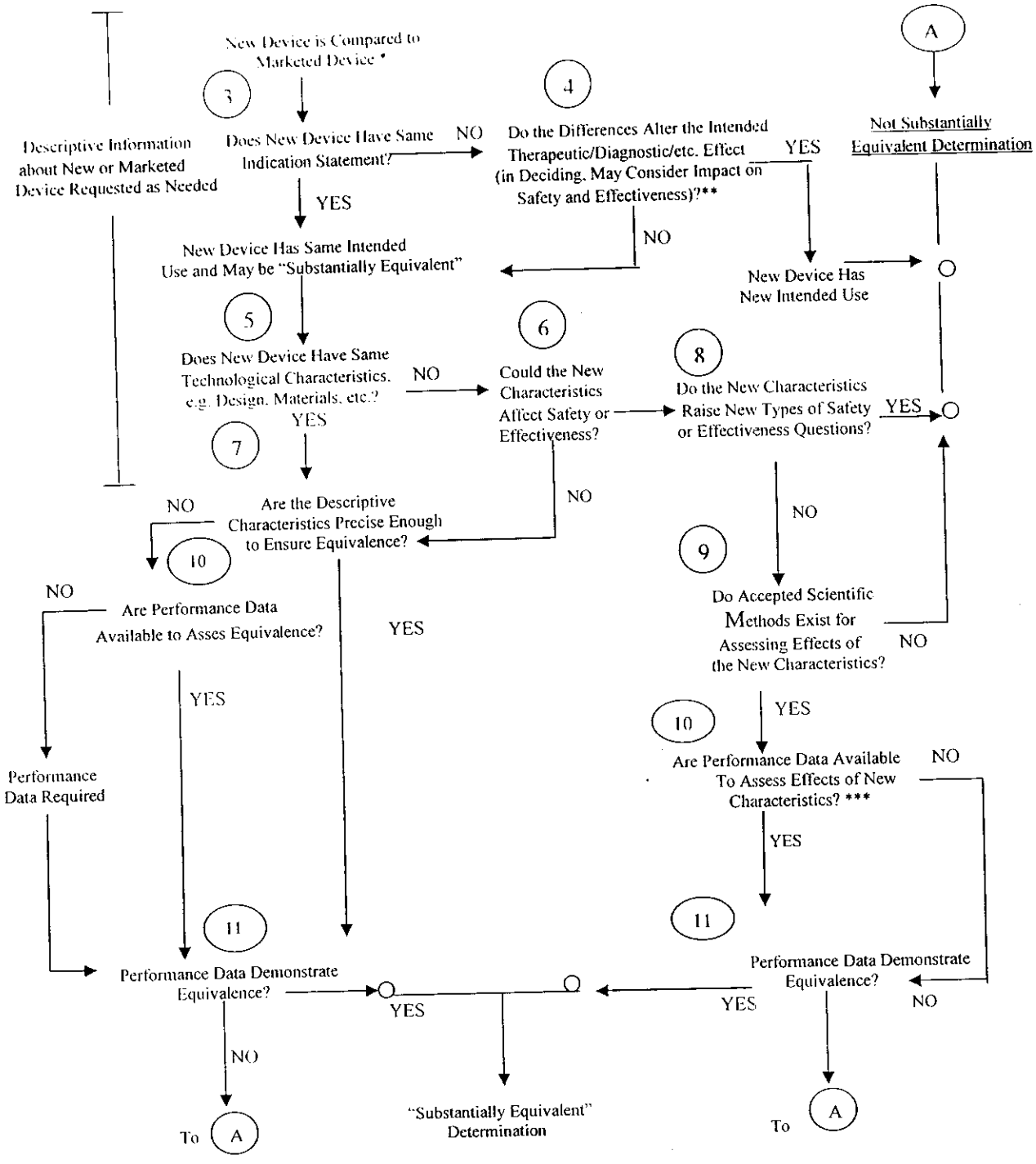
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

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

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

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

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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 required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

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is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

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Date: _____

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

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why t questions are not new:

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

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes? N/A		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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510(k) MEMO

DATE: 3-9-04

FROM: Kristen A. Bowsher, Ph.D., Biomedical and Electrical Engineer KAB
ODE/DGRND/REDB

SUBJECTS: Well-Life Healthcare, Inc. - Models WL-2103A, WL-2203A and WL-2203B and Model WL-2401 Limited Function OTC TENS

TO: K040512

This 510(k) contains two completely separate devices for two completely separate indications. However, both devices are classified as TENS devices. The question as to whether the two devices could be "bundled" in the same submission was raised to Bob Gatling and Heather Rosecrans of 510(k) Staff. It was determined that "bundling" was appropriate in this case. See attached email.

510(k) Statement or Summary
The sponsor has provided both a 510(k) Statement and a 510(k) Summary. They must provide either one or the other but not both. Therefore, they should specify which one they would like to use in the submission.

Models WL-2103A, WL-2203A and WL-2203B ("Limited Function WL/OTC TENS")

Indications for use
For the 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.

Request is for over-the-counter (OTC) use.

Comments
The indication is consistent with those cleared for the legally marketed predicate to which they are claiming substantial equivalence (i.e., the UltraStim Kit manufactured by Axelgaard Mfg. Co, Ltd. (K013532)).

Device Description and Predicate Device
The sponsor is claiming substantial equivalence to their previously cleared devices for the standard TENS indication of the symptomatic relief of chronic intractable pain and relief of acute post-surgical and post-traumatic pain: WL-2103A (K002874), WL-2203A (K033857) and the WL-2203B (K030537). The sponsor states that they have made the following changes to the cleared devices for this indication:

- "Change the fixing device so as to limit the device being used on some specified area.
- "Change the device label so as to state the limited use of the new devices."

For the new indication the sponsor is claiming substantial equivalence to the UltraStim Kit manufactured by Axelgaard Mfg. Co, Ltd. (K013532) which was cleared for the requested indication.

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Device & Predicate Device(s):	WL-2103A (K002874)	WL-2203A (K033857	WL-2203B (K030537)	UltraStim (K013532)
Basic Unit Characteristics:				
Power Source	Battery	Battery	Battery	Battery
Method of Line Current Isolation	?	?	?	?
Number of Output Channels	2	2	2	2
Number of Output Modes	7	7	3	5
Timer Range (min)	60	15-60	15-60	60
Compliance with 21 CFR 898	Yes	Yes	Yes	Yes
Output Specifications:				
Waveform (e.g., monophasic, bi-phasic)	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Max output voltage (V) @ 500 Ω (± ___ %)	40	40	40	40
Max output current (mA) @ 500 Ω (± ___ %)	80	80	80	80
Pulse Width	30-260	30-260	30-260	30-260
Frequency (Hz)	2-150	1-150	1-160	1-150
Max Phase Charge (μC) @ 500 Ω	20.8	20.8	20.8	20.8
Max Current Density (mA/cm^2)	Electrode Info not provided	Electrode Info not provided	Electrode Info not provided	?
Max Power Density (W/cm^2)	Electrode Info not provided	Electrode Info not provided	Electrode Info not provided	?
ON time (seconds)	?	?	?	**N/A**
OFF time (seconds)	?	?	?	N/A

Comments

The sponsor should provide the following additional information:

- You are requesting clearance for the following three models: the WL/OTC-TENS WL-2103A, the WL/OTC-TENS WL-2203A and the WL/OTC-TENS WL-2203B. However, it is not clear how these models differ from each other. Therefore, please provide a listing of all differences between the three models (e.g., output modes for each model, timer control, output specification ranges and controls,

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(b)(4)

[redacted]

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Please refer to the following documents, which were used in review of your patient labeling:

Guidance on Medical Device Patient Labeling, Final Guidance for Industry and FDA Reviewers (issued 4/19/01). Copies are available at http://www.fda.gov/cdrh/ohip/guidance/1128.pdf

(b)(4)

[redacted]

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

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(b)(4)

[redacted]

Questions? Contact FOIA@CDRH/OCE/DIB at CDRH-FOIA-OCE@ida.hhs.gov or 301-796-8110

(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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(b)(4)

[redacted]

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

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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

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(b)(4)

[redacted]

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

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Bowsher, Kristen

ɔm: Gatling, Bob
ɹnt: Tuesday, March 09, 2004 5:39 PM
To: Bowsher, Kristen
Cc: Stevens, Ted; Rosecrans, Heather S.
Subject: RE: K040512 - OTC TENS. Bundling issue?

Kristen, thanks for the information that you sent me on this file; it helped a lot. I believe that these can be bundled in one submission because this situation meets one of the criteria for bundling as listed in the guidance - these are of the same type (TENS) but have different indications for use. As such, these will "sink or swim" together. So if one is OK but the other has remaining questions, then both are held up. If one device is going to be an NSE decision, then the decision is NSE. If that might be the case, let's discuss the appropriate steps before you talk to the firm. The submitter can always break out one of these and send in a new 510(k) for it. If you want to talk about this file, please let me know. Sorry for the delay.

Bob Gatling
Director, Program Operations Staff
Office of Device Evaluation
301-594-1190x140

-----Original Message-----
From: Bowsher, Kristen
Sent: Tuesday, March 09, 2004 12:36 PM
To: Gatling, Bob; Rosecrans, Heather S.
Cc: Stevens, Ted
Subject: FW: K040512 - OTC TENS. Bundling issue?

Any decision? I have almost completed my review(s) and need to know how to proceed.

Thanks!

Kristen

-----Original Message-----
From: Bowsher, Kristen
Sent: Thursday, March 04, 2004 8:25 AM
To: Gatling, Bob; Rosecrans, Heather S.; Stevens, Ted
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

This is a summary of the submission:

First Device:
TENS for OTC use for low back pain

Description: Consists of electrodes attached to a back support belt with lead wires connected to a hand held stimulator

History: I believe FDA has only cleared one device for OTC use for this specific claim. It requires very clear labeling, comparison with output specification for this specific indication which falls under the general TENS claim and we required a usability study from the device we cleared.

Second Device
TENS device for the relief of nausea and vomiting due to motion sickness and pregnancy

Description: Watch like device with electrodes that stimulate the bottom of the wrist

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History: I believe FDA has only cleared three devices for OTC use for this specific claim. It requires very clear labeling, comparison with output specification for this specific indication which falls under the general TENS claim and if the output specification are different from the predicate clinical data has been required. Two of the cleared devices required clinical data.

Hope this helps!

Kristen

-----Original Message-----
From: Gatling, Bob
Sent: Wednesday, March 03, 2004 4:04 PM
To: Bowsher, Kristen; Rosecrans, Heather S.; Stevens, Ted
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

Clarification needed - is electroacupuncture (BWK) part in the same regulation as the TENS (GZJ)? Also, are there other devices like these on the market that are OTC? Thanks

Bob Gatling
Director, Program Operations Staff
Office of Device Evaluation
301-594-1190x140

-----Original Message-----
From: Bowsher, Kristen
Sent: Wednesday, March 03, 2004 3:24 PM
To: Rosecrans, Heather S.; Stevens, Ted; Gatling, Bob
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

Any decision yet?

-----Original Message-----
From: Rosecrans, Heather S.
Sent: Tuesday, March 02, 2004 11:16 AM
To: Bowsher, Kristen; Stevens, Ted; Gatling, Bob
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

Hi,
Did you all check with the guidance. It does allow multiple devices of the same classification in one 510k. I still think it fits. Bob?

-----Original Message-----
From: Bowsher, Kristen
Sent: Tuesday, March 02, 2004 11:13 AM
To: Rosecrans, Heather S.; Stevens, Ted; Gatling, Bob
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

They also have 2 separate instruction manuals if that helps (one for each device and its associated indications). From my perspective as a reviewer it is like reviewing 2 separate devices.

-----Original Message-----
From: Rosecrans, Heather S.
Sent: Tuesday, March 02, 2004 11:01 AM
To: Stevens, Ted; Bowsher, Kristen; Gatling, Bob
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

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Hi Bob,
Do you want to "rule" on this since you are the bundling guru?

-----Original Message-----
From: Stevens, Ted
Sent: Tuesday, March 02, 2004 10:53 AM
To: Rosecrans, Heather S.; Bowsher, Kristen
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

I still don't they belong bundled.

-----Original Message-----
From: Rosecrans, Heather S.
Sent: Tuesday, March 02, 2004 10:53 AM
To: Bowsher, Kristen; Stevens, Ted
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

Then doesn't that make a better case for bundling?

-----Original Message-----
From: Bowsher, Kristen
Sent: Tuesday, March 02, 2004 9:23 AM
To: Rosecrans, Heather S.; Stevens, Ted
Cc: Hinckley, Stephen M.
Subject: RE: K040512 - OTC TENS. Bundling issue?

I believe Steve Hinckley had the electro acupuncture procode removed from the classification of the ReliefBand and replaced it with the TENS procode only. Steve -- am I correct?

-----Original Message-----
From: Rosecrans, Heather S.
Sent: Monday, March 01, 2004 3:41 PM
To: Stevens, Ted; Bowsher, Kristen
Subject: RE: K040512 - OTC TENS. Bundling issue?

I thought the wristband was classified under TENS last time (electro acupuncture).

-----Original Message-----
From: Stevens, Ted
Sent: Monday, March 01, 2004 3:39 PM
To: Rosecrans, Heather S.; Bowsher, Kristen
Subject: RE: K040512 - OTC TENS. Bundling issue?

Really? This is two completely separate devices, for two completely separate indications, with two completely separate classifications.

Device 1: TENS pulse generator + cutaneous electrodes for pain, procode GZJ, classified at 21 CFR 882.5890

Device 2: wristband stimulator for nausea, procode BWK (electroacupuncture), pre-amendments unclassified.

Each has separate indications for use with no overlap.

Indications for use, classification, output parameters, device configuration, are all different.

-----Original Message-----
From: Rosecrans, Heather S.
Sent: Monday, March 01, 2004 2:52 PM
To: Stevens, Ted; Bowsher, Kristen
Subject: RE: K040512 - OTC TENS. Bundling issue?

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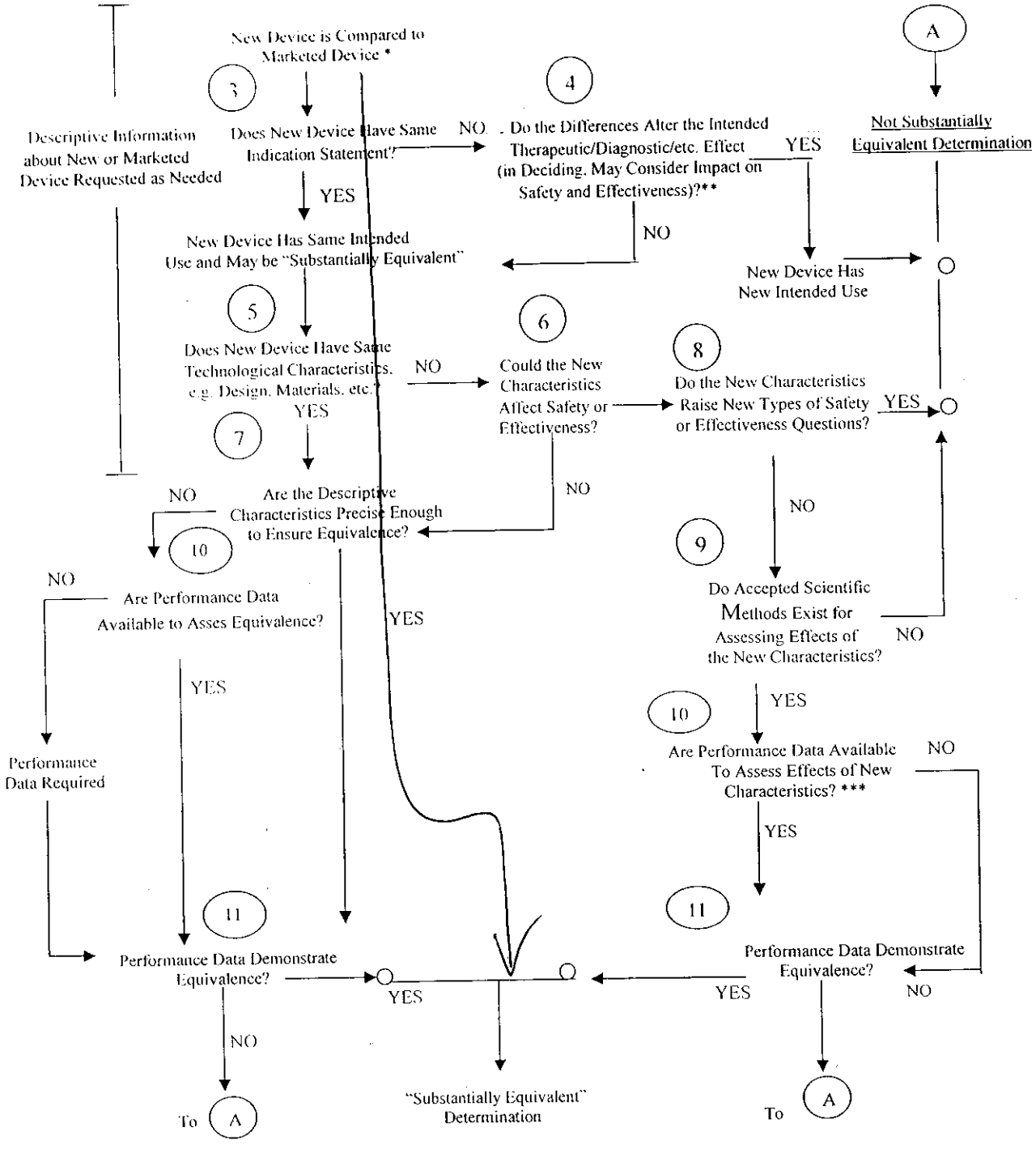
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

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

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

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

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K040512/S1

Well-Life Healthcare Inc.

Dear Mr. Witten,

This mail is to response to the FDA review comments for our 510(k) Submission (K040512). For this review comment, we have applied for the extension of time (see application letter).

Based on this extension time application, we believe our response is still within the time limit of receiving our additional information.

Because too much information is to be provided, we would like to separate our additional information into two parts:

- Part I. Response and Additional Information.
- Part II. Revised User Manual.

Please review our additional information provided hereafter.

Thank you very much!

Best Regard,

Grace Chang

Official Correspondent
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

SK3

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

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

Re: K040512
Trade name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS

Dear Mr. Witten:

Thank you very much for the review comments of our 510(k) submission (K040512).

As requested in your review comments, we have to provide additional information so as to response to your comments within 30 days.

Because too much information is to be provided according to your comments, we are not able to complete our information with this time limit.

Therefore, we need more time to complete our information. Please kindly allow the extension of time, and give us the information when is the time limit for our additional information if our request for extension of time is allowed.

Sincerely yours,

Grace Chang
Well-Life Healthcare, Inc.
1FL, NO. 16, Lane 454
Jungjeng Rd., Yunghe City
Taipei County, Taiwan, R.O.C.

845155303129

Fedex
Grace

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Part I. Response and Additional Information

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Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

Well-Life Healthcare Inc.

Re: K040512

Trade Name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS

To: Celia M. Witten, Ph.D., Director

From: Grace Chang

Date: February 27, 2004

Dear Celia M. Witten,

Thank you very much for your quick review to our 510(k) submission. For your review comments, basically we have revised our labeling for individual model. The revised manuals are provided in part II of our response.

In this part (Part I), we would like to provided our response to your comments one by one, and then attach the additional information so as to indicate what we have done.

Please see the following statement and attachment for the answer to your review comment.

Comment 1
1. You are requesting clearance for the following three models: the WL/OTC-TENS WL-2103A, the WL/OTC-TENS WL-2203A and the WL/OTC-TENS WL-2203B. However, it is not clear how these models differ from each other. Therefore, please provide a listing of all differences between the three models (e.g., output modes for each model, timer control, output specification ranges and controls, etc.).

(b)(4)

[redacted]

Comment 2
2. On page of the instruction manual you state that the devices contain several output modes (i.e., B, N, M, MR, MRW, SDR, and SDW). Please provide a complete description of each output mode (e.g., waveform, amplitude, frequency, pulse width, bursts, etc.). Waveform tracings for each output mode should also be provided.

(b)(4)

[redacted]

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The operation modes for WL-2103A, and WL-2203A are "B, C, M".

To describe clearly about the operation modes for each model, we would like to provide and additional information for the explanation of every operation mode in attachment 2-1, and then provide the waveform tracings for each mode in attachment 2-2.

Basically the waveform tracings were abstracted from the information of our previous 510(k) submission.

Comment 3
3. You state that your devices have two channels each. However, you only have two electrodes (one electrode set) and it is not clear how these channels are associated with the two electrodes. Please provide a a discussion as to how each channel controls the two electrodes.

(b)(4)

[redacted]

Comment 4
4. Please provide a complete description of the electrodes supplied with your device (i.e., sizes and materials). If the electrodes to be supplied with your device are legally marketed please provide the document tracking number (i.e., 510(k) number) under which they were cleared for marketing. If the electrodes are not legally marketed please verify that the biocompatibility testing provided in your submission was performed on the electrodes supplied with your devices.

(b)(4)

[redacted]

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Comment 5
5. Please provide the current density, charge density and power density of your devices when used with the smallest available electrodes for use with the devices.

(b)(4)

[redacted]

Comment 6
6. Please discuss whether various belt sizes are available. If so, please provide the sizes and revise the instruction manual to discus how to choose the appropriate size. If not, please revise the labeling to discuss how to properly adjust the belt according to waist size.

(b)(4)

[redacted]

Comment 7
7. Because of the level of risk associated with the indications for use of your device for OTC use you should perform a usability study to answer the following questions: a. Can the user identify whether they are an appropriate candidate for use of the device? b. Can the user use the device properly based on the instructions for use (i.e., choose the correct belt size they should use, apply electrodes to belt properly, adjust stimulation properly, choose appropriate output modes to use, etc.)?

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(b)(4)

[redacted]

Comment 8
8. Since you are requesting to market this device OTC, i.e., without a prescription, the instructions for use need to provide the lay reader with information regarding risks, benefits, alternatives, instructions for how the device is to be used, etc. Patient labeling should be understood by users with the average reading ability in the United States, i.e., 6th to 8th grade level. In many sections, the writing style you use is too complex and instructions for setting up and using the device are not clear.

(b)(4)

[redacted]

Comment 9
9. Your instruction manual includes many misspelled words, e.g., "stimnlator", "children", "pregnancu", "throal", "soasms", "electrides", "canution", "Phsician", etc. Please carefully review your instruction manual and correct all misspellings.

(b)(4)

[redacted]

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Comment 10

10. Please revise the instruction manual and your package labeling to include the following contraindications, warnings, and precautions. Note that you have provided some of them in the manual already but they may not be adequate for OTC labeling (i.e., understandable to the "lay person") and/or may not be under the appropriate heading. Therefore you should review your manual and modify accordingly. You should include these statements prominently in the device user manual. You may make a warning or precaution a contraindication but may not make a contraindication a warning or precaution and likewise for warnings and precautions. You may revise these statements to be more (but not less) restrictive and additional items may be included to provide further limitations or instructions regarding the use of the device. In addition, some statements may not be applicable to some devices due to particular design characteristics, for example. These statements are not intended to capture all possible limitations and instructions for all possible transcutaneous electrical stimulators. Therefore, you are encouraged to consider including additional specific contraindications, warnings, precautions, and/or other instructions necessary to address any device-specific issues or concerns.

(b)(4)

[redacted]

Comment 11

11. Please revise your instruction manual to include the following precaution in bold faced font: "If your pain does not improve, becomes more than mild or if it continues for four to six days, stop using the device and consult your physician."

(b)(4)

[redacted]

Comment 12

12. Please revise your labeling so that it conforms to the following:

a. Graphics and text could be printed using these combinations: black print on white paper, black print on yellow paper, dark blue print on white paper, or grass green on white paper. The line drawings should include only necessary detail. Key items should be labeled, using arrows, if necessary.

b. Use simple, clearly drawn line drawings on a white background, which are easy to understand and easy to photocopy. Photos may have distracting extra images and poor contrast. Use arrows to identify items of interest.

c. Be certain to maintain legibility in the final version by using a serif-type font of at least 12 point and small blocks of text to make use of "white space." The elderly and those with impaired vision would benefit from at least 14-point type.

d. Use non-glossy paper.

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<Response> Our labeling has been revised according to this general requirement. Please check the additional information provide in part II.

Comment 13
13. Please either include a separate instruction manual for each specific model or provide separate sections with instructions for use for each specific model.

(b)(4) [redacted]

Comment 14
14. Please revise your instruction manual to include clearly labeled pictures or diagrams of each component of your system. You should also clearly label the key aspects of each component (i.e., stimulator control knobs, lead wire connections, electrode connectors, etc.). Your instructions for applying the device and adjusting stimulation levels should refer to these pictures.

(b)(4) [redacted]

Comment 15
15. The predicate device to which you claim substantial equivalence, the UltraStim Kit, differs from your device in that it uses four separate electrodes with two independently controlled channels and the electrode are smaller. The predicate device instruction manual also includes specific instructions for ensuring proper electrode placement on the belt and location on the lower back to achieve pain relief. Therefore, please provide a valid scientific rationale for using the electrode arrangement you have selected for your device for the requested indication for use. Additionally, please revise your instruction manual to provide instructions to the user for determining proper pad placement for the pain relief. Note that with a prescription TENS device the health care provider will help the patient adjust the electrodes, belt and output settings to the right location for pain relief. Your instructions need to be able to instruct the user on how to do that without a medical practitioner.

(b)(4) [redacted]

Comment 16
16. Please provide instructions on how to put on the support belt including where on the waist the belt should be placed. For example, should the belt be placed over, under, on top of, etc. the belly button? How should the user ensure that they consistently apply the belt in the correct location to achieve pain relief? Pictures may be helpful.

(b)(4) [redacted]

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

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Comment 17
17. Please remove the following statement, "You can use it home to relieve your pain quickly and effectively, wherever and whenever you want". This statement is misleading because there are certain times (e.g., while sleeping) and places (e.g., shower, driving, etc.) the device should not be used.

(b)(4) [redacted]

Comment 18
18. Please provide instructions for determining when new electrodes are needed and for replacing the electrodes (i.e., use only electrodes supplied by manufacturer and where and how to order them).

<Response> The information to determine when new electrode are needed has been provided in our revised manual. Please see information in attachment 12 and our revised user manual.

Comment 19
19. Your instructions on page 4 of your instruction manual under the heading "How to Use WL/OTC-TENS Device" are unclear. Please revise them to provide concise instructions. You should specifically provide the following at a minimum: a. The instructions should be numbered according to the order of application and not bulleted. Individual instructions for the following should be provided: inserting the battery, applying the electrodes to the belt, connecting the lead wires to the belt or electrodes, connecting the lead wires to the stimulator, putting on the support belt, turning on the stimulator and, choosing the appropriate output settings, and defining what each setting means, turning off the stimulator, cleaning and storing the device, and how and when to get replacement parts. Pictures and clearly labeled headings for each instructional step are recommended. b. You state, "Put on the stimulation module and turn it on." This should be revised to provide clearly labeled separate instructions for how to attach electrodes, how to put on the support belt including where on the waist the belt should be placed (e.g., should the belt be placed over, under, on top of, etc. the belly button and how should the user ensure that they consistently apply the belt in the correct location to achieve pain relief?), how to attach the lead wires, and how to turn the device on. c. You instruct the user to "Select stimulation pattern" and "Adjust the intensity level". Please revise these instructions to include instructions for determining the appropriate "stimulation pattern" and "intensity level" for pain relief.

<Response> The required information as requested by this comment has been provided in the revised user manual. Please see the information provided in attachment 11 and the revised user manual.

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

Exemption 4 and 5 CCI and Internal Memoranda

Exemption 4 and 5 CCI and Internal Memoranda

Exemption 4 and 5 CCI and Internal Memoranda

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Att1

ATTACHMENT 1

Difference Comparison between WL-2103A, WL-2203A, and WL-2203B

§1. Main Specification Comparison

Please see the information of the following table.

Features	*Models*		
	WL-2103A	*WL-2203A*	*WL-2203B*
510(k) Number	K002874	K0033857	K030537
Manufacturer	Well-Life	Well-Life	Well-Life
Classification	Class II	Class II	Class II
Basic Specification Comparison			
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual	Dual
Power supply	9 volt battery	9 volt battery	9 volt battery
Circuit designed	Analog	Digital	Digital
Software	Yes	Yes	Yes
Amplitude (mA)	0-80	0-80	0-80
Pulse rate (Hz)	2-150	2-150	1-160
Width (μs)	30-260	30-260	50-260
Power ON indicator	LED	LCD	LCD
Timer (min)	C, 15, 30	C, 10 ~ 60	C, 10 ~ 60
Weight (grams) (batt. Include)	135	142	142
Size (mm)	92×62×25	110×62×27	110×62×27
Prescription or OTC	OTC	OTC	OTC
Operation Mode	B, C, M	B, C	B, C, M, SDR, SDW
Indication for use	All models as above mentioned 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.		

§2. Description of difference

Based on the information provide in the comparison table the main difference may be described as the following items.

1> The circuit design: WL-2103A is analog type, WL-2203A and WL-2203B are digital type.

2> The pulse rate range: for detail information, see comparison table.

3> The pulse width range: for detail information, see comparison table.

4> Indicator type: for detail information, see comparison table.

5> Timer control: for detail information, see comparison table.

6> Size and weight: for detail information, see comparison table.

7> Operation Mode: for detail information, see comparison table.

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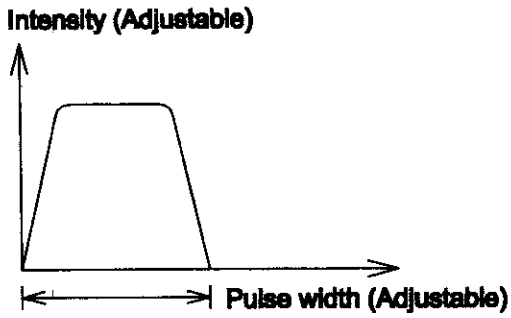
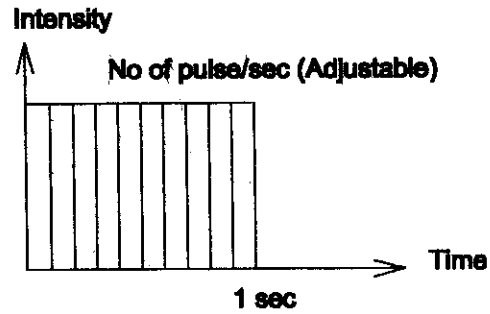
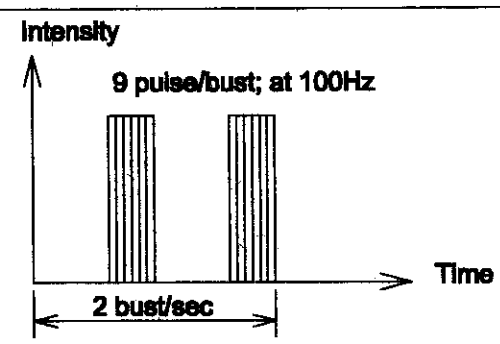
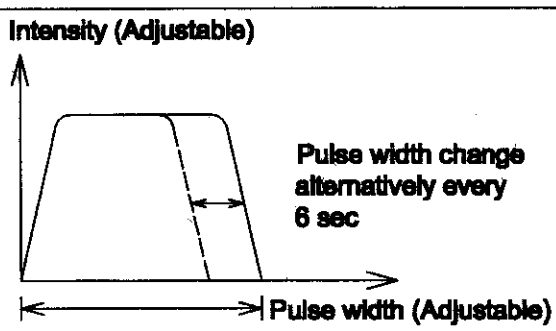
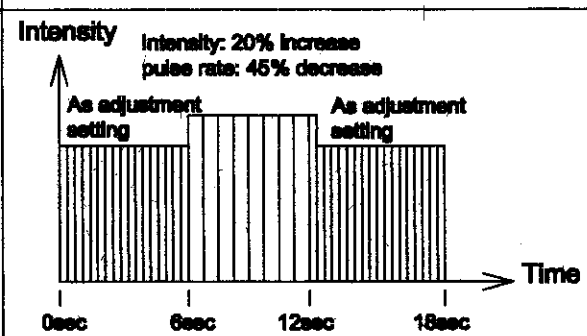
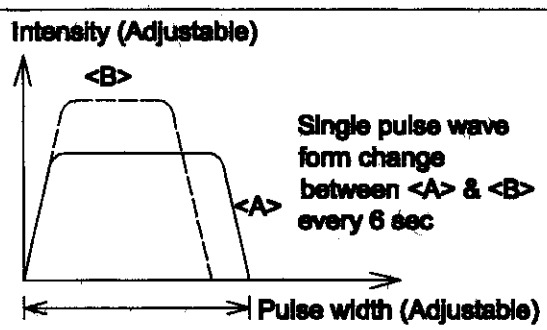
ATTACHMENT 2-1

Records processed under FOIA request - partial release on Oct 22, 2014

Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
C or N		
B	Identical to that of C Mode	
M or MR		Identical to that of C Mode
SDR	Identical to that of C Mode	
SDW		Identical to that of C Mode

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Att2

ATTACHMENT 2-2

Wave form

Basically, the diagrams of wave form are indicated as in the following table. All the information of wave form are provided in photos hereafter.

(b)(4)

[redacted]

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ATTACHMENT 2-2

The Waveform of WELL-LIFE TENS

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 2-2

(b)(4)

(b)(4)

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

H' 115

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 2-2

(b)(4)

[redacted]

(b)(4)

[redacted]

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

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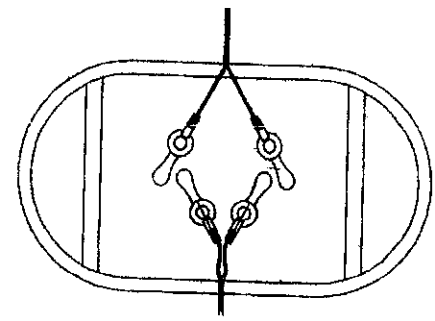
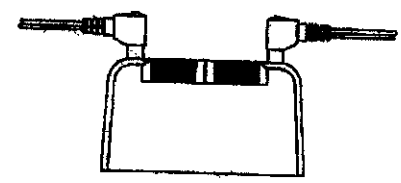
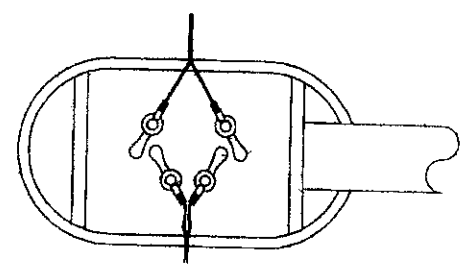
ATTACHMENT 3

Description of operation	Diagram Indication
Step 4 – Connecting snap cables	
Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro in two sides. Take one cable, and snap two connectors onto the metal snaps on one side of the thumbhole. Repeat with second cable for the other side of the thumbhole. Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket.	 Channel 1 Channel 2 
Step 5 – Choose elastic waist band	
For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those pads are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. After the elastic waist band is chosen connect the band with one side of Velcro in support belt. For the connection of band and Velcro, be sure to place the band at the center part of Velcro and close to the sewing line of Velcro part and blue electrode connection part.	L: For 46" ~ 38" waist size. M: For 36" ~ 28" waist size. S: For 28" ~ 20" waist size. 
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions.	

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

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Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2001

ATTACHMENT 4

Ms. Janis Yang
General Manager
Wandy Rubber Industrial Co., Ltd.
Number 22, Allay 37, Lane 266
Fu Teh I Road
Shi-Chih, Taipei
Taiwan

Re: K002219
Trade Name: Wandy Self-Adhesive Neurostimulation Electrodes
Regulatory Class: II
Product Code: GXY
Dated: October 27, 2000
Received: November 6, 2000

Dear Ms. Yang:

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

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ATTACHMENT 4

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) 594-4595. 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/dsma/main.html".

Sincerely yours,

for Mark N Melkerson

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

Enclosure

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

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ATTACHMENT 5

8.1.2. Discussion of comparison for group 1 models.

For both the chosen 510(k) cleared device and our new device provided the following accessories to attach the stimulation unit on abdominal area for the specified indication for use of device:
1 Support Belt
1 TENS Stimulator
1 package of self-adhesive pads
1 set of plastic Storage Liners (not shown)
1 pair of Snap Cable
1 User Manual (not shown)
1 9-volt Alkaline Battery

The main difference exists in the stimulation output. This difference may cause some impact on the performance and safety. The possible impact was evaluated hereafter.

As information from the manufacturer of UltraStim Lit, the stimulation specification is as the indication of the following table.

Program	Max. Amplitude	Phase duration	Rate	Cycle Time
1	80mA	200μs	50Hz	10 Seconds
2	80mA	200μs	60-100Hz	10 Seconds
3	80mA	120-72μs	80Hz	10 Seconds
4	80mA	260-78μs	100Hz	15 Seconds
5	80mA	260μs	3-5Hz	15 Seconds

For our new device, the stimulation specification is as the indication of the following table.

Model	Max. Amplitude	Phase duration	Rate	Cycle Time
WL-2103A	80mA	30-260μs	2-150Hz	60 minutes
WL-2203A	80mA	50-260μs	1-160Hz	15-60 minutes
WL-2203B	80mA	30-260μs	1-150Hz	15-60 minutes

Based on the information as above mentioned, the safety for the stimulation output may be calculated as the following details.

For the UltraStim Kit (K013532)
<1> Maximum phase charge = 0.26 ms × 80mA = 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)x(35x0.26) = 27.28μc
<3> Maximum average current (measured at program 4/80mA; 260μs; and 100Hz)
= maximum charge per pulse × No. of pulse per second
= 20.8μc × 100 = 2080μA = 2.08mA
<4> Maximum Current Density (A/cm^2) @ 500Ω
= maximum average current / cross-sectional area
= 2.08mA / (4x4) = $0.13mA/cm^2$
<5> Maximum power density = Maximum current density × Voltage
= 0.13x40 = $5.2mVA/cm^2$ = $0.052W/cm^2$

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ATTACHMENT 5

For WL-2103A, and WL-2203A (New Device)

<1> Maximum phase charge = 0.26 ms × 80mA = 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)x(35x0.26) = 27.28μc

<3> Maximum average current (measured at 80mA; 260μs; and 150Hz)

= maximum charge per pulse × No. of pulse per second

= 20.8μc × 150 = 3120μA = 3.12mA

<4> Maximum Current Density (A/cm^2) @ 500Ω

= maximum average current / cross-sectional area

= 3.12mA / (4x4) = 0.195mA/cm^2

<5> Maximum power density = 0.195x40 = 7.8mVA/cm^2 = 0.078 W/cm^2

For WL-2203B (New Device)

<1> Maximum phase charge = 0.26 ms × 80mA = 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)x(35x0.26) = 27.28μc

<3> Maximum average current (measured at 80mA; 260μs; and 150Hz)

= maximum charge per pulse × No. of pulse per second

= 20.8μc × 160 = 3328μA = 3.328mA

<4> Maximum Current Density (A/cm^2) @ 500Ω

= maximum average current / cross-sectional area

= 3.328mA / (4x4) = 0.208mA/cm^2

<5> Maximum power density = 0.208x40 = 8.32mVA/cm^2 = 0.0832 W/cm^2

Summary for the safety comparison of stimulation output

Based on the calculation information as above mentioned, the main stimulation output characteristics may be listed as the following table.

Characteristic	Max. phase charge		Max. charge per pulse		Max. average current	
Limited value acc. to NS4	25μc		75μc		10mA	
Calculated value	K013532	New device	K013532	New device	K013532	New device
	20.8μc	20.8μc	27.28μc	27.28μc	2.08mA	3.12mA/3.328mA
Verdict	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Conclusions of group 1 comparison

For the comparison information provided in this clause, it is very clear that the following comparison conclusions could be made:

1> Both the chosen 510(k) clear model and our new device have the similar fixing device to provide the application of the similar stimulation position. So it is very reasonable that all the devices have the similar "indication for use".

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ATTACHMENT 5

2> The stimulation output may have some difference in output characteristics. However, all of the output characteristics are within the acceptable limits of ANSI/AAMI, NS4 standard. So they could be considered as appropriate stimulation output according to ANSI/AAMI NS4 standard.

3> Even though the stimulation output has different level, it does not effect the indication for use as well as the safety of operation. Therefore, the stimulation strength for both 510(k) cleared device and our new devices could adjusted by the patient or user without the involvement of physician.

Based on this reason, we would like to claim that our devices are also capable of being sold as OTC device as that chosen of 510(k) cleared device, UltraStim Kit (K013532).

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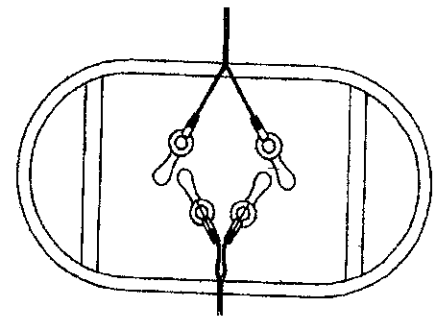
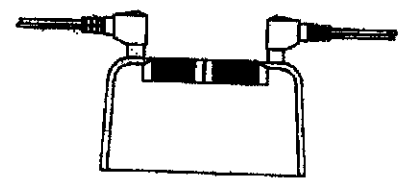
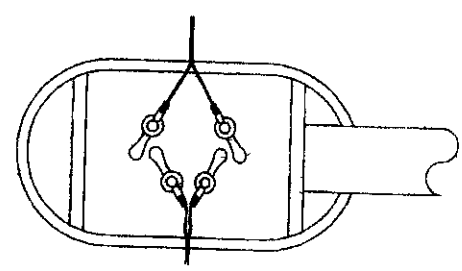
ATTACHMENT 6

Description of operation	Diagram Indication
Step 4 – Connecting snap cables	
Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro in two sides. Take one cable, and snap two connectors onto the metal snaps on one side of the thumbhole. Repeat with second cable for the other side of the thumbhole. Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket.	 Channel 1 Channel 2 
Step 5 – Choose elastic waist band	
For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those pads are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. After the elastic waist band is chosen connect the band with one side of Velcro in support belt. For the connection of band and Velcro, be sure to place the band at the center part of Velcro and close to the sewing line of Velcro part and blue electrode connection part.	L: For 46" ~ 38" waist size. M: For 36" ~ 28" waist size. S: For 28" ~ 20" waist size. 
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions.	

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ATTACHMENT 7

Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 place the pads on or around your head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.

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ATTACHMENT 8

Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 place the pads on or around your head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.

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ATTACHMENT 8

- The safety of using this System during pregnancy or birth has not been established.
- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System.

⚠ Use Caution and consult your Physician before using this 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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ATTACHMENT 9

- The safety of using this System during pregnancy or birth has not been established.
- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System.

⚠ Use Caution and consult your Physician before using this 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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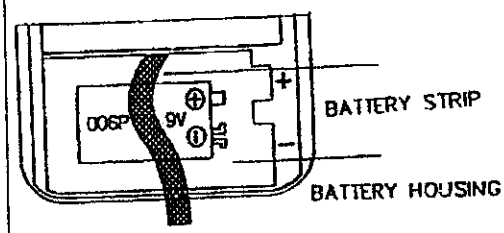
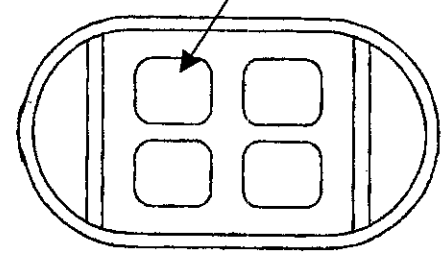
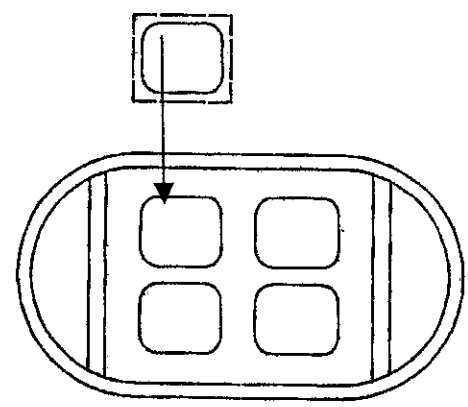
ATTACHMENT 10

Operation Instruction

Description of operation	Diagram Indication
Step 1 – Inserting the 9-volt battery into your Stimulator	
Make sure both power knobs on the stimulator are turned OFF. To insert the battery, slide the front cover downward until the cover pops off by pressing gently on the arrow and pulling, and insert a 9-volt battery according to the diagram in the battery compartment. Close the cover on the stimulator by sliding from the bottom up.	
Step 2 – Preparing Your Support Belt	Sliver conductive square
Lay your Support Belt open on a flat surface, with the electrode applying side facing up. You will see four silver conductive squares marked for the support belt.	 This side being faced upward.
Step 3 – Applying Electrode Pads to the belt	Four electrode pads, attached to the silver conductive squares
Electrode Pads help deliver continuously the stimulation pulses through your skin and into the nerves in your lower back. The pads are designed to fit within the four silver squares on the Support Belt. Open the package of four electrode Pads. Remove the plastic liner from the patterned side and then place the pad with the pattern side down. Repeat this process with the other three pads. IMPORTANT: Leave the other plastic liners with electrode pads until step 5. IMPORTANT: Each electrode pad shall be placed exactly on the silver conductive square, and be pressed firmly on the belt. IMPORTANT: Always use all four pads on the support belt when using the system.	

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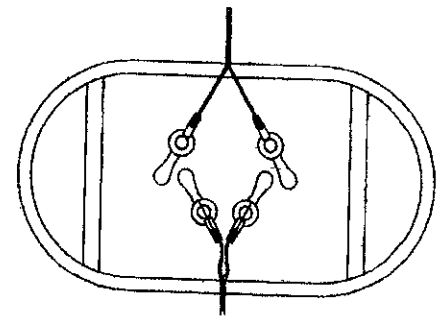
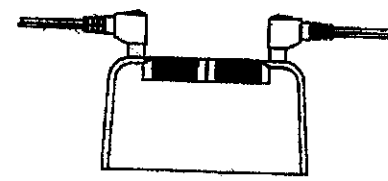
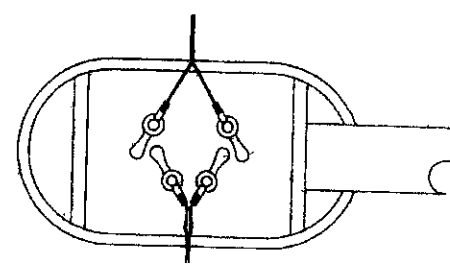
ATTACHMENT II

Description of operation	Diagram Indication
Step 4 – Connecting snap cables	
Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro in two sides. Take one cable, and snap two connectors onto the metal snaps on one side of the thumbhole. Repeat with second cable for the other side of the thumbhole. Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket.	 Channel 1 Channel 2 
Step 5 – Choose elastic waist band	
For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those pads are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. After the elastic waist band is chosen connect the band with one side of Velcro in support belt. For the connection of band and Velcro, be sure to place the band at the center part of Velcro and close to the sewing line of Velcro part and blue electrode connection part.	L: For 46" ~ 38" waist size. M: For 36" ~ 28" waist size. S: For 28" ~ 20" waist size. 
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions.	

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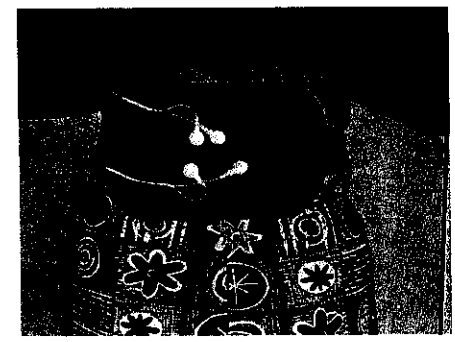
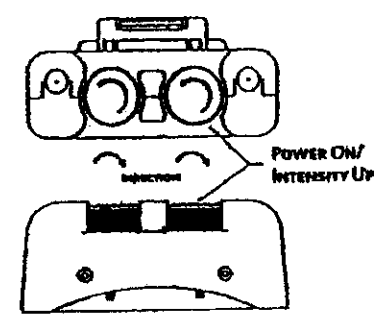
ATTACHMENT (

Description of operation	Diagram Indication
2> If your low-back pain is closer to your waist level than it is to the bottom of your back, place the support belt so that the middle of the belts rests at your waist. 3> If you feel pain closer to the lower part of your back, place the support belt so that the middle of the belt rests an inch or two below your waist. 4> Once you have the support belt in the position you want, fasten the elastic band firmly around your torso with both side of Velcro connected with both end of elastic band. 5> You can tighten or loosen the elastic band to adjust the fasten tension of elastic band so as to attach the support belt firmly belt adjusting the ends of the black tension strap on the outside of the belt and fastening them with their Velcro parches.	 Putting on the support belt.
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user.	
Step 8 – Adjust appropriate stimulation parameters	
The stimulation effect could be different due to the different combination of the following three parameters: - The pulse width (30 ~ 260μs): This parameter control the time duration of each single stimulation pulse. In general, the higher the pulse width, the higher the stimulation energy for each single stimulation pulse.	

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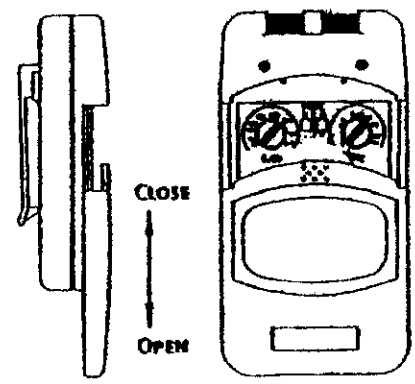
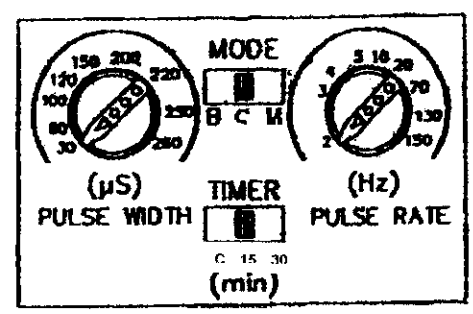
ATTACHMENT U

Description of operation	Diagram Indication
- The pulse rate (2 ~ 150Hz): This parameter control the number of output pulse per second. For instance "100Hz" means 100 stimulation pulses will be generated from stimulator for every second. In general, the higher the pulse rate, the more stimulation energy will be transmitted to user. - The stimulation Mode (B/C/M): This parameter control the output waveform of stimulator. The output characteristics of the stimulation modes is described as the followings: 1> B: Cycle Burst, 2Burst/sec, 9 pulses/Bursts, 100Hz width is adjustable. 2> C: Continuous mode. Pulse rate, pulse width and intensity are adjustable. 3> M: Modulated width. Pulse width vary automatically per interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value, then returns to the setting value. Rate, width and intensity are adjustable.	
For the adjustment of pulse width, pulse rate, and stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different combination of parameters will greatly affect the output characteristics of stimulator. However the combination difference will not cause too mush significant difference on the therapy result. More or less stimulation may have the similar therapy result, the pain relief on low back, and also within the same safety level, because the extreme stimulation output is within the safety operation range of ANSI/AAMI – NS4 standard. Based on this, we suggest you to change the combination of these three control parameters as well as the amplitude setting on both channels so as to have different stimulation output, as long as you feel the stimulation is comfortable and effective.	

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ATTACHMENT 11

Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between C, 15, and 30 for "continuous", "15min", and "30min". The stimulation will be continued until the expiration of setting time or until you switch off the stimulation. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of setting parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use. Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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ATTACHMENT 12

How to Store Your System

1. Store your 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.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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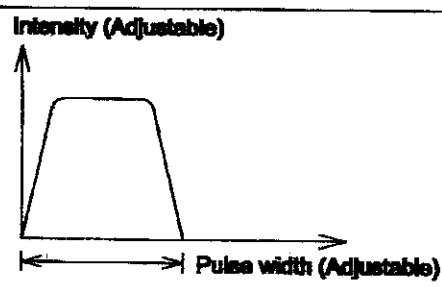
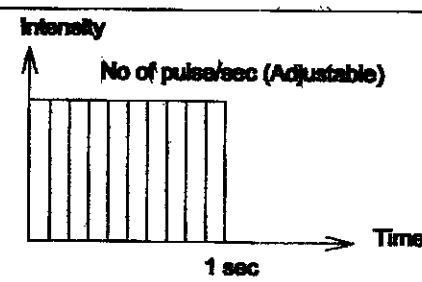
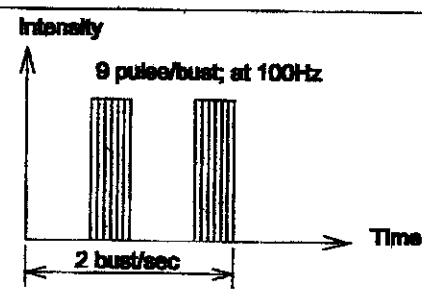
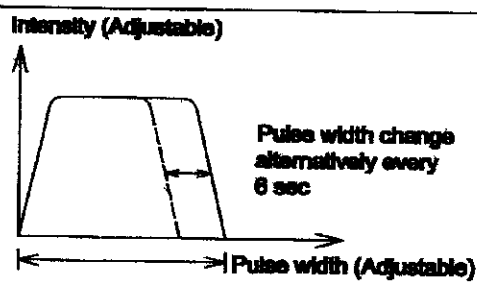
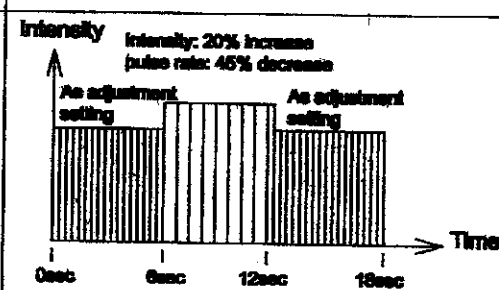
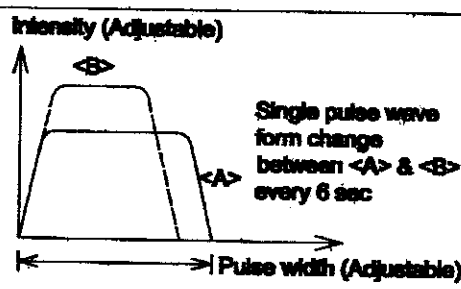
Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
C or N		
B	Identical to that of C Mode	
M or MR		Identical to that of C Mode
SDR	Identical to that of C Mode	
SDW		Identical to that of C Mode

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U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

ATTACHMENT 14

New Search Back To Search Results

510(k) Premarket Notification Database

Device Classification Name	Media, Electroconductive
510(K) Number	K983964
Regulation Number	882.1275
Device Name	Batch #6060 Conductive Gel
Applicant	Skylark Device Co., Ltd. 34 Chung Shan North Rd., 12th Fl., Sec. 3 Taipei, TW
Contact	George Chen
Product Code	GYB
Date Received	11/06/1998
Decision Date	12/09/1998
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Statement Only
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 4/5/2004

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8.2.2. Discussion of comparison for group 2 model.

For the accessories provided in this group of models, both the chosen 510(k) cleared device and our new device have included the accessories to place the stimulation device on wrist for stimulation treatment.

The main difference exists in the stimulation output. This difference may cause some impact on the performance and safety. The possible impact was evaluated hereafter.

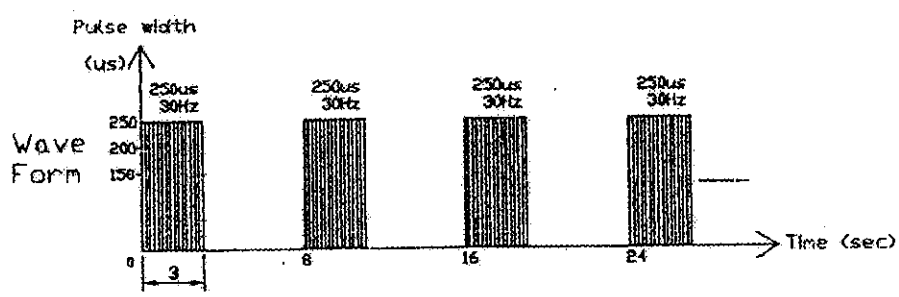
As information from the manufacturer of Relief Band, the stimulation specification is as the indication of the following table.

Program	Max. Amplitude	Phase duration	Rate	Cycle Time
1	10.5mA @500Ω	200μs	135Hz	No timer control
2	17.5mA @500Ω	200μs	135Hz	No timer control
3	24.5mA @500Ω	200μs	135Hz	No timer control
4	31.5mA @500Ω	200μs	135Hz	No timer control
5	35mA @500Ω	200μs	135Hz	No timer control

For our new device, the stimulation specification is as the indication of the following table.

Model	Outlook	Time for each operation cycle	Combination of wave form	Wave form information			
				Type	Pulse rate (Hz)	Pulse width (μs)	Time duration
Mini- TENS WL-2401	Type A	15 minutes	Single wave form (A)	A	30	250	3s/ON, 5s/OFF

The type A wave form is as the indication of the following drawing:



Based on the information as above mentioned, the safety for the stimulation output may be calculated as the following details.

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For the Relief Band (K020180)

<1> Maximum phase charge = 0.20 ms × 35mA = 7.0μc

<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)x(35x0.20) = 25.6μc

<3> Maximum average current (measured at program 35mA; 200μs; and 135Hz)
= maximum charge per pulse × No. of pulse per second
= 7.0μc × 135 = 945μA = 0.945mA

<4> Maximum Current Density (A/cm^2) @ 500Ω
= maximum average current / cross-sectional area
= 0.945mA / (2x1.5x1.5) = 0.134mA/cm^2 = $1.34x10^{-4}$A/cm^2

<5> Maximum power density @ 500Ω
= 0.134x17.5 = 23.45mVA/cm^2 = 0.0234W/cm^2

For WL-2401 (New Device)

<1> Maximum phase charge = 0.25 ms × 50mA = 12.5μc

<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)x(35x0.25) = 27μc

<3> Maximum average current (measured at 50mA; 250μs; and 300Hz)
= maximum charge per pulse × No. of pulse per second
= 12.5μc × 30 = 375μA = 0.375mA

<4> Maximum Current Density (A/cm^2) @ 500Ω
= maximum average current / cross-sectional area
= 0.375mA / (2x3) = 0.0625mA/cm^2 = $6.25x10^{-5}$A/cm^2

<5> Maximum power density @ 500Ω
= 0.0625x25 = 1.5625mVA/cm^2 = 0.00156W/cm^2

Summary for the safety comparison of stimulation output

Based on the calculation information as above mentioned, the main stimulation output characteristics may be listed as the following table.

Characteristic	Max. phase charge		Max. charge per pulse		Max. average current	
Limited value acc. to NS4	25μc		75μc		10mA	
Calculated value	K020180	New device	K020180	New device	K020180	New device
	7.0μc	12.5μc	25.6μc	27μc	0.945mA	0.375mA
Verdict	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

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Safety Information (continued)

- You should notify your doctor, if you are using this device for nausea and/or vomiting during pregnancy.
- If you are unable tp tolerate any food or liquids or are having weight loss, you should contact your doctor.

Caution:

- The WL-2401 Device is water-resistant. This product is resistant to splashing water (rain, waves, eyc). Do not immerse WL-2401 Device in water. The WL-2401 Device is also shock resistant.
- The elastic strap contains natural rubber latex which may cause allergic reactions.

Side Effects:

- For some people, skin irritation may occur beneath or around the gold plates on the back of the device (electrodes). If skin irriation occurs beneath or around the electrode sites, move the device to the other wrist. If irritation does not disappear within 24 hours, stop using the device and consult your doctor or pharmacist. Continued use of the device on irritated skin may cause injury to your skin.

When To Use WL-2401 Device

You can use your WL-2401 Device either before or after your motion sickness starts, and leave it on for as long as your symptoms last. If you are highly susceptible to motion sickness, apply the WL-2401 Device one half hour before a motion sickness event.

What Comes With Your WL-2401 Device?

Please check your package and be sure all of the items listed below are included. Refer to this Instruction for User Manual for details on how to use your WL-2401 Device.

Included in this package are all of the followings:

- WL-2401 Device**
- Instruction for Use
- Conductivity Gel (10ml/.34fl.oz)

**Battery has been pre-installed for customer convenience.

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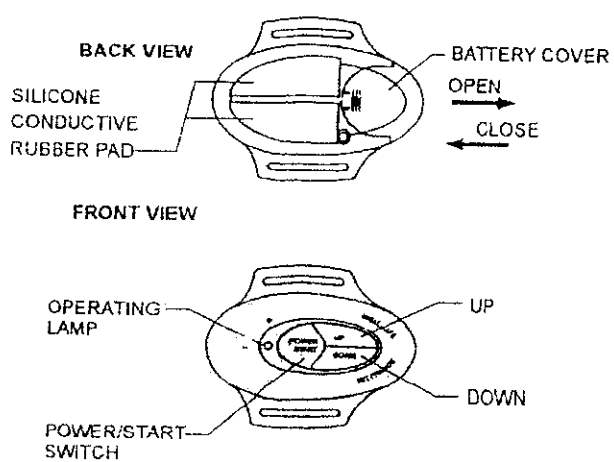
Description Of WL-2401 Device

The WL-2401 Device is a small, medical device incorporated into a wristband worn on the underside of the wrist. It provides relief from nausea and vomiting due to motion sickness and for the relief of mild to moderate nausea and vomiting associated with pregnancy by gentle electrical stimulation on the nerves in your wrist. Batteries will last about 150 hours of total use at middle power level. Batteries are user replaceable. Replace batteries in unit when they become drained.

Indications For Use

The WL-2401 Device is indicated for use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

Parts Of WL-2401



Safety Information

Warnings:

- Nausea and vomiting may be signs of a serious health problem. Contact a doctor if your nausea and vomiting seem to be lasting a long time.
- Do not use the WL-2401 Device when the cause of nausea and vomiting symptoms is undiagnosed because those symptoms might be an important indication of more severe health problems.
- The WL-2401 Device should only be used on the wrist. Do not use it on any other areas of the body because the device might cause undesirable effects such as tingling, muscle twitching or skin irritation.
- The WL-2401 Device does not cure the underlying causes of nausea and vomiting. The relief you get may vary depending on your body's individual characteristics and any medications that you may be taking that could cause your body to respond differently.
- The WL-2401 Devices should be kept out of reach of young children. The battery door, battery tray or batteries may become a choking hazard if removed.
- Pacemaker users – Use this device only as directed on the wrist to prevent possible interference with your pacemaker. Avoid placing the electrodes directly on your chest or near the pacemaker.

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How To Use Well-Life WL-2401 Device

Find the Starting Location:

1) On the underside of either wrist, measure down two finger width from the first crease below the hand (see figure 1). This is the location where the stimulation is to be placed. The electrode should be centered over this spot.

Figure 1. Finding the starting loaction on your wrist for the device.

2) Apply the Gel: Place a very small drop of conductivity gel on the rubber part of the button side of WL-2401 (see figure 2).

Figure 2

3) Attach the WL-2401 onto the wrist: Attach the device WL-2401 onto the placement as measured in step 1). The appropriate attachment of WL-2401 is as the indication of figure 3.

Figuer 3.

How To Turn On The WL-2401 Device

Activate the device by pressing the "Power start" button once. This will activate the unit at the lowest level. The green light will begin to flash indicating the unit is on. It also lets you know if the device is operated.

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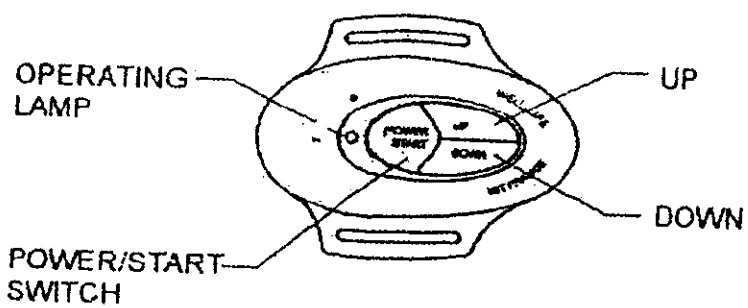
Adjusting Strap and Stimulation Level

1) Without moving the device from the stimulation point, tighten strap until it fits your hand comfortably. (It may be necessary to reposition the device after the strap is tightened.)

2) Adjust the power level for your optimum balance of stimulation and comfort. Set the power level to the highest comfortable setting for maximum relief. The stimulation will cycle every 15 minutes.

The stimulation power level could be increased by pushing "Up" key, and be decreased by pushing "Down" key.



REMEMBER: If you do not feel the tingling in your hand, you will not be getting the relief the WL-2401 device is capable of providing. Adjust location and power setting to the highest comfortable level to get maximum relief.

How To Turn Off WL-2401 Device

To turn off the WL-2401 Device, press and hold down the "Power start" button for 3 seconds.

Usage Tips

1) Try the WL-2401 Device on each wrist and use it on the wrist where the greatest tingling is felt at the lowest setting.
2) For some people, applying and rubbing in the gel twice assists in nerve stimulation.
3) Gel should be re-applied every 6-8 hours, any time after washing, or if stimulation decreases.
4) While still on the wrist, turn the WL-2401 Device off periodically to determine if motion sickness symptoms are present. If they are, turn it on again immediately.
5) When finished using the WL-2401 Device, take it off your wrist and remove the gel from your wrist and the device with a tissue.
6) When not using the WL-2401 Device, be sure to turn the power off to extend battery life.
7) Store the WL-2401 Device in a safe, dry place. Keep it away from young children.

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Part II. Revised User Manual

User Manual for WL-2103A

User Manual for WL-2203A

User Manual for WL-2203B

User Manual for WL-2401

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Operation Manual

Model: WL-2103A

CE 0434

Well-Life Healthcare Inc.

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

European Representative:

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Well-Life Healthcare Inc.

Low Back Pain Relief System

Purpose of your Well-Life low back pain relief system

The Well-Life low back pain relief System is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and work activities.

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Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 place the pads on or around your head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.

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- The safety of using this System during pregnancy or birth has not been established.
- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System.

⚠ Use Caution and consult your Physician before using this 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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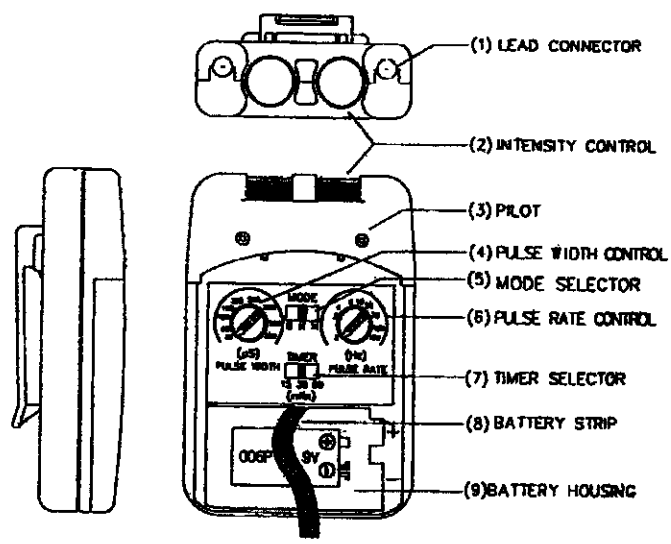
Introduction to your System

Your System includes the following items:

1 Support Belt
3 Elastic Waist Band (L/M/S)
1 Stimulator
1 Package of 4 self-adhesive pads
1 Set of Storage Liners (not shown)
1 Pair of Snap Cables
1 User Manual (not shown)
1 9-volt Battery

Parts of Stimulator

Part of TENS



How Your System works

The main function of pain relief comes from the continuous stimulation pulse generated from the dual channels stimulator. This stimulation can block the pain signals sent to brain, so you may feel that the pain has been relieved and comfortable accompanied by the relief of pain.

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.

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Conditions that may affect your System

Since the stimulator is a battery-operated electronic device, 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.

Quick operation guide

You may follow the following simple operation steps to operate this device.

Step 1. Inserting the 9-volt battery into your Stimulator.
Step 2. Preparing Your Support Belt.
Step 3. Applying Electrode Pads to the belt.
Step 4. Connecting snap cables.
Step 5. Choose elastic waist band.
Step 6. Putting on the support belt.
Step 7. Turning stimulator ON, adjusting appropriate stimulation strength.
Step 8. Adjust appropriate stimulation parameters.
Step 9. Select the stimulation time.
Step 10. Enjoying the stimulation.
Step 11. Turning off the stimulator.

For the details of operation, please see the following description.

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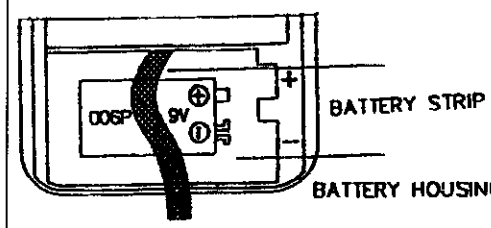
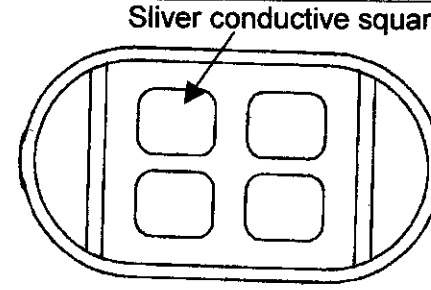
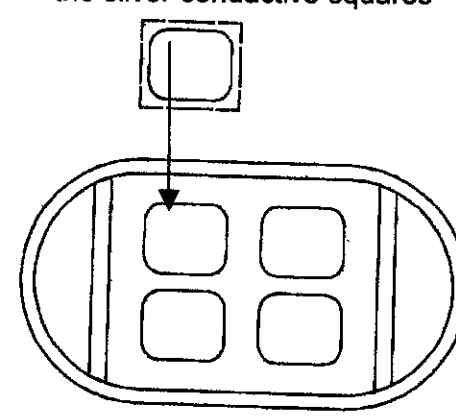
Operation Instruction

Description of operation	Diagram Indication
Step 1 – Inserting the 9-volt battery into your Stimulator	
Make sure both power knobs on the stimulator are turned OFF. To insert the battery, slide the front cover downward until the cover pops off by pressing gently on the arrow and pulling, and insert a 9-volt battery according to the diagram in the battery compartment. Close the cover on the stimulator by sliding from the bottom up.	
Step 2 – Preparing Your Support Belt	Sliver conductive square
Lay your Support Belt open on a flat surface, with the electrode applying side facing up. You will see four silver conductive squares marked for the support belt.	 This side being faced upward.
Step 3 – Applying Electrode Pads to the belt	
Electrode Pads help deliver continuously the stimulation pulses through your skin and into the nerves in your lower back. The pads are designed to fit within the four silver squares on the Support Belt. Open the package of four electrode Pads. Remove the plastic liner from the patterned side and then place the pad with the pattern side down. Repeat this process with the other three pads. IMPORTANT: Leave the other plastic liners with electrode pads until step 5. IMPORTANT: Each electrode pad shall be placed exactly on the silver conductive square, and be pressed firmly on the belt. IMPORTANT: Always use all four pads on the support belt when using the system.	Four electrode pads, attached to the silver conductive squares 

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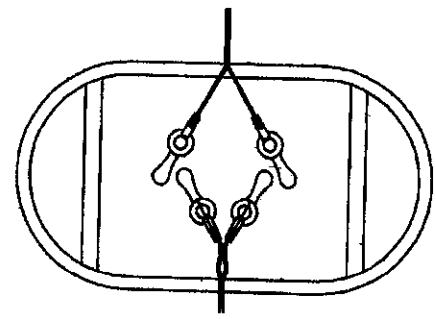
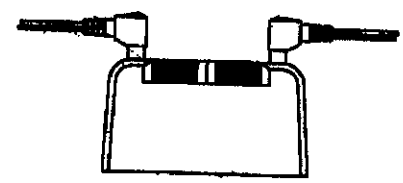
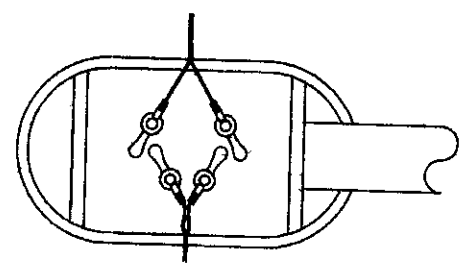
Description of operation	Diagram Indication
Step 4 – Connecting snap cables	
Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro in two sides. Take one cable, and snap two connectors onto the metal snaps on one side of the thumbhole. Repeat with second cable for the other side of the thumbhole. Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket.	Channel 1 Channel 2 
Step 5 – Choose elastic waist band	
For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those bands are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. After the elastic waist band is chosen connect the band with one side of Velcro in support belt. For the connection of band and Velcro, be sure to place the band at the center part of Velcro and close to the sewing line of Velcro part and blue electrode connection part, as indicated in drawing.	L: For 46" ~ 38" waist size. M: For 36" ~ 28" waist size. S: For 28" ~ 20" waist size. 
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions.	

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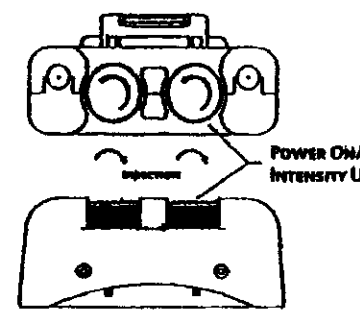
Description of operation	Diagram Indication
2> If your low-back pain is closer to your waist level than it is to the bottom of your back, place the support belt so that the middle of the belts rests at your waist. 3> If you feel pain closer to the lower part of your back, place the support belt so that the middle of the belt rests an inch or two below your waist. 4> Once you have the support belt in the position you want, fasten the elastic band firmly around your torso with both side of Velcro connected with both end of elastic band. 5> You can tighten or loosen the elastic band to adjust the fasten tension of elastic band so as to attach the support belt firmly belt adjusting the ends of the black tension strap on the outside of the belt and fastening them with their Velcro parches.	 Putting on the support belt.
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user.	
Step 8 – Adjust appropriate stimulation parameters	
The stimulation effect could be different due to the different combination of the following three parameters: - The pulse width (30 ~ 260μs): This parameter control the time duration of each single stimulation pulse. In general, the higher the pulse width, the higher the stimulation energy for each single stimulation pulse.	

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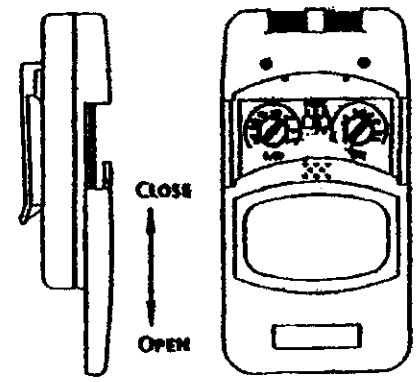
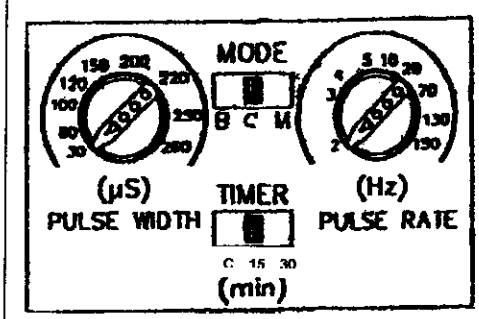
Description of operation	Diagram Indication
- The pulse rate (2 ~ 150Hz): This parameter control the number of output pulse per second. For instance "100Hz" means 100 stimulation pulses will be generated from stimulator for every second. In general, the higher the pulse rate, the more stimulation energy will be transmitted to user. - The stimulation Mode (B/C/M): This parameter control the output waveform of stimulator. The output characteristics of the stimulation modes is described as the followings: 1> B: Cycle Burst, 2Burst/sec, 9 pulses/Bursts, 100Hz width is adjustable. 2> C: Continuous mode. Pulse rate, pulse width and intensity are adjustable. 3> M: Modulated width. Pulse width vary automatically per interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value, then returns to the setting value. Rate, width and intensity are adjustable.	
For the adjustment of pulse width, pulse rate, and stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different combination of parameters will greatly affect the output characteristics of stimulator. However the combination difference will not cause too much significant difference on the therapy result. More or less stimulation may have the similar therapy result, the pain relief on low back, and also within the same safety level, because the extreme stimulation output is within the safety operation range of ANSI/AAMI – NS4 standard. Based on this, we suggest you to change the combination of these three control parameters as well as the amplitude setting on both channels so as to have different stimulation output, as long as you feel the stimulation is comfortable and effective.	

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Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between C, 15, and 30 for "continuous", "15min", and "30min". The stimulation will be continued until the expiration of setting time or until you switch off the stimulation. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of setting parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use. Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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How to clean Your System

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 a clothes dryer.

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.

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 large amounts of water.

Maintaining Your System

1. Your Stimulator uses a standard 9-volt battery. If the stimulation seems to be weakening, or the stimulator will not turn on, check the battery. To replace the battery, make sure both power knobs are turned OFF. Side the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert a 9-volt 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 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 System

1. Store your 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.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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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.

Troubleshooting Guide

If you have a problem using your System, 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 a new 9-volt battery, but will not turn on.	Call Customer Service +886-2-2928-2112.
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-2103A Stimulator Technical Specifications

Features	*WL-2103A*
510(k) Number	K002874
Manufacturer	Well-Life
Classification	Class II
Basic Specification Comparison	
Waveform	Asymmetrical Biphasic Square
Channels	Dual
Power supply	9 volt battery
Circuit designed	Analog
Software	Yes
Amplitude (mA)	0-80
Pulse rate (Hz)	2-150
Width (μs)	30-260
Power ON indicator	LED
Timer (min)	60
Weight (grams) (batt. Include)	135
Size (mm)	92×62×25
Prescription or OTC	OTC
Indication for use	All models as above mentioned 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.

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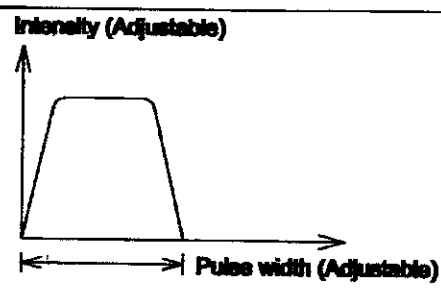
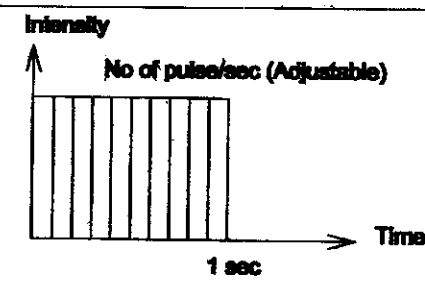
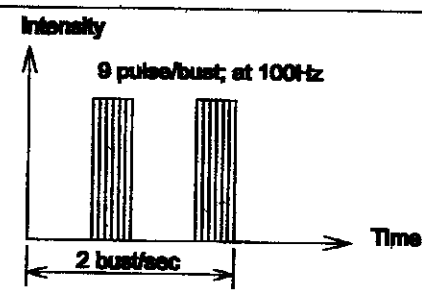
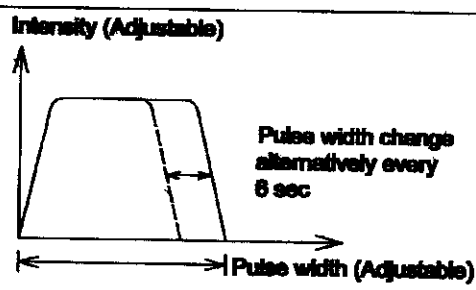
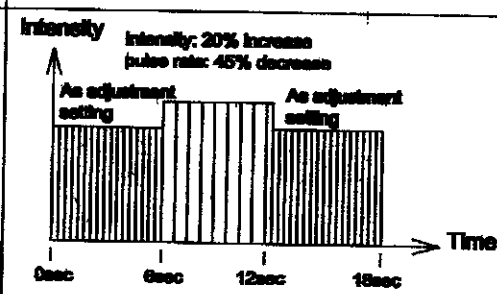
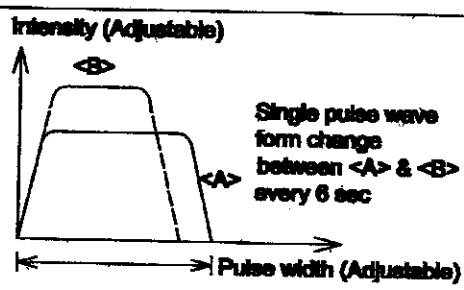
Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
C or N		
B	Identical to that of C Mode	
M or MR		Identical to that of C Mode
SDR	Identical to that of C Mode	
SDW		Identical to that of C Mode

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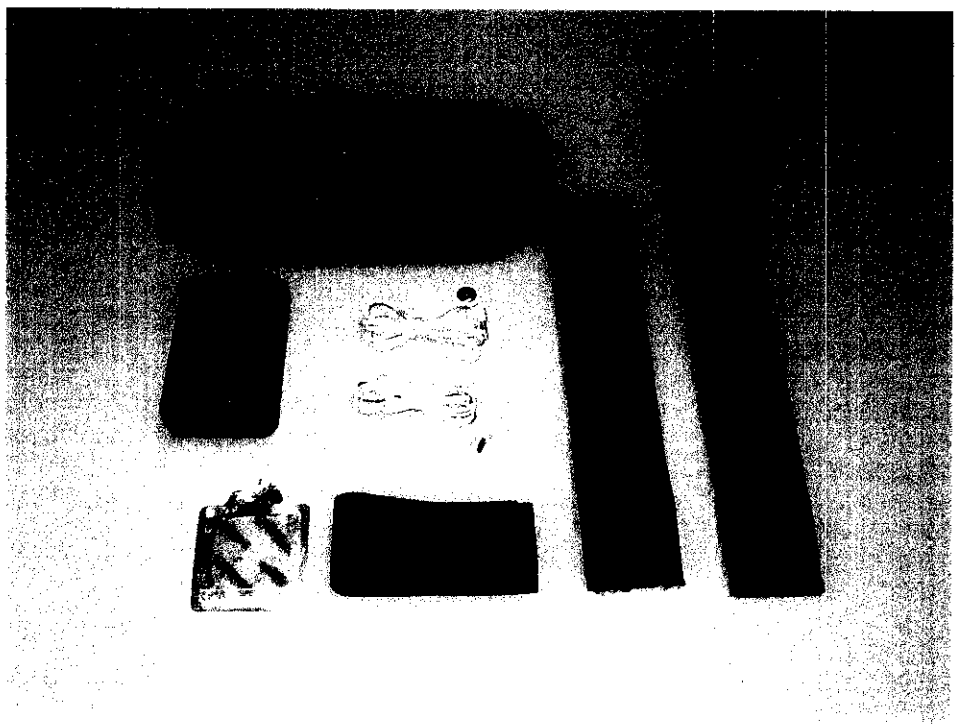
Operation Manual



Model: WL-2203A

CE 0434

Well-Life Healthcare Inc.

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

European Representative:

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Well-Life Healthcare Inc.

Low Back Pain Relief System

Purpose of your Well-Life low back pain relief system

The Well-Life low back pain relief System is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and work activities.

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Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 place the pads on or around your head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.

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- The safety of using this System during pregnancy or birth has not been established.
- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System.

⚠ Use Caution and consult your Physician before using this 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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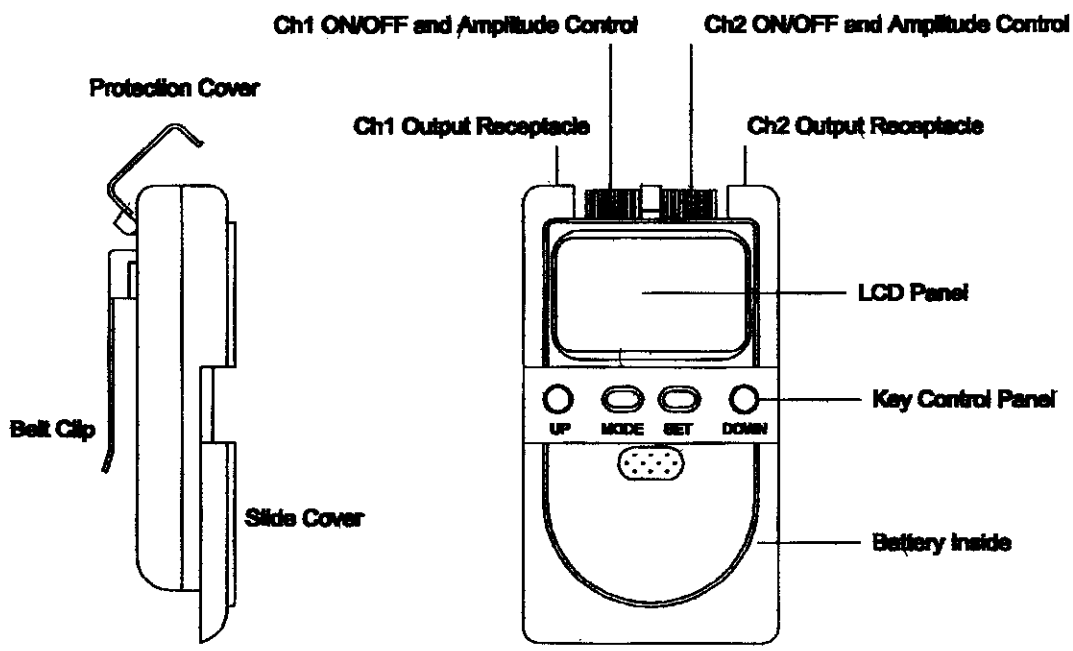
Introduction to your System

Your System includes the following items:

1 Support Belt
3 Elastic Waist Band (L/M/S)
1 Stimulator
1 Package of 4 self-adhesive pads
1 Set of Storage Liners (not shown)
1 Pair of Snap Cables
1 User Manual (not shown)
1 9-volt Battery

Parts of Stimulator



How Your System works

The main function of pain relief comes from the continuous stimulation pulse generated from the dual channels stimulator. This stimulation can block the pain signals sent to brain, so you may feel that the pain has been relieved and comfortable accompanied by the relief of pain.

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.

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Conditions that may affect your System

Since the stimulator is a battery-operated electronic device, 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.

Quick operation guide

You may follow the following simple operation steps to operate this device.

Step 1. Inserting the 9-volt battery into your Stimulator.
Step 2. Preparing Your Support Belt.
Step 3. Applying Electrode Pads to the belt.
Step 4. Connecting snap cables.
Step 5. Choose elastic waist band.
Step 6. Putting on the support belt.
Step 7. Turning stimulator ON, adjusting appropriate stimulation strength.
Step 8. Adjust appropriate stimulation parameters.
Step 9. Select the stimulation time.
Step 10. Enjoying the stimulation.
Step 11. Turning off the stimulator.

For the details of operation, please see the following description.

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

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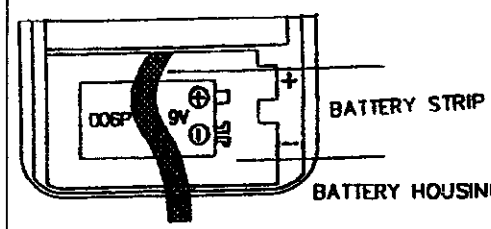
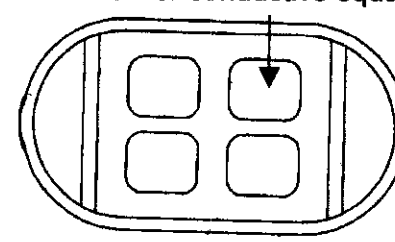
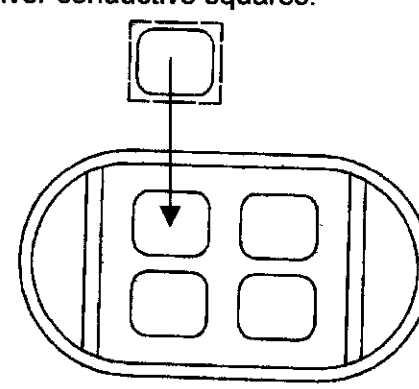
Operation Instruction

Description of operation	Diagram Indication
Step 1 – Inserting the 9-volt battery into your Stimulator	
Make sure both power knobs on the stimulator are turned OFF. To insert the battery, slide the front cover downward until the cover pops off by pressing gently on the arrow and pulling, and insert a 9-volt battery according to the diagram in the battery compartment. Close the cover on the stimulator by sliding from the bottom up.	
Step 2 – Preparing Your Support Belt	Sliver conductive square  This side being faced upward.
Lay your Support Belt open on a flat surface, with the electrode applying side facing up. You will see four silver conductive squares marked for the support belt.	
Step 3 – Applying Electrode Pads to the belt	Four electrode pads, attached to the silver conductive squares. 
Electrode Pads help deliver continuously the stimulation pulses through your skin and into the nerves in your lower back. The pads are designed to fit within the four silver squares on the Support Belt. Open the package of four electrode Pads. Remove the plastic liner from the patterned side and then place the pad with the pattern side down. Repeat this process with the other three pads. IMPORTANT: Leave the other plastic liners with electrode pads until step 5. IMPORTANT: Each electrode pad shall be placed exactly on the silver conductive square, and be pressed firmly on the belt. IMPORTANT: Always use all four pads on the support belt when using the system.	

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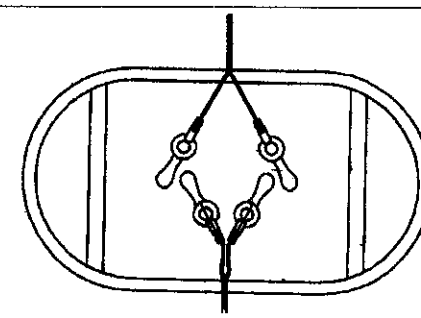
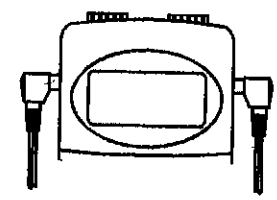
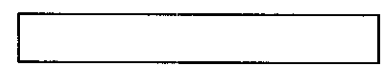
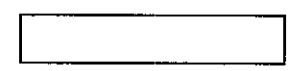
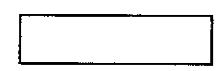
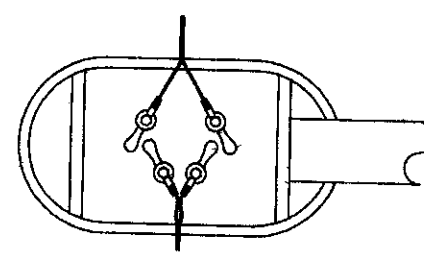
Description of operation	Diagram Indication
Step 4 – Connecting snap cables	
Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro in two sides. Take one cable, and snap two connectors onto the metal snaps on one side of the thumbhole. Repeat with second cable for the other side of the thumbhole. Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket.	Channel 1 Channel 2 
Step 5 – Choose elastic waist band	 L: For 46" ~ 38" waist size  M: For 38" ~ 28" waist size  L: For 28" ~ 20" waist size
For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those bands are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. After the elastic waist band is chosen connect the band with one side of Velcro in support belt. For the connection of band and Velcro, be sure to place the band at the center part of Velcro and close to the sewing line of Velcro part and blue electrode connection part, as indicated in drawing.	
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions.	

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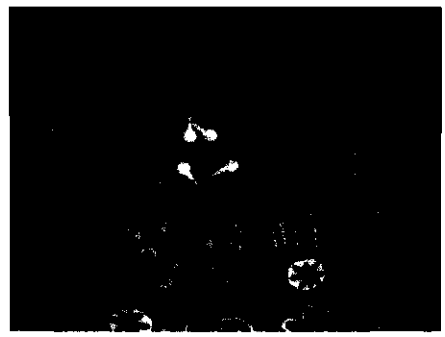
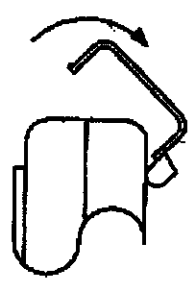
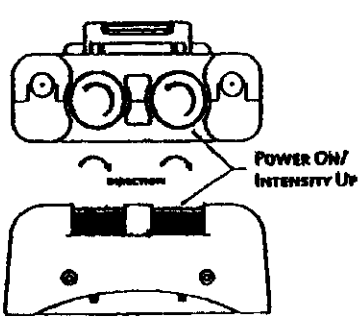
Description of operation	Diagram Indication
2> If your low-back pain is closer to your waist level than it is to the bottom of your back, place the support belt so that the middle of the belts rests at your waist. 3> If you feel pain closer to the lower part of your back, place the support belt so that the middle of the belt rests an inch or two below your waist. 4> Once you have the support belt in the position you want, fasten the elastic band firmly around your torso with both side of Velcro connected with both end of elastic band. 5> You can tighten or loosen the elastic band to adjust the fasten tension of elastic band so as to attach the support belt firmly belt adjusting the ends of the black tension strap on the outside of the belt and fastening them with their Velcro parches.	 Putting on the support belt.
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
For turning stimulator ON, the knobs protection cover shall be opened first. Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user.	

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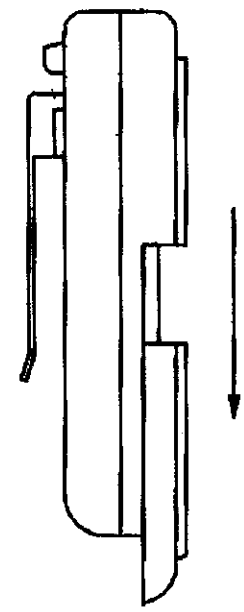
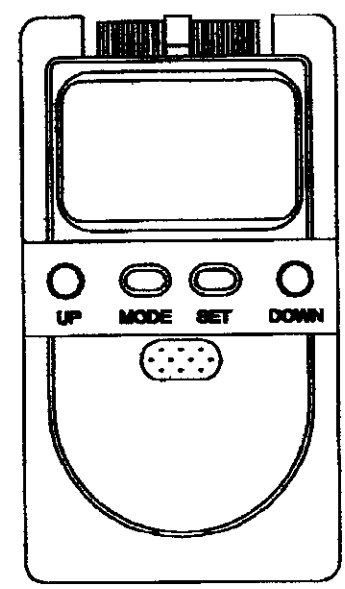
Description of operation	Diagram Indication
Step 8 – Adjust appropriate stimulation parameters	
The operation buttons and LCD display are as the indication of the drawing. For the adjustment of stimulator, you may do it as the followings: 1> Slide the front cover open by pressing gently on the black area of top area and pulling down. After the cover is opened, you may see the four operation buttons. 2> Continuously push "MODE" key so as to change the operation of "Burst Mode", "Continuous Mode", and also ship to the adjustment of frequency and pulse width. While the symbol flashes on the LCD display, it means that this parameter is to be adjusted or selected. For the operation mode, you may choose between "Burst Mode", and "Continuous Mode". The "Burst Mode" is shown as "◐", and the Continuous Mode" is shown as "◯". The wave form of "burst Mode" and "Continuous Mode" will be presented as the following description : - "Burst Mode". Cycle Burst, 2Burst/sec, 9 pulses/Bursts, 100Hz width is adjustable. - "Continuous Mode". Pulse rate, pulse width and intensity are adjustable. 3> While the LCD display flashes at pulse rate in the unit of "μs", you may select the pulse rate ranging from 30μs to 260μs. After completing the setting of operation mode and pulse rate you may change the operation time as the following step.	 

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Description of operation	Diagram Indication
Basically the different combination of parameters will greatly affect the output characteristics of stimulator. However the combination difference will not cause too much significant difference on the therapy result. More or less stimulation may have the similar therapy result, the pain relief on low back, and also within the same safety level, because the extreme stimulation output is within the safety operation range of ANSI/AAMI – NS4 standard. Based on this, we suggest you to change the combination of these three control parameters as well as the amplitude setting on both channel so as to have different stimulation output, as long as you feel comfortable and effective.	
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between 10min, 20min, 30min, 40min, 50min, 60min and continuous operation. For the operation. TIME = Therapy time selection / setting. After switch on the device, time is set as last operation memory. With the key, you set the therapy time that will be shown in 10, 20, 30, 40, 50, 60 minutes and/or continuous. The stimulation will be continued until the expiration of setting time. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of setting parameters.	

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Description of operation	Diagram Indication
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use. Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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How to clean Your System

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 a clothes dryer.

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.

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 large amounts of water.

Maintaining Your System

2. Your Stimulator uses a standard 9-volt battery. If the stimulation seems to be weakening, or the stimulator will not turn on, check the battery. To replace the battery, make sure both power knobs are turned OFF. Side the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert a 9-volt battery according to the diagram in the battery compartment. To close the cover, slide from the bottom up.

3. Be sure to put the storage liners on the pads when not using your 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.

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

5. 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 System

1. Store your 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.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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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.

Troubleshooting Guide

If you have a problem using your System, 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 a new 9-volt battery, but will not turn on.	Call Customer Service +886-2-2928-2112.
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-2203A Stimulator Technical Specifications

Features	*WL-2203A*
510(k) Number	K0033857
Manufacturer	Well-Life
Classification	Class II
Basic Specification Comparison	
Waveform	Asymmetrical Biphasic Square
Channels	Dual
Power supply	9 volt battery
Circuit designed	Digital
Software	Yes
Amplitude (mA)	0-80
Pulse rate (Hz)	1-150
Width (μs)	30-260
Power ON indicator	LCD
Timer (min)	15-60
Weight (grams) (batt. Include)	142
Size (mm)	110×62×27
Prescription or OTC	OTC
Indication for use	All models as above mentioned 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.

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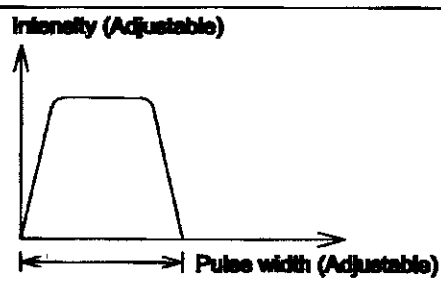
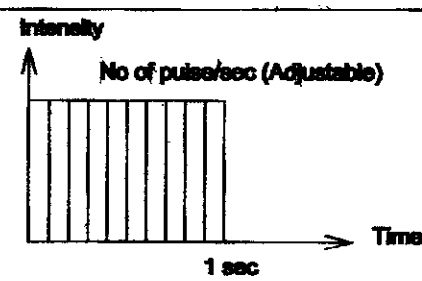
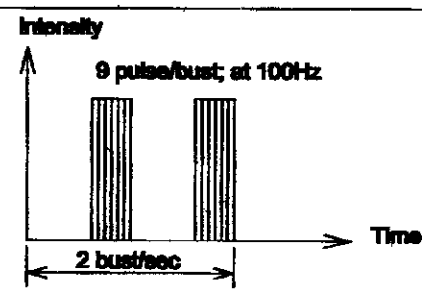
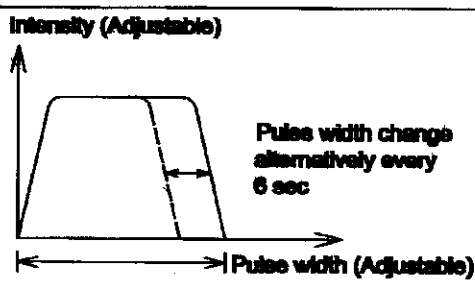
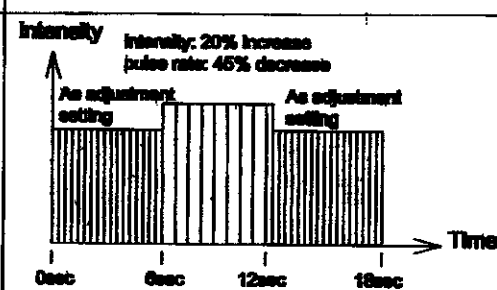
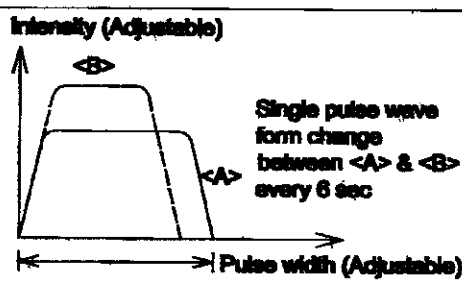
Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
C or N		
B	Identical to that of C Mode	
M or MR		Identical to that of C Mode
SDR	Identical to that of C Mode	
SDW		Identical to that of C Mode

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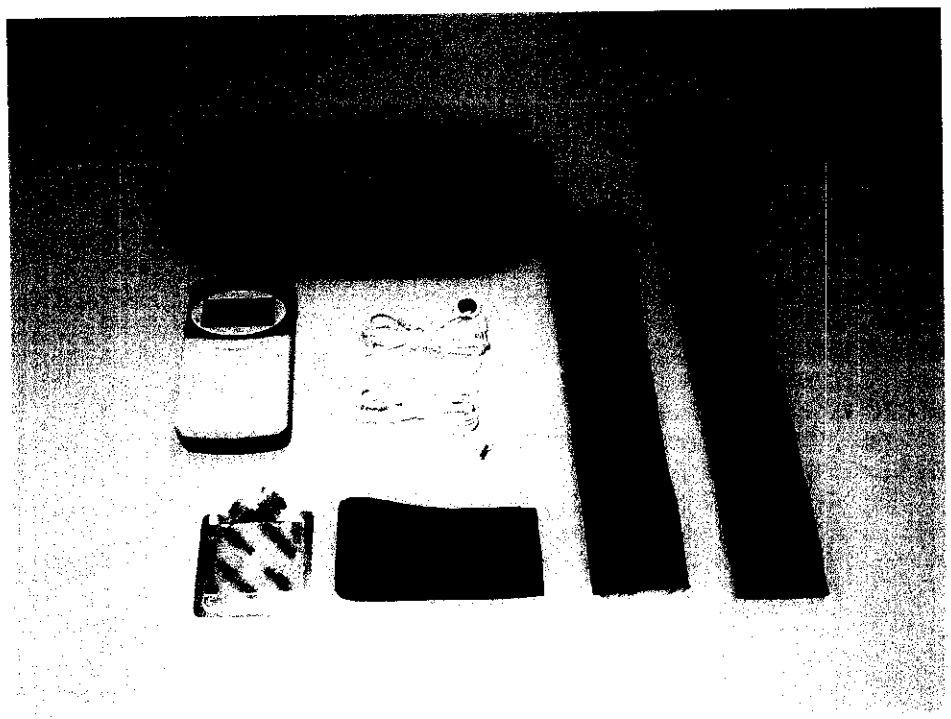
Operation Manual



Model: WL-2203B

CE 0434

Well-Life Healthcare Inc.

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

European Representative:

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Well-Life Healthcare Inc.

Low Back Pain Relief System

Purpose of your Well-Life low back pain relief system

The Well-Life low back pain relief System is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and work activities.

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Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 place the pads on or around your head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.

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- The safety of using this System during pregnancy or birth has not been established.
- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System.

⚠ Use Caution and consult your Physician before using this 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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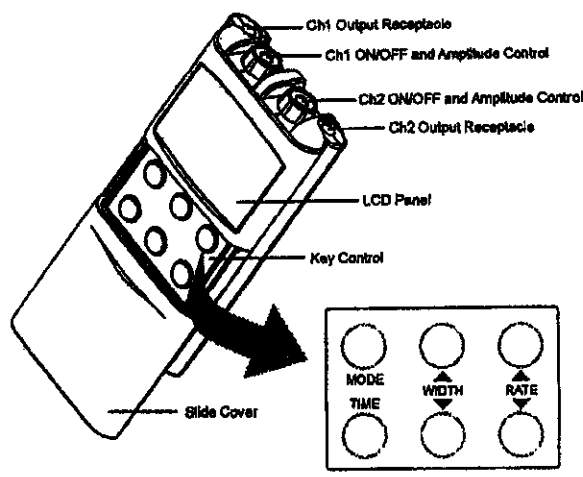
Introduction to your System

Your System includes the following items:

1 Support Belt
3 Elastic Waist Band (L/M/S)
1 Stimulator
1 Package of 4 self-adhesive pads
1 Set of Storage Liners (not shown)
1 Pair of Snap Cables
1 User Manual (not shown)
1 9-volt Battery

Parts of Stimulator



How Your System works

The main function of pain relief comes from the continuous stimulation pulse generated from the dual channels stimulator. This stimulation can block the pain signals sent to brain, so you may feel that the pain has been relieved and comfortable accompanied by the relief of pain.

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.

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Conditions that may affect your System

Since the stimulator is a battery-operated electronic device, 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.

Quick operation guide

You may follow the following simple operation steps to operate this device.

Step 1. Inserting the 9-volt battery into your Stimulator.
Step 2. Preparing Your Support Belt.
Step 3. Applying Electrode Pads to the belt.
Step 4. Connecting snap cables.
Step 5. Choose elastic waist band.
Step 6. Putting on the support belt.
Step 7. Turning stimulator ON, adjusting appropriate stimulation strength.
Step 8. Adjust appropriate stimulation parameters.
Step 9. Select the stimulation time.
Step 10. Enjoying the stimulation.
Step 11. Turning off the stimulator.

For the details of operation, please see the following description.

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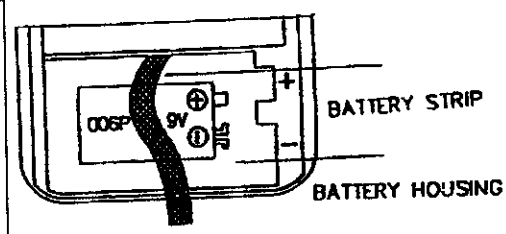
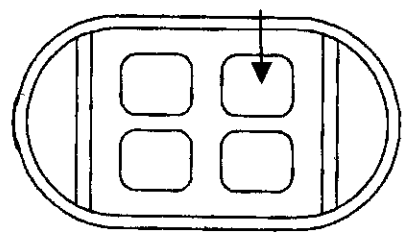
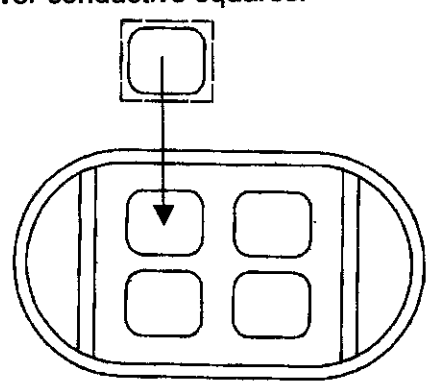
Operation Instruction

Description of operation	Diagram Indication
Step 1 – Inserting the 9-volt battery into your Stimulator	
Make sure both power knobs on the stimulator are turned OFF. To insert the battery, slide the front cover downward until the cover pops off by pressing gently on the arrow and pulling, and insert a 9-volt battery according to the diagram in the battery compartment. Close the cover on the stimulator by sliding from the bottom up.	
Step 2 – Preparing Your Support Belt	Sliver conductive square
Lay your Support Belt open on a flat surface, with the electrode applying side facing up. You will see four silver conductive squares marked for the support belt.	 This side being faced upward.
Step 3 – Applying Electrode Pads to the belt	Four electrode pads, attached to the silver conductive squares.
Electrode Pads help deliver continuously the stimulation pulses through your skin and into the nerves in your lower back. The pads are designed to fit within the four silver squares on the Support Belt. Open the package of four electrode Pads. Remove the plastic liner from the patterned side and then place the pad with the pattern side down. Repeat this process with the other three pads. IMPORTANT: Leave the other plastic liners with electrode pads until step 5. IMPORTANT: Each electrode pad shall be placed exactly on the silver conductive square, and be pressed firmly on the belt. IMPORTANT: Always use all four pads on the support belt when using the system.	

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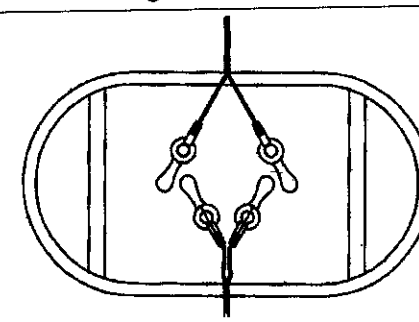
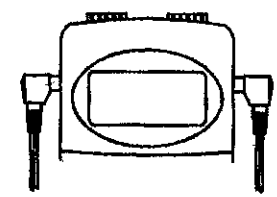
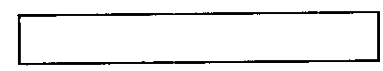
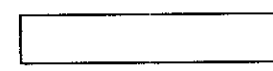
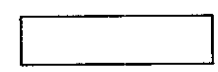
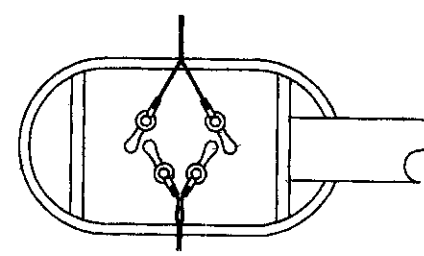
Description of operation	Diagram Indication
Step 4 – Connecting snap cables Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro in two sides. Take one cable, and snap two connectors onto the metal snaps on one side of the thumbhole. Repeat with second cable for the other side of the thumbhole. Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket.	 Channel 1 Channel 2 
Step 5 – Choose elastic waist band For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those bands are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. After the elastic waist band is chosen connect the band with one side of Velcro in support belt. For the connection of band and Velcro, be sure to place the band at the center part of Velcro and close to the sewing line of Velcro part and blue electrode connection part, as indicated in drawing.	 L: For 46" ~ 38" waist size  M: For 38" ~ 28" waist size  L: For 28" ~ 20" waist size 
Step 6 – Putting on the support belt Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions.	

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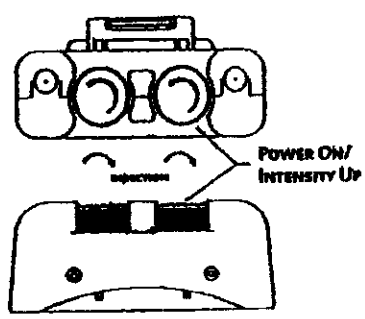
Description of operation	Diagram Indication
2> If your low-back pain is closer to your waist level than it is to the bottom of your back, place the support belt so that the middle of the belts rests at your waist. 3> If you feel pain closer to the lower part of your back, place the support belt so that the middle of the belt rests an inch or two below your waist. 4> Once you have the support belt in the position you want, fasten the elastic band firmly around your torso with both side of Velcro connected with both end of elastic band. 5> You can tighten or loosen the elastic band to adjust the fasten tension of elastic band so as to attach the support belt firmly belt adjusting the ends of the black tension strap on the outside of the belt and fastening them with their Velcro parches.	 Putting on the support belt.
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user.	
Step 8 – Adjust appropriate stimulation parameters	
The stimulation effect could be different due to the different combination of the following three parameters, mode, width, and rate. For the adjustment of these three parameter please see the following description.	

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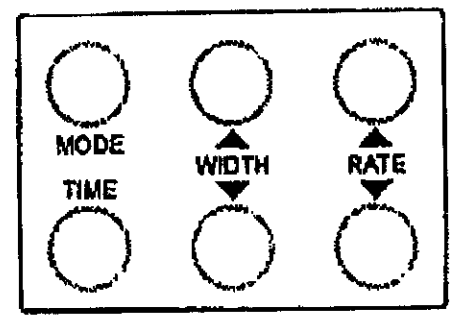
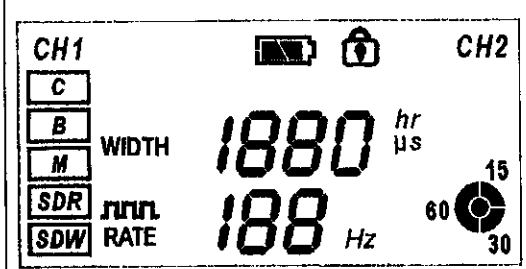
Description of operation	Diagram Indication
MODE = Therapy mode selection / setting. With this key you can select the seven preset modes. With each depression of the key, you switch to the next mode. The selected mode will be blinking. WIDTH ▲▼= Pulse Width setting With this key you adjust the pulse width of the individual current pulses. By pressing the key p, you can adjust the frequency in 1us/step increasing. Hold the key continuous, the frequency in 5us/step increasing rapidly. By pressing the key ▼you can adjust the frequency in 1us/step decreasing. Hole the key continuous, the frequency in 5us/step decreasing rapidly. RATE ▲▼= Pulse Rate setting With the key you set the frequency of the therapy current. By pressing the key ▼you can adjust the frequency in 5Hz/step increasing. Hold the key continuous, the frequency in 5Hz/step increasing rapidly. For the operation mode, they may be chosen from pushing "MDDE" key. The stimulation characteristics of different operation modes, please see the following explanation. For TENS: B: Cycle Burst. 2Burst/sec, 9 pulses/Bursts, 100Hz, width is adjustable. C: Continuous mode. Pulse rate, pulse width and intensity are adjustable. M: Modulated Width. Pulse width vary automatically per interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value, then returns to the setting value. Rate, width and intensity are adjustable.	 

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Description of operation	Diagram Indication
SDR: Strength-Duration and Rate modulation. SDR consists of alternating modulated intensity (amplitude) and pulse rate so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse rate increase 45% from the modulated rate to the setting value and return to the modulated rate. Total cycle time is 6 seconds. Rate, width and intensity are adjustable. SDW: Strength Duration and Width modulation. SDW consists of Alternating modulated intensity (amplitude) and pulse width so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse width increase 54% from the modulated width to the setting value and return to the modulated width. Total cycle time is 6secinds. Rate, width and intensity are adjustable, For the adjustment of pulse width, pulse rate, and stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different combination of parameters will greatly affect the output characteristics of stimulator. However the combination difference will not cause too much significant difference on the therapy result. More or less stimulation may have the similar therapy result, the pain relief on low back, and also within the same safety level, because the extreme stimulation output is within the safety operation range of ANSI/AAMI – NS4 standard. Based on this, we suggest you to change the combination of these three control parameters as well as the amplitude setting on both channel so as to have different stimulation output, as long as you feel comfortable and effective.	

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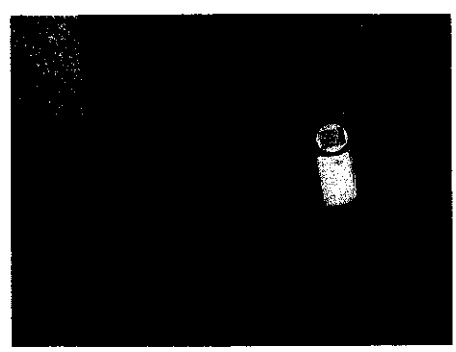
Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between 10min, 20min, 30min, 40min, 50min, 60min and continuous operation. For the operation. TIME = Therapy time selection / setting. After switch on the device, time is set as last operation memory. With the key, you set the therapy time that will be shown in 15, 30, 60 minutes or continuous. The stimulation will be continued until the expiration of setting time. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of setting parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use.	

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Description of operation	Diagram Indication
Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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How to clean Your System

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 a clothes dryer.

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.

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 large amounts of water.

Maintaining Your System

1. Your Stimulator uses a standard 9-volt battery. If the stimulation seems to be weakening, or the stimulator will not turn on, check the battery. To replace the battery, make sure both power knobs are turned OFF. Side the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert a 9-volt 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 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 System

1. Store your 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.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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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.

Troubleshooting Guide

If you have a problem using your System, 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 a new 9-volt battery, but will not turn on.	Call Customer Service +886-2-2928-2112.
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-2203B Stimulator Technical Specifications

Features	*WL-2203B*
510(k) Number	K030537
Manufacturer	Well-Life
Classification	Class II
Basic Specification Comparison	
Waveform	Asymmetrical Biphasic Square
Channels	Dual
Power supply	9 volt battery
Circuit designed	Digital
Software	Yes
Amplitude (mA)	0-80
Pulse rate (Hz)	1-160
Width (μs)	50-260
Power ON indicator	LCD
Timer (min)	15-60
Weight (grams) (batt. Include)	142
Size (mm)	110×62×27
Prescription or OTC	OTC
Indication for use	All models as above mentioned 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.

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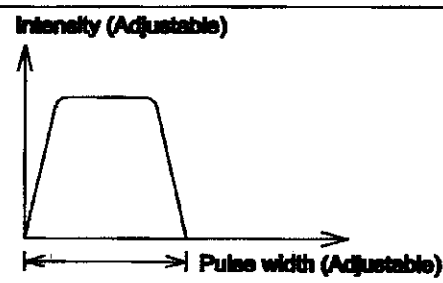
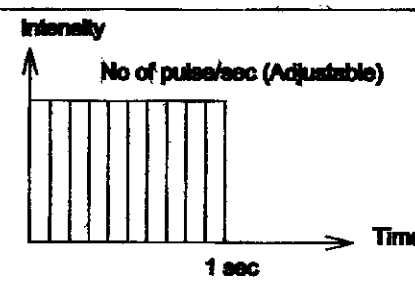
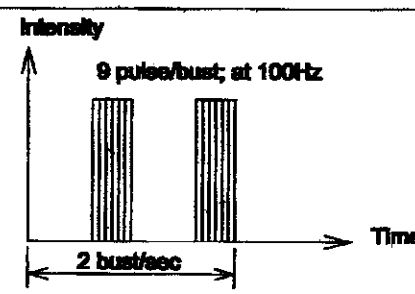
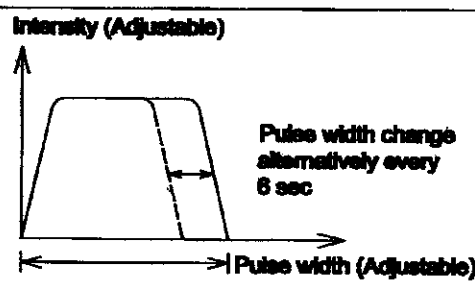
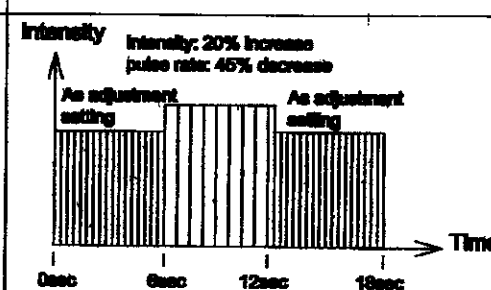
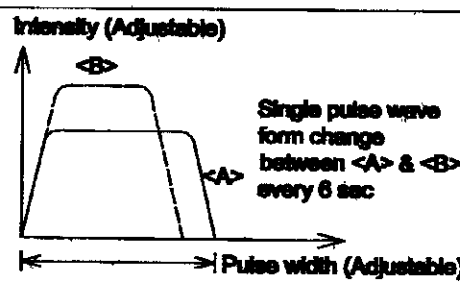
Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
C or N		
B	Identical to that of C Mode	
M or MR		Identical to that of C Mode
SDR	Identical to that of C Mode	
SDW		Identical to that of C Mode

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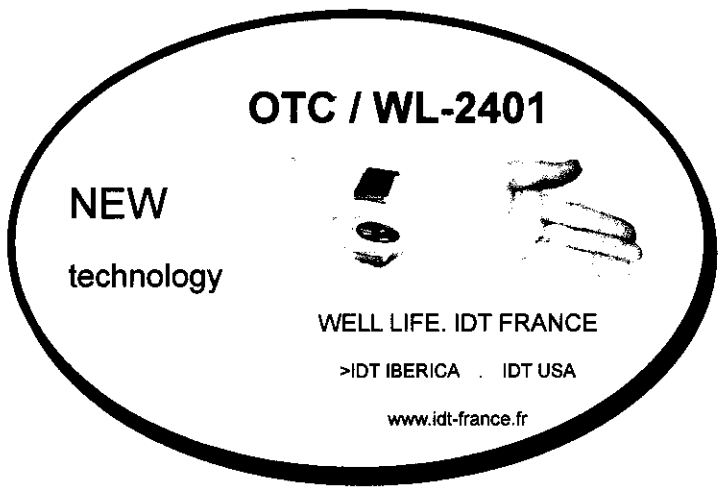
Operation Manual

For OTC Use



CE 0434

Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

European Representative:

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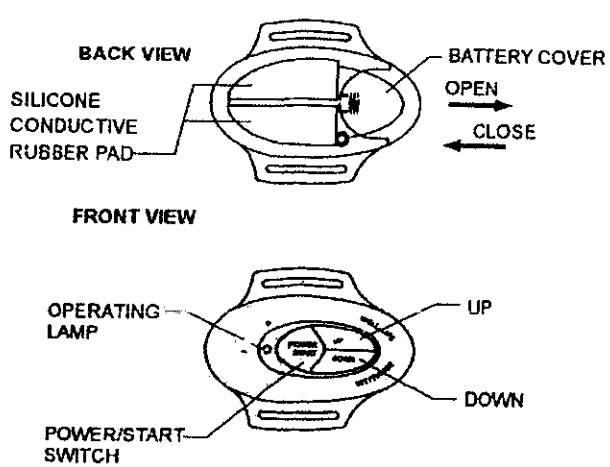
Description Of WL-2401 Device

The WL-2401 Device is a small, medical device incorporated into a wristband worn on the underside of the wrist. It provides relief from nausea and vomiting due to motion sickness and for the relief of mild to moderate nausea and vomiting associated with pregnancy by gentle electrical stimulation on the nerves in your wrist.

Indications For Use

The WL-2401 Device is indicated for use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

Parts Of WL-2401



Safety Information

Warnings:

- Nausea and vomiting may be signs of a serious health problem. Contact a doctor if your nausea and vomiting seem to be lasting a long time.
- Do not use the WL-2401 Device when the cause of nausea and vomiting symptoms is undiagnosed because those symptoms might be an important indication of more severe health problems.
- The WL-2401 Device should only be used on the wrist. Do not use it on any other areas of the body because the device might cause undesirable effects such as tingling, muscle twitching or skin irritation.
- The WL-2401 Device does not cure the underlying causes of nausea and vomiting. The relief you get may vary depending on your body's individual characteristics and any medications that you may be taking that could cause your body to respond differently.
- The WL-2401 Devices should be kept out of reach of young children. The battery door, battery tray or batteries may become a choking hazard if removed.
- Pacemaker users – Use this device only as directed on the wrist to prevent possible interference with your pacemaker. Avoid placing the electrodes directly on your chest or near the pacemaker.

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Safety Information (continued)

- You should notify your doctor, if you are using this device for nausea and/or vomiting during pregnancy.
- If you are unable to tolerate any food or liquids or are having weight loss, you should contact your doctor.

Caution:

- The WL-2401 Device is water-resistant. This product is resistant to splashing water (rain, waves, eyc). Do not immerse WL-2401 Device in water. The WL-2401 Device is also shock resistant.
- The elastic strap contains natural rubber latex which may cause allergic reactions.

Side Effects:

- For some people, skin irritation may occur beneath or around the gold plates on the back of the device (electrodes). If skin irriation occurs beneath or around the electrode sites, move the device to the other wrist. If irritation does not disappear within 24 hours, stop using the device and consult your doctor or pharmacist. Continued use of the device on irritated skin may cause injury to your skin.

When To Use WL-2401 Device

You can use your WL-2401 Device either before or after your motion sickness starts, and leave it on for as long as your symptoms last. If you are highly susceptible to motion sickness, apply the WL-2401 Device one half hour before a motion sickness event.

What Comes With Your WL-2401 Device?

Please check your package and be sure all of the items listed below are included. Refer to this Instruction for User Manual for details on how to use your WL-2401 Device.

Included in this package are all of the followings:

- WL-2401 Device**
- Instruction for Use
- Conductivity Gel (10ml/.34fl.oz)

**Battery has been pre-installed for customer convenience.

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How To Use Well-Life WL-2401 Device

Find the Starting Location:

1) On the underside of either wrist, measure down two finger width from the first crease below the hand (see figure 1). This is the location where the stimulation is to be placed. The electrode should be centered over this spot.

Figure 1. Finding the starting loaction on your wrist for the device.

2) Apply the Gel: Place a very small drop of conductivity gel on the rubber part of the button side of WL-2401 (see figure 2).

Figure 2

3) Attach the WL-2401 onto the wrist: Attach the device WL-2401 onto the placement as measured in step 1). The appropriate attachment of WL-2401 is as the indication of figure 3.

Figuer 3.

How To Turn On The WL-2401 Device

Activate the device by pressing the "Power start" button once. This will activate the unit at the lowest level. The green light will begin to flash indicating the unit is on. It also lets you know if the device is operated.

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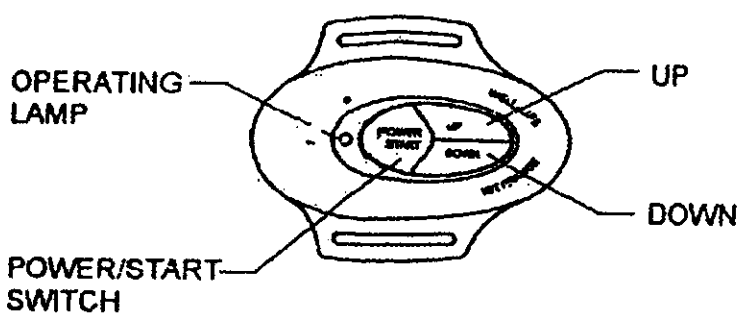
Adjusting Strap and Stimulation Level

1) Without moving the device from the stimulation point, tighten strap until it fits your hand comfortably. (It may be necessary to reposition the device after the strap is tightened.)

2) Adjust the power level for your optimum balance of stimulation and comfort. Set the power level to the highest comfortable setting for maximum relief. The stimulation will cycle every 15 minutes.

The stimulation power level could be increased by pushing "Up" key, and be decreased by pushing "Down" key.



REMEMBER: If you do not feel the tingling in your hand, you will not be getting the relief the WL-2401 device is capable of providing. Adjust location and power setting to the highest comfortable level to get maximum relief.

How To Turn Off WL-2401 Device

To turn off the WL-2401 Device, press and hold down the "Power start" button for 3 seconds.

Usage Tips

1) Try the WL-2401 Device on each wrist and use it on the wrist where the greatest tingling is felt at the lowest setting.
2) For some people, applying and rubbing in the gel twice assists in nerve stimulation.
3) Gel should be re-applied every 6-8 hours, any time after washing, or if stimulation decreases.
4) While still on the wrist, turn the WL-2401 Device off periodically to determine if motion sickness symptoms are present. If they are, turn it on again immediately.
5) When finished using the WL-2401 Device, take it off your wrist and remove the gel from your wrist and the device with a tissue.
6) When not using the WL-2401 Device, be sure to turn the power off to extend battery life.
7) Store the WL-2401 Device in a safe, dry place. Keep it away from young children.

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

Changing The Battery

1) Peel back the battery door at the bottom end of device (see figure 4).
2) Remove used battery and then replace it with fresh battery (3V, CR2025 Lithium coin cells only) available at grocery or drug stores.
3) IMPORTANT: Make sure the new battery is inserted in the correct direction (+ side down – see figure 4), the battery tray is inserted correctly, and the door is closed. Be sure the WL-2401 Device is dry before changing the battery.

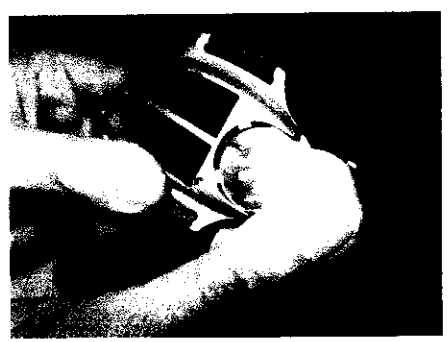

Figure 4.

*NOTE: Battery tray only fits in one way. Always insert into WL-2401 Device with arrows up, as shown above.

Environmental Conditions That Can Affect Use

The WL-2401 Device is water-resistant. This product is resistant to splashing water (rain, waves, etc). Do not immerse WL-2401 Device in water or wear while bathing. The device is also shock-resistant.
The WL-2401 Device should only be used within the temperature range of 10°C to 45°C (50°F to 113°F), and a relative humidity range of 20% to 90% (non-condensing). If the product has been stored or transported in conditions outside these ranges, keep it within the normal ranges for at least 30 minutes before using.

The product can be stored and transported in the temperature range of 0°C to 50°C (32°F to 122°F), and a relative humidity range of 20% to 90% (non-condensing). The device may not operate if stored in conditions outside of this range.

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Questions and Answers

How can I be sure I have found the area for maximum stimulation?

- After the device is turned on, move it slightly up or down, and side to side on the wrist until the maximum "tingling" feeling is felt. You will feel a tingling sensation in your palm and/or middle fingers when the WL-2401 Device is in the proper wrist location. Stimulation will be operated every 15 minutes.
- If little or no tingling is felt after moving it around, increase the power level.
- Try the band on the opposite wrist. Use it on the wrist where you feel the most tingling. Increase the power setting to the highest comfortable setting for maximum relief.

On which wrist should I wear the WL-2401 Device?

- On the wrist that gives you the greatest tingling in the hand at the lowest stimulation level.

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

Questions and Answers (continued)

Is dry or sensitive skin a problem?

- For dry skin, the gel may be lightly more often.
- If you have especially sensitive skin, switch wrists every 2-3 hours. Be sure to re-apply gel as directed.

How long will the battery last?

- The battery should last for about 150 hours of total use at middle, power level, less time at higher power levels. Battery life depends on individual usage of product.

How do I know when the battery are getting low?

- The low battery light on the display will flash slowly to let you know when the battery is low.
  At this time, about 10 hours of use remain depending on the power level used and how long you have used the device.
- Once the battery light goes out, the battery need to be replaced. It is a good idea to carry an extra set of battery with you.

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Troubleshooting

The WL-2401 Device has been designed to provide feedback to ensure proper usage to relieve the symptoms of motion sickness and the mild to moderate nausea and vomiting associated with pregnancy. The Troubleshooting Chart below will help to assist you in handling situations that may arise while you use the product.

Situation	Recommended Solution
Green light flashing, but no stimulation is felt.	Move the WL-2401 Device around the underside of the wrist. Check for proper placement, and Increase the power setting. Re-apply a small amount of gel. Be sure gel is rubbed in to a sheen. The area should appear shiny. Be sure the strap is secure around wrist. Be sure green light is flashing.
No lights flashing	Check that device is on. You should see green flashing light on device. If not, turn device OFF and replace battery.

User Assistance Information

If you have any questions about how to use the Well-Life Device Model WL-2401 please call Well-Life Healthcare Inc. Room 6C01, No. 5, Sec. 5, Hsin Yi Rd., Taipei, Taiwan, R.O.C. TEL: +886-2-2928-2112, FAX: +886-2-2928-1880

Maintenance Information

Cleaning:

Keep the electrode area clean. A moist cloth may be used to remove gel buid-up, which may decrease stimlation. Avoid immersion of the device in water.

To purchase additional WL-2401 Device or accessory items, including conductivity gel, call Well-Life.

Storage Information

Remove battery if the device is going to be stored. See Environmental Conditions Section for additional information.

Disposal Information

The product and battery do not contain any environmentally hazardous substances and can be disposed normally. The battery used in this device may explode if mistreated. Do not recharge, disassemble or dispose them in fire.

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

Technical Information

The WL-2401 Device complies with IEC 601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, including Am. No.1 (1991) and Am. No.2 (1995), and EN 60601-1.

The WL-2401 Device has been verified to meet the requirements of the following Electromagnetic Compatibility standards, EN 55011 (CISPR II) Radiated Emissions, EN 61000-4-2 Electrostatic Discharge Immunity, EN 61000-4-3 Radiated Electromagnetic Field Immunity.

The WL-2401 Device is classified as TYPE B equipment.

Attention, the WL-2401 Device produces physiological effects as described in this guide.

Technical Specifications

Channel	Single channel
Output Volt.	0-140 volt (open circuits)
On function	Power ON and intensity setting (up 10 levels)
Off function	Power OFF and intensity setting (down)
Pulse amplitude	Adjustable, 0-50mA peak into 500Ω load.

Mode	Pulse rate	Pulse width	Interval	Duration
A	30Hz	250μs	ON: 3sec, OFF: 5sec	continuous

Power source	1xDC 3V Lithium battery (CR2032)
Dmensions	60(L) x 47.3(W) x 14.6(H) mm
Weight	Approx 19 grams (include battery)

* The allowable variation in supply voltage is 70% for 3V battery.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

May 17, 2004

WELL-LIFE HEALTHCARE, INC.
C/O THERATECH, INC.
1109 MYATT BLVD.
MADISON, TN 37115
ATTN: MIKE PRICE

510(k) Number: K040512
Product: LIMITED FUNCTION WL/OTC-TENS DEVICE, MODEL WL-2103A,

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

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K040512/S2

Well-Life Healthcare Inc.

Re: K040512/S1

Trade Name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS

To: Celia M. Witten, Ph.D., M.D. Director

From: Grace Chang

Date: May 11, 2004

FDA/CDRH/CDE/CMO
2004 MAY 17 A 10: 42

Dear Mr. Celia M. Witten,

This mail is to response to the FDA review comments for our 510(k) Submission (K040512) release at May 10, 2004, as well as the providing of revised additional information according the our request letter sent at May 5, 2004.

Because too much information is to be provided, we would like to separate our additional information into the following two parts:

- Part A: Correction report and additional revised information.
- Part B: Revised user manual for WL-2402 and WL-2403 (Previous know as WL-2203A and WL-2203B).

Please review our additional information provided hereafter.

Best Regards,

Grace Chang

Official Correspondent
Well-Life Healthcare Inc.,
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

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Part A: Correction Report and Additional revised information

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

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Well-Life Healthcare Inc.

Re: K040512/S1

Trade Name: Models WL-2103A, WL-2203A, WL-2203B and Model WL-2401 Limited Function OTC TENS

To: Celia M. Witten, Ph.D., M.D. Director

From: Grace Chang

Date: May 11, 2004

Dear Mr. Celia M. Witten,

Thank you for your quick response to our additional information provided at April 21, 2004. For this additional information we have submitted a letter to FDA to inform that there may be some further revised information provided for this submission. This letter was delivered at May 5, 2004. For this notification letter, please see attachment 1.

I think, perhaps you did not received our letter so far. So, you completed your review and send this letter to us. In this condition, we would like to combine the details which are to be provided in our revised information with the response to your comment letter in this correction report. Please allow us to do.

Based on this explanation, we separate this correction report into two parts – part I, the information for the application of change concerning the operation of our device, and part II concerning the responses to your review comments. For these two parts of correction report, please see the followings:

Part I. <u>The modification for the operation of our device</u>

According to the suggestion from our marketing department, we were suggested to simply the operation of OTC-TENS. Our marketing department said that most OTC-TENS does not provide too much and too complicated operation as that of prescription TENS. We believe this may be one of the important issue in your previous review comments.

Based on this main concept, our R&D department made the following decisions for the models of our submission. The main decisions could be presented as the following items:

1> (b)(4) [redacted]

2> [redacted]

3> [redacted]

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

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(b)(4)

[redacted]

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Records processed under FOIA Request 2013-4395; Released by CDRH on 12/31/2014

(b)(4)

[redacted]

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

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(b)(4)

[redacted]

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

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(b)(4)

[redacted]

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

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Food and Drug Administration
9200 Corporate Boulevard, (HFZ-401)
Rockville, Maryland 20850
U.S.A.

ATTACHMENT 1

ate: May 5, 2004

Dear Sirs:

Dear Mr. Shulman:

We have received your letter concerning our additional information provided for our 510(k) submission K040512. Thank you very much.

However, based on some information from our marketing department, we decided to make some further modification on our product so as to simplify the operation for OTC market.

.his is also the main suggestion made on the review comment we received. Therefore, we sincerely request FDA to allow us to provide further revised additional information. As estimated, the revised information will be completed within 10 days. As soon as it is completed, we will send tem to you immediately.

Please kindly keep the reviewer informed about this request. For the providing of revised additional information, our US agent will contact with you so as to help the process of the review work of our submission.

The information of our US agent is:

Mr. mike price
THERATECH, INC.
1109 Myatt blvd., Madison, TN 37115
Phone: 615-865-4000
Fax: 800-485-2626
Email: mikeprice@stimsupply.com

Best regards,

Grace Chang

845155303379

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

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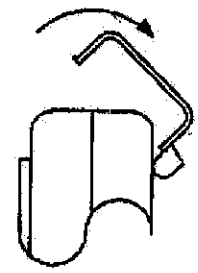
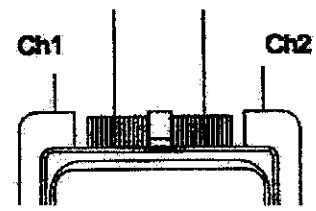
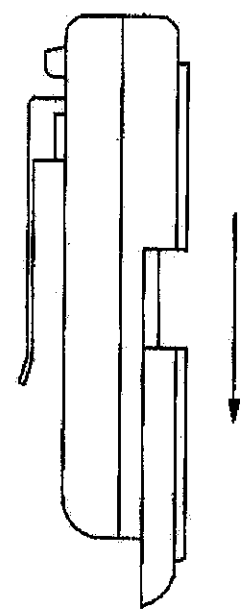
ATTACHMENT 27
for WC-2402

Description of operation	Diagram Indication
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
For turning stimulator ON, the knobs protection cover shall be opened first. Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user. For the suitable adjustment of output, you may feel strong or weak sensation, but with no muscle contractions.	Amplitude Adjustment Knob 
Step 8 – Adjust appropriate stimulation mode	
The operation buttons and LCD display are as the indication of the drawing. For the adjustment of stimulator, you may do it as the followings: 1> Slide the front cover open by pressing gently on the black area of top area and pulling down. After the cover is opened, you may see the four operation buttons. 2> Continuously push "MODE" key so as to change the operation mode. It may be changed among "A", "B", "C", "D", and "E" operation mode alternatively. While the symbol flashes on the "Mode" display, it means that this operation mode has been selected. For the meaning of operation mode, please see the following explanation: A: Cycle Burst. 2Burst/sec, 9 pulses/Bursts, 100Hz, width is adjustable. (Also known as "B" mode)	

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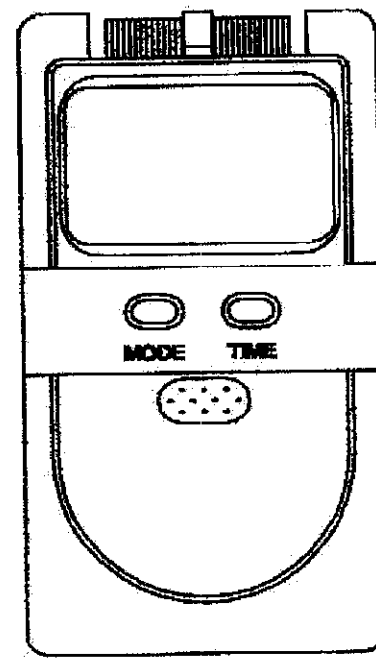
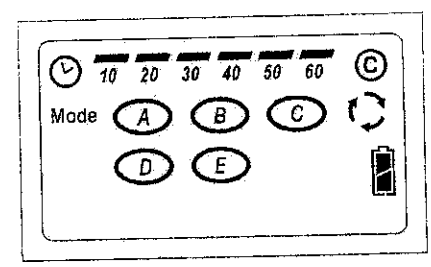
ATTACHMENT 21

for WL-2402

Description of operation	Diagram Indication
B: Continuous mode. Pulse rate, pulse width and intensity are adjustable. (Also known as "C" mode) C: Modulated Width. Pulse width vary automatically per interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value, then returns to the setting value. Rate, width and intensity are adjustable. (Also known as "M" mode) D: Strength-Duration and Rate modulation. SDR consists of alternating modulated intensity (amplitude) and pulse rate so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse rate increase 45% from the modulated rate to the setting value and return to the modulated rate. Total cycle time is 6 seconds. Rate, width and intensity are adjustable. (Also known as "SDR" mode) E: Strength Duration and Width modulation. SDW consists of Alternating modulated intensity (amplitude) and pulse width so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse width increase 54% from the modulated width to the setting value and return to the modulated width. Total cycle time is 6secinds. Rate, width and intensity are adjustable. (Also known as "SDW" mode) For the adjustment of stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different stimulation mode will not cause too much significant difference on the therapy result. The therapy result may be greatly affected by the strength of stimulation output. The providing of different output waveform is to prevent the user from losing sensation feeling if he use a single stimulation only. Based on this, we suggest you to change the operation mode so as to have different stimulation output waveform. In general it is not matter for you to start from any mode and/or change to any mode, as long as you feel comfortable and effective.	 LCD Display 

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for WC-2402 ATTACHMENT B-4

Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between 10min, 20min, 30min, 40min, 50min, 60min and continuous operation. For the operation. TIME = Therapy time selection / setting. After switch on the device, time is set as last operation memory. With the key, you set the therapy time that will be shown in 10, 20, 30, 40, 50, 60 minutes and/or continuous. The stimulation will be continued until the expiration of setting time. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of stimulation parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use. Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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

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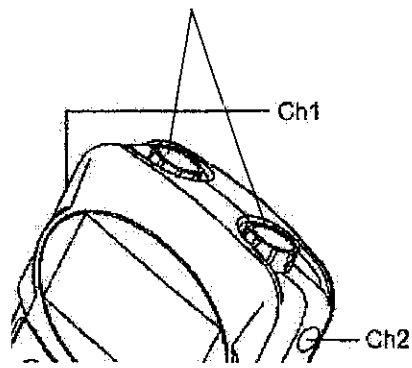
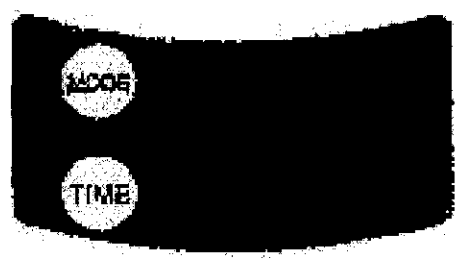
ATTACHMENT 2-2
for WL-2403

Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user. For the suitable adjustment of output, you may feel strong or weak sensation, but with no muscle contractions.	Amplitude Adjustment Knob 
Step 8 – Adjust appropriate stimulation mode	
The stimulation effect could be different due to the different stimulation mode. For this device you may select stimulation mode by following the instruction described below: MODE = Therapy mode selection / setting. With this key you can select the seven preset modes. With each depression of the key, you switch to the next mode. The selected mode will be blinking. For the operation mode, they may be chosen from pushing "MODE" key. The stimulation characteristics of different operation modes, are described hereafter. A: Cycle Burst. 2Burst/sec, 9 pulses/Bursts, 100Hz, width is adjustable. (Also known as "B" mode) B: Continuous mode. Pulse rate, pulse width and intensity are adjustable. (Also known as "C" mode)	

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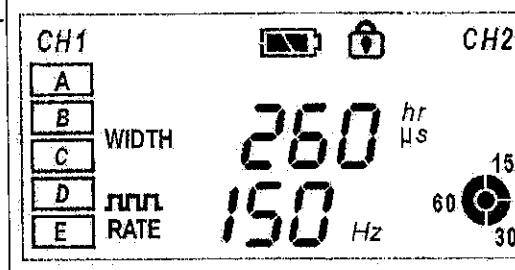
ATTACHMENT 2-2
for WC-2403

Description of operation	Diagram Indication
D: Strength-Duration and Rate modulation. SDR consists of alternating modulated intensity (amplitude) and pulse rate so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse rate increase 45% from the modulated rate to the setting value and return to the modulated rate. Total cycle time is 6 seconds. Rate, width and intensity are adjustable. (Also known as "SDR" mode) E: Strength Duration and Width modulation. SDW consists of Alternating modulated intensity (amplitude) and pulse width so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse width increase 54% from the modulated width to the setting value and return to the modulated width. Total cycle time is 6secinds. Rate, width and intensity are adjustable. (Also known as "SDW" mode) For the adjustment of stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different stimulation mode will not cause too much significant difference on the therapy result. The different stimulation mode will not cause too much significant difference on the therapy result. The therapy result may be greatly affected by the strength of stimulation output. The providing of different output waveform is to prevent the user from losing sensation feeling if he use a single stimulation only for a long period of time. Based on this, we suggest you to change the operation mode so as to have different stimulation output waveform. In general it is not matter for you to start from any mode and/or change to any mode, as long as you feel comfortable and effective.	

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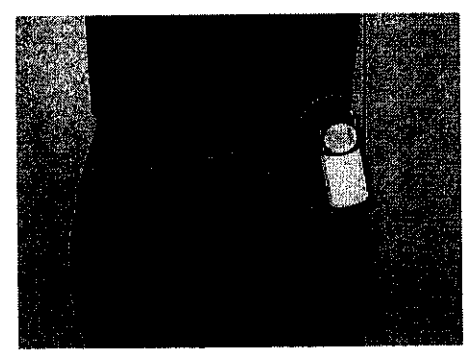
ATTACHMENT 2-2
for WL-2403

Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between 15min, 30min, 60min and continuous operation. For the operation. TIME = Therapy time selection / setting. After switch on the device, time is set as last operation memory. With the key, you set the therapy time that will be shown in 15, 30, 60 minutes or continuous. The stimulation will be continued until the expiration of setting time. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of setting parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use.	

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ATTACHMENT 3

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[redacted]

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ATTACHMENT 3-1

Indications For Use

510(k) Number (if known): K040512

Device Name: Limited Function WL/OTC-TENS / Model: WL-2401, WL-2402, and WL-2403.

Indications For Use:

- The model WL-2402, WL-2403 TENS 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.
- The model WL-2401 TENS is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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)

Page 1 of __1__

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ATTACHMENT 3-2

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: K040512 .

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

   Contact:
   Ms. Jenny Hsieh
   Sales Manager

   Date of Summary Preparation: February 09, 2004.

2. Device Identification:
   Classification Name: Transcutaneous Nerve Stimulator.

   Trade/Proprietary Name: Limited Function device, model WL-2401, WL-2402, and WL-2403.

   Classification: Class II (21 CFR 882.5890)

   Product Code: GZJ

3. Identification of predicate device
   The Well-Life models WL-2401, WL-2402, and WL-2403 are of comparable type and are substantially equivalent to the following predicate devices:

New Device Model	Predicate Device	Manufacturer	510(k) No.	Date Cleared
WL-2401	ReliefBand Device Models	Woodside Biomedical, Inc.	K020180	January 17, 2002
WL-2402, WL-2403	Ultra Stim Kit	Axelgaard Mfg. Co., Ltd.	K013532	June, 6, 2002

4. Device Description:

   For WL-2402, and WL-2403
   The Well-life models WL-2402, and WL-2403 are non-invasive devices which are intended for over the counter use in temporary relied of pain associated with sore and aching muscles in the lower back due to stain from exercise or normal household and work activities.

   The devices contain the following main parts: TENS stimulation unit, Support Belt, Self-adhesive pads, and Snap Cable.

   The device can be worn on the low back part of user so as to place the stimulation pads on the treatment location of low back.

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The main stimulation function is achieved through the stimulation unit of WL-2402 or WL-2403. those stimulation units have been cleared for 510(k) before being submitted on this new submission for OTC application. The K-number for these two models are K003857, and K030537.

For the detail description of these three stimulation models, please refer to the information provided in K003857, and K030537.

For WL-2401
The Well-Life model WL-2401 is a non-invasive device which is indicated for over the counter use in the relief nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy. This device is contained within a wristband, and provide relief through electrical stimulation of the nerves in the patient's wrist.

The device can be worn on the ventral or palmar (i.e., inside) surface of either or both wrists, approximately 2 fingers breadth above the distal skin crease of the wrist joint, between the tendons of the palmaris longus and flexor carpi radialis muscles.

WL-2401 device is equipped with three operation keys to control the ON/OFF operation and amplitude of stimulation. The stimulation is fixed at certain wave form. The output amplitude may be adjusted up to 50mA via "up" and "down" control key.

The Well-Life model WL-2401 is powered by one 3V lithium battery. This battery may be replaced by user while the battery power becomes low.

5. Intended Use:

For WL-2402, and WL-2403
The models WL-2402, and WL-2403 are indicated for over the counter use in the temporary relief of pain associated with sore and aching muscles in the low back due to stain from exercise or normal household and work activities.

Foe WL-2401
The WL-2401 is indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

6. Technological characteristics:

A comparison of the technological characteristics of the Well-Life models WL-2402, WL-2403, and WL-2401 and the predicate device has been performed. The results of this demonstrate that the Well-Life model WL-2402, WL-2403, and WL-2401 are equivalent to the marketed predicate device. The differences between the Well-Life models WL-2402, WL-2403, and WL-2401 and the predicate models are insignificant and do not affect the safety or effectiveness of the device.

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ATTACHMENT 3-2

7. Performance data:
Since there is not any significant change in the construction specification for the main stimulation unit WL-2402, WL-2403, and WL-2401, the performance testing reports according to ANSI/AAMI NS4, and the safety testing reports according to EN 60601-1, EN 60601-1-1, and EN 60601-1-2 as mentioned in the previous 510(k) submission documents are still available for this submission.

For the additional fixing part, the neoprene conductive belt, the bio-compatibility testing report done according to ISO 10993-1 as well as the relevant standards are included in this submission.

8. Conclusions
Well-Life Healthcare Inc, has demonstrated through its evaluation of the Well-Life models WL-2402, WL-2403, and WL-2401 that the devices are equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

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ATTACHMENT 3-3

6.2. Specification of Limited Function TENS series.

Features	*New models*		
	WL-2402	*WL-2403*	*WL-2401*
510(k) Number	K0033857	K030537	K010010
Manufacturer	Well-Life	Well-Life	Well-Life
Classification	Class II	Class II	Class II
Basic Specification Comparison			
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual	Single
Power supply	9 volt battery	9 volt battery	3 volt battery
Circuit designed	Digital	Digital	Analog
Software	Yes	Yes	Yes
Amplitude (mA)	0-80 (Adjustable)	0-80 (Adjustable)	0-50
Pulse rate (Hz)	150 fixed	150 fixed	30 fixed
Width (μs)	260 fixed	260 fixed	250 fixed
Power ON indicator	LCD	LCD	LED
Timer (min)	10, 20, 30, 40, 50, 60, C	15, 30, 60, C	15
Weight (grams) (batt. Include)	142	142	19
Size (mm)	110×62×27	110×62×27	60×47.3×14.6
Prescription or OTC	OTC	OTC	OTC
Indication for use	All models as above mentioned 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.		All models as above mentioned are intended for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.
Output Specification Comparison			
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square	Square
Maximum Output Voltage (V) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	 40 68 92	 40 68 92	 25 68 92
Maximum Output Current (mA) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	 80 68 46	 80 68 46	 50 68 46
Pulse Width (μS)	30-260	50-260	250 fixed
Frequency (Hz)	1-150	1-160	30 fixed
Maximum Phase charge (μC) @500Ω	20.8	20.8	7.0
Maximum Current Density (A/cm^2) @500Ω	1.95×10^{-5}	1.95×10^{-5}	13.4×10^{-5}

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ATTACHMENT 3-4

8.1. Substantial Equivalent comparison for WL-2402, and WL-2403 (Group 1 model).

8.1.1. Table of comparison.

Basically, the main comparison between the models WL-2402, and WL-2403 as well as their 510(k) cleared device is listed as the following table:

Features	*New models*		*510(k) cleared device*
	WL-2402	*WL-2403*	*Ultra Stim Kit*
510(k) Number	K0033857	K030537	K013532
Manufacturer	Well-Life	Well-Life	Axelgaard Mfg. Co., Ltd.
Classification	Class II	Class II	Class II
Basic Specification Comparison			
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual	Dual
Power supply	9 volt battery	9 volt battery	9 volt battery
Circuit designed	Digital	Digital	Analog
Software	Yes	Yes	Yes
Amplitude (mA)	0-80 (Adjustable)	0-80 (Adjustable)	0-80
Pulse rate (Hz)	150 fixed	150 fixed	3-100
Width (μs)	260 fixed	260 fixed	72-260
Power ON indicator	LCD	LCD	LCD
Timer (min)	10, 20, 30, 40, 50, 60, C	15, 30, 60, C	NIL
Weight (grams) (batt. Include)	142	142	120
Size (mm)	110×62×27	110×62×27	100×60×21
Prescription or OTC	OTC	OTC	OTC
Indication for use	All models as above mentioned 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.		
Output Specification Comparison			
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square	Square
Maximum Output Voltage (V) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	40 68 92	40 68 92	40 68 92
Maximum Output Current (mA) (±10%) @ 500Ω @ 1kΩ @ 2kΩ	80 68 46	80 68 46	80 68 46
Pulse Width (μS)	30-260	50-260	72-260
Frequency (Hz)	1-150	1-160	3-100
Maximum Phase charge (μC) @500Ω	20.8	20.8	20.8
Maximum Current Density (A/cm^2) @500Ω	1.95×10^{-5}	1.95×10^{-5}	2.3×10^{-5}

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ATTACHMENT 3-5

8.1.2. Discussion of comparison for group 1 models.

For both the chosen 510(k) cleared device and our new device provided the following accessories to attach the stimulation unit on abdominal area for the specified indication for use of device:
1 Support Belt
1 TENS Stimulator
1 package of self-adhesive pads
1 set of plastic Storage Liners (not shown)
1 pair of Snap Cable
1 User Manual (not shown)
1 9-volt Alkaline Battery

The main difference exists in the stimulation output. This difference may cause some impact on the performance and safety. The possible impact was evaluated hereafter.

As information from the manufacturer of UltraStim Lit, the stimulation specification is as the indication of the following table.

Program	Max. Amplitude	Phase duration	Rate	Cycle Time
1	80mA	200μs	50Hz	10 Seconds
2	80mA	200μs	60-100Hz	10 Seconds
3	80mA	120-72μs	80Hz	10 Seconds
4	80mA	260-78μs	100Hz	15 Seconds
5	80mA	260μs	3-5Hz	15 Seconds

For our new device, the stimulation specification is as the indication of the following table.

Model	Max. Amplitude	Phase duration	Rate	Cycle Time
WL-2402	80mA	260μs	150Hz	15-60 minutes
WL-2403	80mA	260μs	150Hz	15-60 minutes

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[redacted]

Summary for the safety comparison of stimulation output

Based on the calculation information as above mentioned, the main stimulation output characteristics may be listed as the following table.

Characteristic	Max. phase charge		Max. charge per pulse		Max. average current	
Limited value acc. to NS4	25μc		75μc		10mA	
Calculated value	K013532	New device	K013532	New device	K013532	New device
	20.8μc	20.8μc	27.28μc	27.28μc	2.08mA	3.12mA
Verdict	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Conclusions of group 1 comparison

For the comparison information provided in this clause, it is very clear that the following comparison conclusions could be made:

1> Both the chosen 510(k) clear model and our new device have the similar fixing device to provide the application of the similar stimulation position. So it is very reasonable that all the devices have the similar "indication for use".

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ATTACHMENT 3-5

2> The stimulation output may have some difference in output characteristics. However, all of the output characteristics are within the acceptable limits of ANSI/AAMI, NS4 standard. So they could be considered as appropriate stimulation output according to ANSI/AAMI NS4 standard.

3> Even though the stimulation output has different level, it does not effect the indication for use as well as the safety of operation. Therefore, the stimulation strength for both 510(k) cleared device and our new devices could adjusted by the patient or user without the involvement of physician.

Based on this reason, we would like to claim that our devices are also capable of being sold as OTC device as that chosen of 510(k) cleared device, UltraStim Kit (K013532).

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ATTACHMENT 3-6

Att1

Difference Comparison between WL-2402, (previous know asWL-2203A) and WL-2403 (previous know as WL-2203B)

§1. Main Specification Comparison

Please see the information of the following table.

Features	*Models*	
	WL-2402	*WL-2403*
510(k) Number	K0033857	K030537
Manufacturer	Well-Life	Well-Life
Classification	Class II	Class II
Basic Specification Comparison		
Waveform	Asymmetrical Biphasic Square	Asymmetrical Biphasic Square
Channels	Dual	Dual
Power supply	9 volt battery	9 volt battery
Circuit designed	Digital	Digital
Software	Yes	Yes
Amplitude (mA)	0-80 (Adjustable)	0-80 (Adjustable)
Pulse rate (Hz)	150 fixed	150 fixed
Width (μs)	260 fixed	260 fixed
Power ON indicator	LCD	LCD
Timer (min)	10, 20, 30, 40, 50, 60, C	15, 30, 60, C
Weight (grams) (batt. Include)	142	142
Size (mm)	110×62×27	110×62×27
Prescription or OTC	OTC	OTC
Operation Mode	A, B, C, D, E	A, B, C, D, E
Indication for use	All models as above mentioned 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.	

§2. Description of difference

Based on the information provide in the comparison table the main difference may be described as the following items.

1> The outlook of stimulation device is different.

2> Timer control: for detail information, see comparison table.

3> Size and weight: for detail information, see comparison table.

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ATTACHMENT 4

Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 effects on the hear rhythm 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, which could be lethal.
- Do not place the pads on or around your head. The effects of stimulation of the brain are unknown. Therefore, do not apply stimulation across the head and do not place electrodes on opposite sides of the head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.
- The safety of using this System during pregnancy or birth has not been established.

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ATTACHMENT 5

- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System. You should contact your physician prior to using the device following recent surgical procedures on your back (e.g., disc surgery, spinal cages inserted, etc.) because stimulation may disrupt the healing process.

⚠ Use Caution and consult your Physician before using this 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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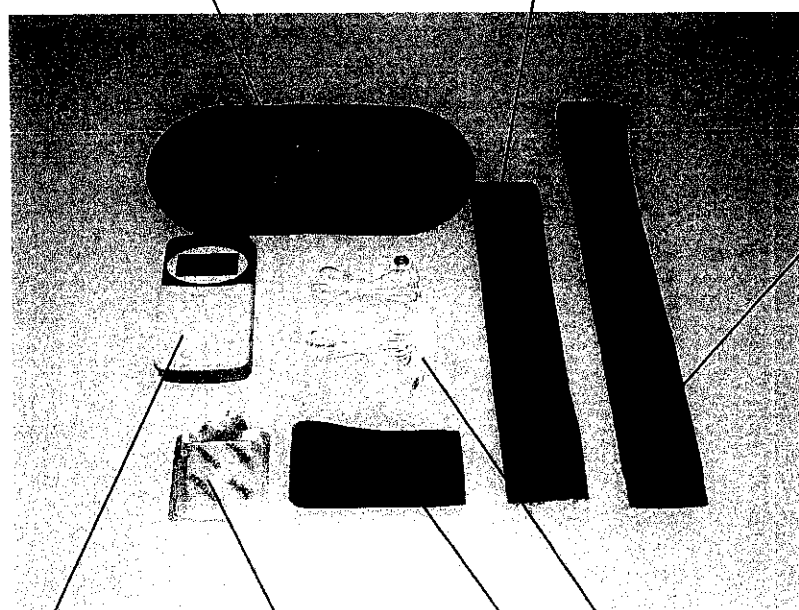
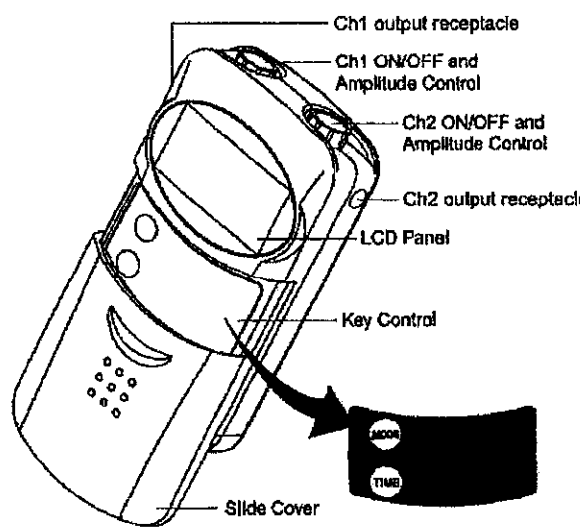
ATTACHMENT 6

Introduction to your System

Your System includes the following parts:



Parts of Stimulator



How Your System works

The main function of pain relief comes from the continuous stimulation 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.

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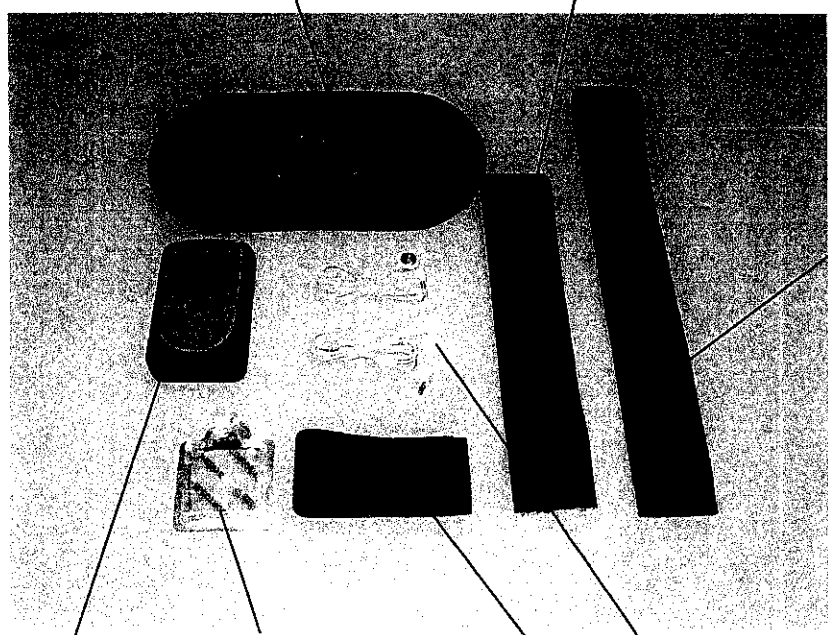
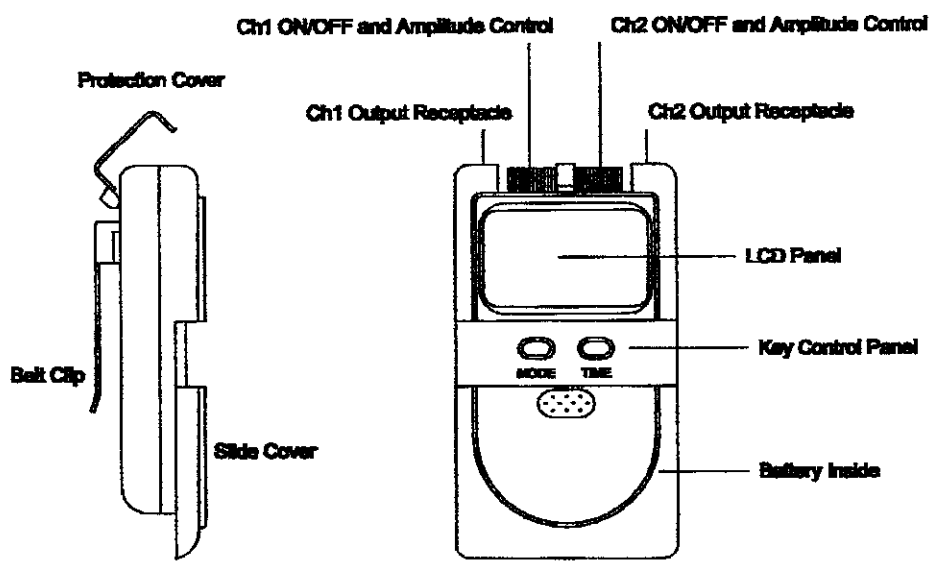
ATTACHMENT 6

Introduction to your System

Your System includes the following parts:



Parts of Stimulator



How Your System works

The main function of pain relief comes from the continuous stimulation 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.

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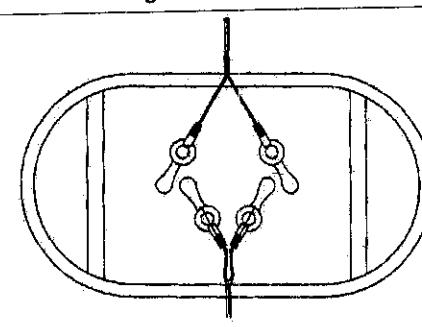
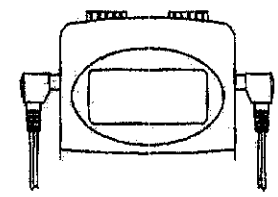
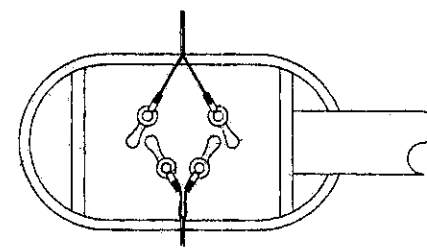
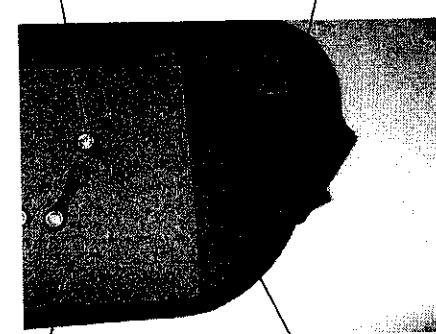
ATTACHMENT 7

Description of operation	Diagram Indication
Step 4 – Connecting snap cables Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro extrude in two sides. Take one cable, and snap two connectors onto the metal snaps (facing upward). Repeat with second cable onto the other snaps (facing downward). Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket. IMPORTANT: Make sure both channel 1and channel 2 are turned "OFF" prior to plugging in the load cables.	 Channel 1 Channel 2 
Step 5 – Choose and connect the elastic waist band For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those bands are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. Connect waist band at one side of support belt as indication of drawing. The connection of belt and hand is done through putting the Velcro side of band onto the connecting extrude area of support belt. For the connection of waist band and support belt, please see the indication of photo.	L: For 46" ~ 38" waist size M: For 38" ~ 28" waist size L: For 28" ~ 20" waist size  Velcro side of band Metal snap  Support belt Velcro Extrude

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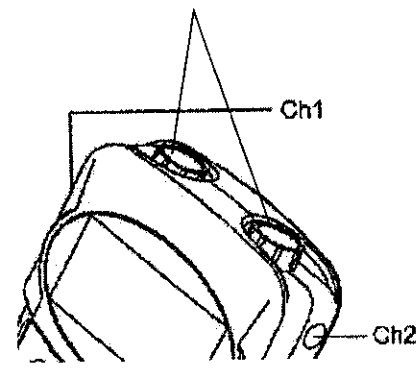
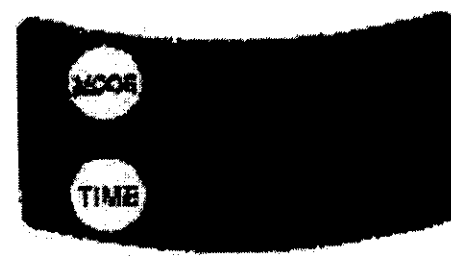
ATTACHMENT 8

Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user. For the suitable adjustment of output, you may feel strong or weak sensation, but with no muscle contractions.	Amplitude Adjustment Knob 
Step 8 – Adjust appropriate stimulation mode	
The stimulation effect could be different due to the different stimulation mode. For this device you may select stimulation mode by following the instruction described below: MODE = Therapy mode selection / setting. With this key you can select the seven preset modes. With each depression of the key, you switch to the next mode. The selected mode will be blinking. For the operation mode, they may be chosen from pushing "MDDE" key. The stimulation characteristics of different operation modes, are described hereafter. A: Cycle Burst. 2Burst/sec, 9 pulses/Bursts, 100Hz, width is adjustable. (Also known as "B" mode) B: Continuous mode. Pulse rate, pulse width and intensity are adjustable. (Also known as "C" mode)	

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ATTACHMENT 9

How to Store Your System

1. Store your 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.

For the ordering of new pads, you may call our service center at THERATECH, 1109 Myatt Blvd. Madison, TN 37115. TEL: 615-865-4000 / 800-788-1705
FAX: 800-485-2626.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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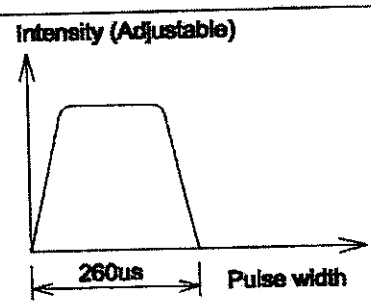
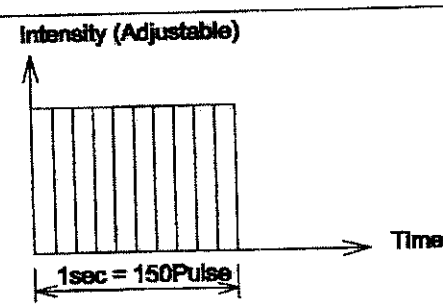
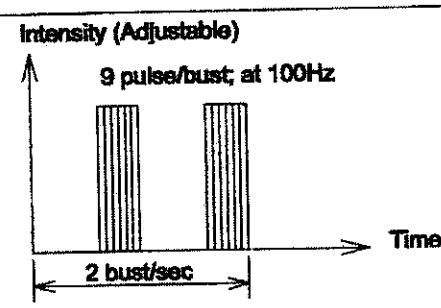
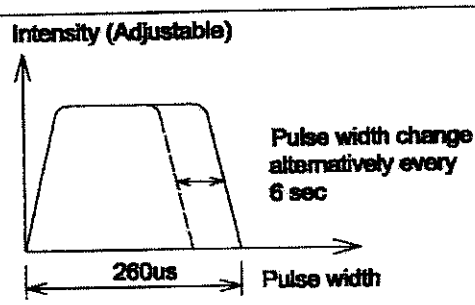
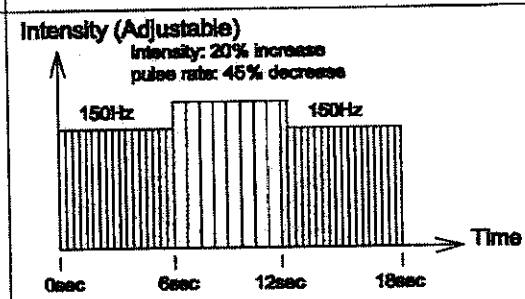
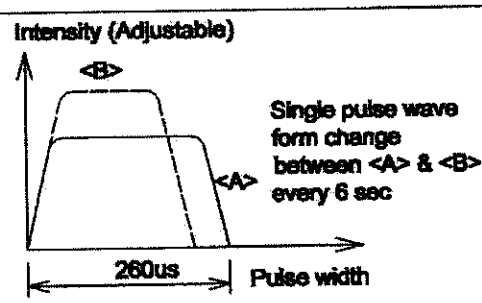
ATTACHMENT 10.

Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
A		
B	Identical to that of A Mode	
C		Identical to that of A Mode
D	Identical to that of A Mode	
E		Identical to that of A Mode

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Part B: Revised User Manual for WL-2402 and WL-2403 (Previous known as WL-2203A and WL-2203B)

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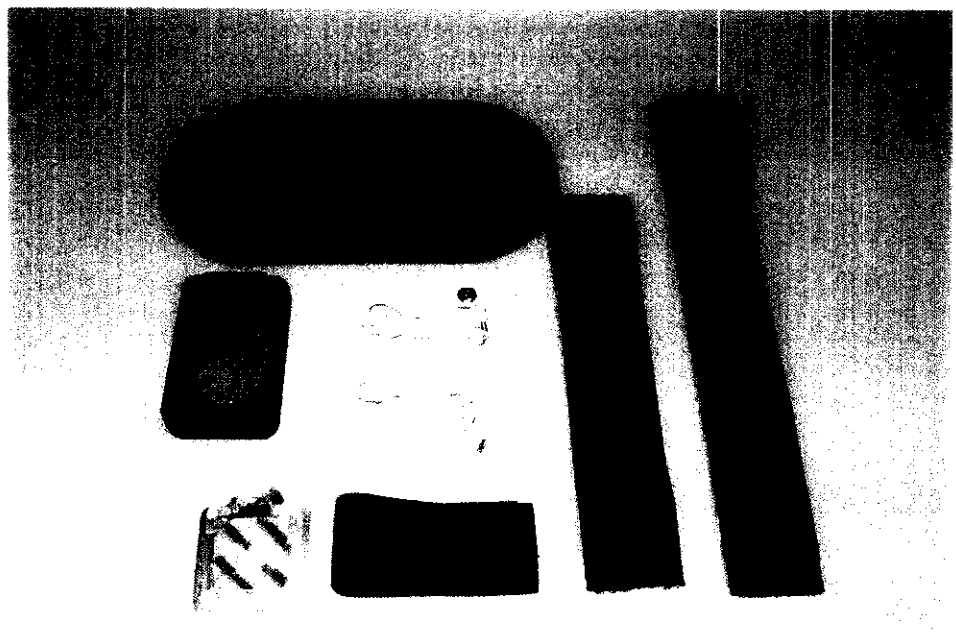
Operation Manual



Model: WL-2402

CE 0434

Well-Life Healthcare Inc.

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

European Representative:

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Well-Life Healthcare Inc.

Low Back Pain Relief System

Purpose of your Well-Life low back pain relief system

The Well-Life low back pain relief System is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and work activities.

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Parts of Stimulator 3
How the System works 3
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Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 effects on the hear rhythm 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, which could be lethal.
- Do not place the pads on or around your head. The effects of stimulation of the brain are unknown. Therefore, do not apply stimulation across the head and do not place electrodes on opposite sides of the head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.
- The safety of using this System during pregnancy or birth has not been established.

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- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System. You should contact your physician prior to using the device following recent surgical procedures on your back (e.g., disc surgery, spinal cages inserted, etc.) because stimulation may disrupt the healing process.

⚠ Use Caution and consult your Physician before using this 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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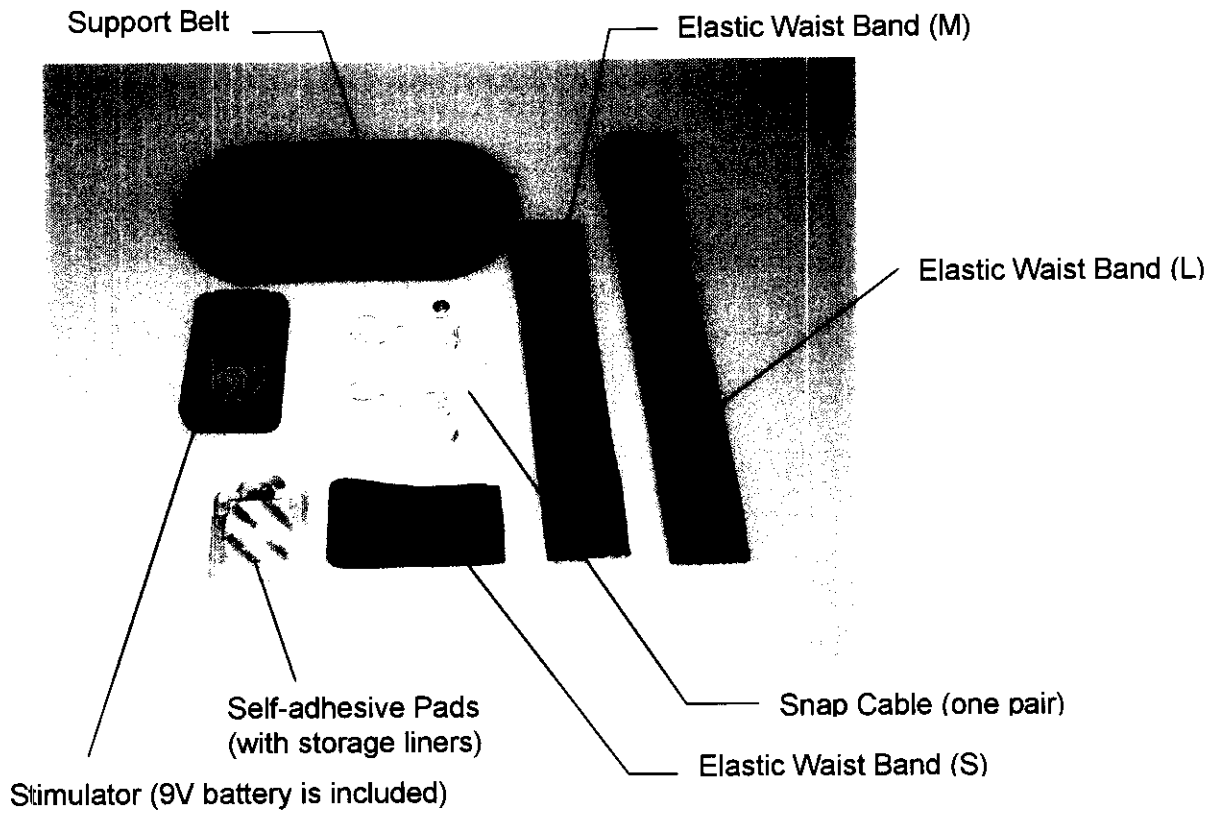
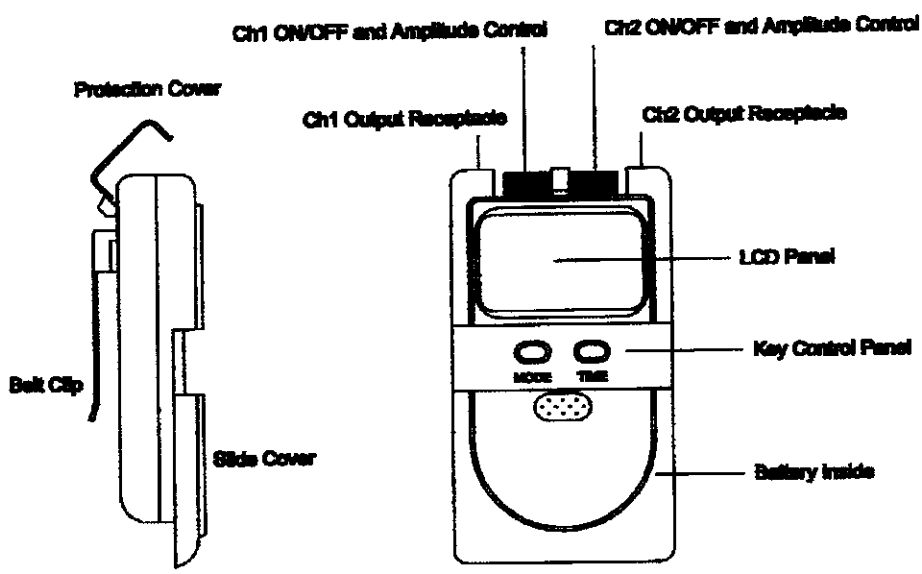
Introduction to your System

Your System includes the following parts:



Parts of Stimulator



How Your System works

The main function of pain relief comes from the continuous stimulation 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.

5D

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Conditions that may affect your System

Since the stimulator is a battery-operated electronic device, 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.

Quick operation guide

You may follow the following simple operation steps to operate this device.

Step 1. Inserting the 9-volt battery into your Stimulator.
Step 2. Preparing Your Support Belt.
Step 3. Applying Electrode Pads to the belt.
Step 4. Connecting snap cables.
Step 5. Choose and connect the elastic waist band.
Step 6. Putting on the support belt.
Step 7. Turning stimulator ON, adjusting appropriate stimulation strength.
Step 8. Adjust appropriate stimulation mode.
Step 9. Select the stimulation time.
Step 10. Enjoying the stimulation.
Step 11. Turning off the stimulator.

For the details of operation, please see the following description.

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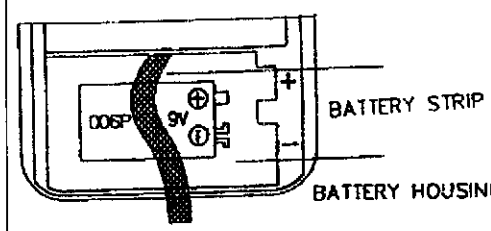
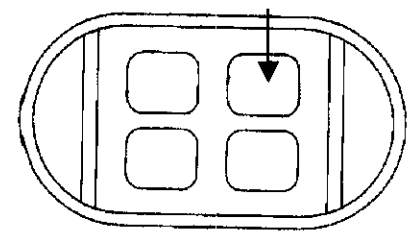
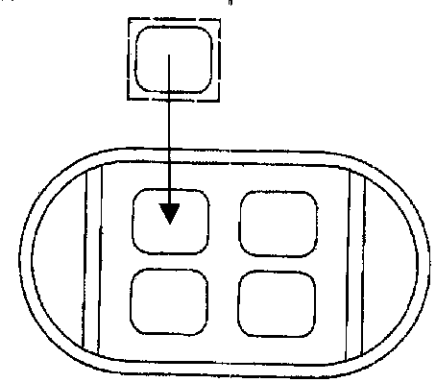
Operation Instruction

Description of operation	Diagram Indication
Step 1 – Inserting the 9-volt battery into your Stimulator	
Make sure both power knobs on the stimulator are turned OFF. To insert the battery, slide the front cover downward until the cover pops off by pressing gently on the arrow and pulling, and insert a 9-volt battery according to the diagram in the battery compartment. Close the cover on the stimulator by sliding from the bottom up.	
Step 2 – Preparing Your Support Belt	Sliver conductive square  This side being faced upward.
Lay your Support Belt open on a flat surface, with the electrode applying side facing up. You will see four silver conductive squares marked for the support belt.	
Step 3 – Applying Electrode Pads to the belt	Four electrode pads, attached to the silver conductive squares. 
Electrode Pads help deliver continuously the stimulation pulses through your skin and into the nerves in your lower back. The pads are designed to fit within the four silver squares on the Support Belt. Open the package of four electrode Pads. Remove the plastic liner from the patterned side and then place the pad with the pattern side down. Repeat this process with the other three pads. IMPORTANT: Leave the other plastic liners with electrode pads until step 5. IMPORTANT: Each electrode pad shall be placed exactly on the silver conductive square, and be pressed firmly on the belt. IMPORTANT: Always use all four pads on the support belt when using the system.	

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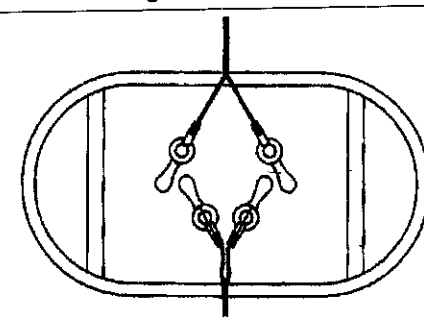
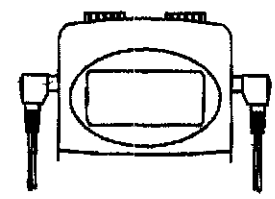
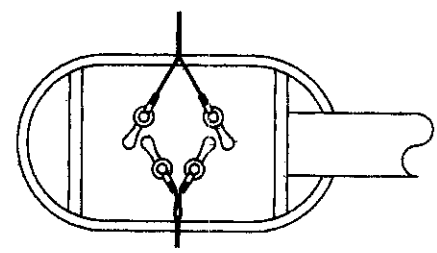
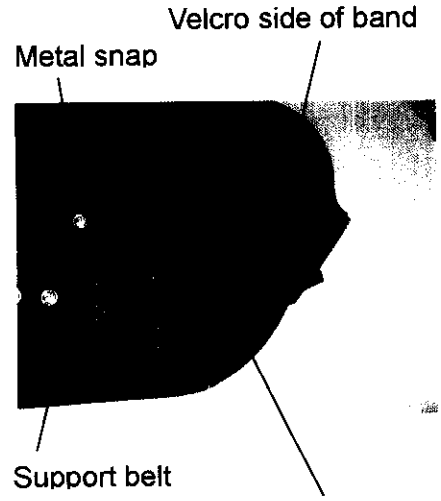
Description of operation	Diagram Indication
Step 4 – Connecting snap cables Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro extrude in two sides. Take one cable, and snap two connectors onto the metal snaps (facing upward). Repeat with second cable onto the other snaps (facing downward). Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket. IMPORTANT: Make sure both channel and channel 2 are turned "OFF" prior to plugging in the load cables.	 Channel 1 Channel 2 
Step 5 – Choose and connect the elastic waist band For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those bands are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. Connect waist band at one side of support belt as indication of drawing. The connection of belt and hand is done through putting the Velcro side of band onto the connecting extrude area of support belt. For the connection of waist band and support belt, please see the indication of photo.	L: For 46" ~ 38" waist size M: For 38" ~ 28" waist size L: For 28" ~ 20" waist size  Velcro side of band Metal snap  Support belt Velcro Extrude

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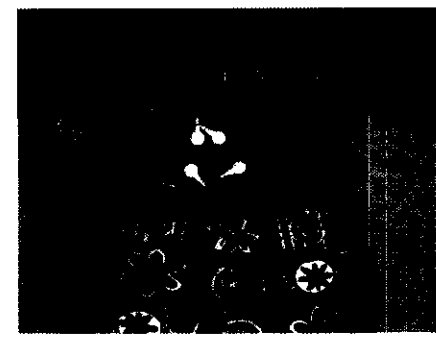
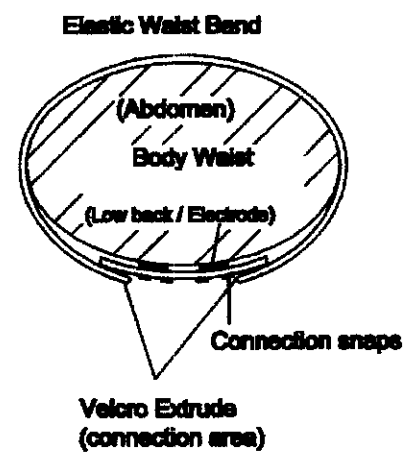
Description of operation	Diagram Indication
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions. 2> If your low-back pain is closer to your waist level than it is to the bottom of your back, place the support belt so that the middle of the belts rests at your waist. 3> If you feel pain closer to the lower part of your back, place the support belt so that the middle of the belt rests an inch or two below your waist. 4> Once you have the support belt in the position you want, fasten the elastic band firmly around your torso with both side of Velcro connected with both end of elastic band. 5> You can tighten or loosen the elastic band to adjust the fasten tension of elastic band so as to attach the support belt firmly belt adjusting the ends of the black tension strap on the outside of the belt and fastening them with their Velcro parches.	 Putting on the support belt. **Diagram of wearing support belt** 

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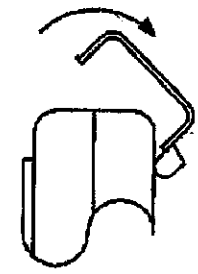
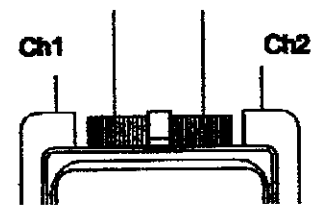
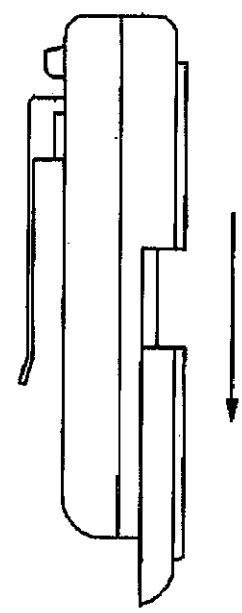
Description of operation	Diagram Indication
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
For turning stimulator ON, the knobs protection cover shall be opened first. Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user. For the suitable adjustment of output, you may feel strong or weak sensation, but with no muscle contractions.	Amplitude Adjustment Knob 
Step 8 – Adjust appropriate stimulation mode	
The operation buttons and LCD display are as the indication of the drawing. For the adjustment of stimulator, you may do it as the followings: 1> Slide the front cover open by pressing gently on the black area of top area and pulling down. After the cover is opened, you may see the four operation buttons. 2> Continuously push "MODE" key so as to change the operation mode. It may be changed among "A", "B", "C", "D", and "E" operation mode alternatively. While the symbol flashes on the "Mode" display, it means that this operation mode has been selected. For the meaning of operation mode, please see the following explanation: A: Cycle Burst. 2Burst/sec, 9 pulses/Bursts, 100Hz, width is adjustable. (Also known as "B" mode)	

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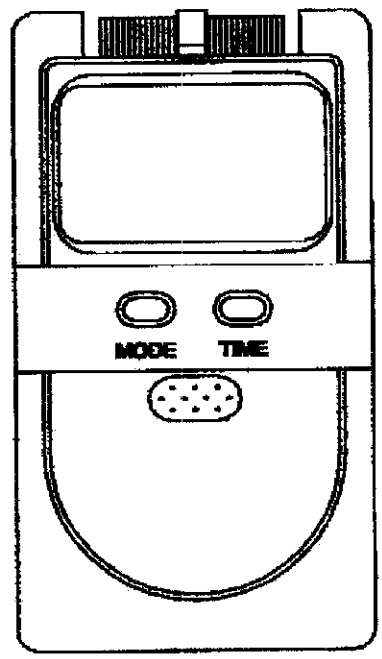
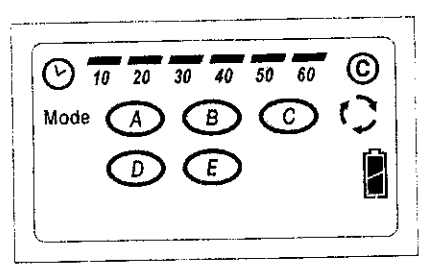
Description of operation	Diagram Indication
B: Continuous mode. Pulse rate, pulse width and intensity are adjustable. (Also known as "C" mode) C: Modulated Width. Pulse width vary automatically per interval of 6 seconds. The modulation range of pulse width is from setting value to 35% less than the control setting value, then returns to the setting value. Rate, width and intensity are adjustable. (Also known as "M" mode) D: Strength-Duration and Rate modulation. SDR consists of alternating modulated intensity (amplitude) and pulse rate so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse rate increase 45% from the modulated rate to the setting value and return to the modulated rate. Total cycle time is 6 seconds. Rate, width and intensity are adjustable. (Also known as "SDR" mode) E: Strength Duration and Width modulation. SDW consists of Alternating modulated intensity (amplitude) and pulse width so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse width increase 54% from the modulated width to the setting value and return to the modulated width. Total cycle time is 6secinds. Rate, width and intensity are adjustable. (Also known as "SDW" mode) For the adjustment of stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different stimulation mode will not cause too much significant difference on the therapy result. The therapy result may be greatly affected by the strength of stimulation output. The providing of different output waveform is to prevent the user from losing sensation feeling if he use a single stimulation only. Based on this, we suggest you to change the operation mode so as to have different stimulation output waveform. In general it is not matter for you to start from any mode and/or change to any mode, as long as you feel comfortable and effective.	 LCD Display 

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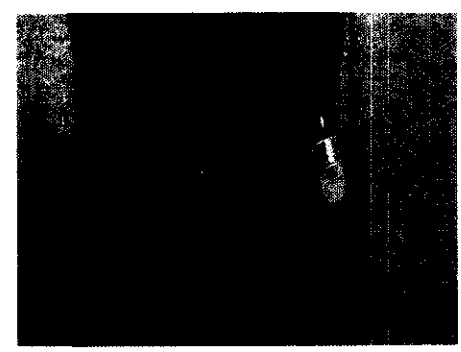
Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between 10min, 20min, 30min, 40min, 50min, 60min and continuous operation. For the operation. TIME = Therapy time selection / setting. After switch on the device, time is set as last operation memory. With the key, you set the therapy time that will be shown in 10, 20, 30, 40, 50, 60 minutes and/or continuous. The stimulation will be continued until the expiration of setting time. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of stimulation parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use. Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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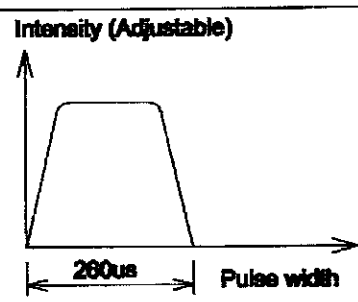
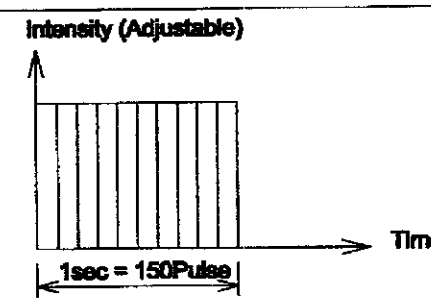
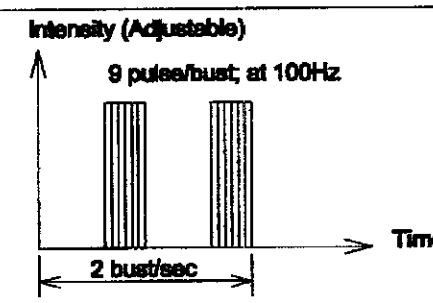
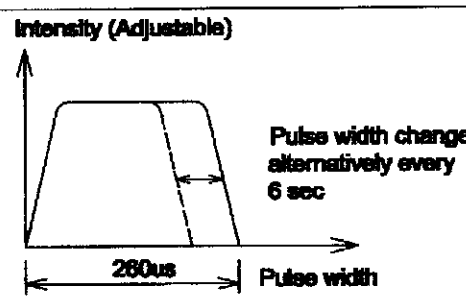
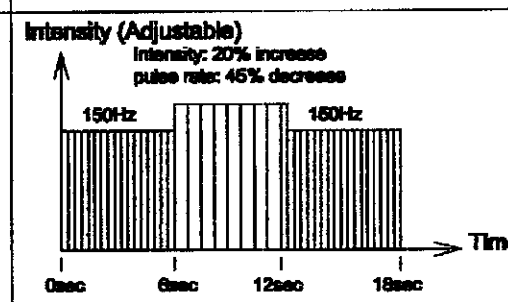
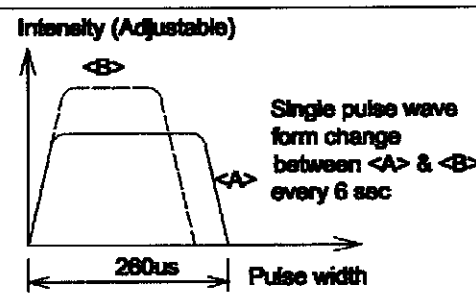
Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
A		
B	Identical to that of A Mode	
C		Identical to that of A Mode
D	Identical to that of A Mode	
E		Identical to that of A Mode

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How to clean Your System

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 a clothes dryer.

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.

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 large amounts of water.

Maintaining Your System

2. Your Stimulator uses a standard 9-volt battery. If the stimulation seems to be weakening, or the stimulator will not turn on, check the battery. To replace the battery, make sure both power knobs are turned OFF. Side the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert a 9-volt battery according to the diagram in the battery compartment. To close the cover, slide from the bottom up.

3. Be sure to put the storage liners on the pads when not using your 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.

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

5. 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 System

1. Store your 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.
For the ordering of new pads, you may call our service center at THERATECH, 1109 Myatt Blvd. Madison, TN 37115. TEL: 615-865-4000 / 800-788-1705
FAX: 800-485-2626.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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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.

Troubleshooting Guide

If you have a problem using your System, 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 a new 9-volt battery, but will not turn on.	Call Customer Service +886-2-2928-2112.
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-2402 Stimulator Technical Specifications

Features	*WL-2402*
510(k) Number	K0033857
Manufacturer	Well-Life
Classification	Class II
Basic Specification Comparison	
Waveform	Asymmetrical Biphasic Square
Channels	Dual
Power supply	9 volt battery
Circuit designed	Digital
Software	Yes
Amplitude (mA)	0-80 (Adjustable)
Pulse rate (Hz)	150 (fix)
Width (μs)	260 (fix)
Power ON indicator	LCD
Timer (min)	15-60
Weight (grams) (batt. Include)	142
Size (mm)	110×62×27
Prescription or OTC	OTC
Indication for use	All models as above mentioned 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.

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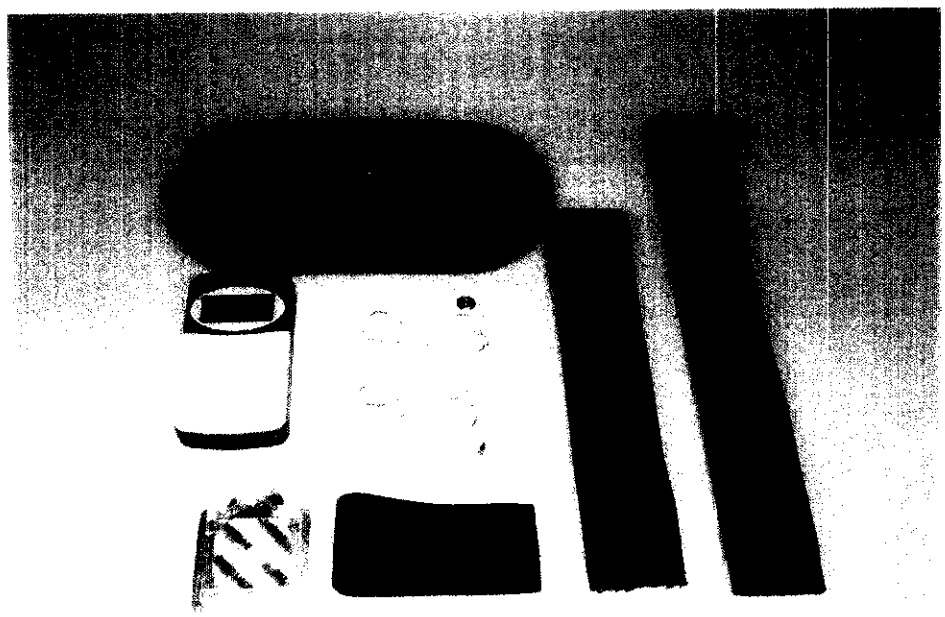
Operation Manual



Model: WL-2403

CE 0434

Well-Life Healthcare Inc.

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

European Representative:

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Well-Life Healthcare Inc.

Low Back Pain Relief System

Purpose of your Well-Life low back pain relief system

The Well-Life low back pain relief System is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and work activities.

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Contraindications, Warnings, Precautions & Adverse Reactions

For the first time you start using this system, you shall read this section carefully so as to ensure your personal safety.

Contraindications: Who should not use this System

- 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 are under the care of a Physician, consult with your Physician before using this device because it may be possible to cause lethal rhythm disturbances to the heart in susceptible individuals.
- 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 effects on the hear rhythm 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, which could be lethal.
- Do not place the pads on or around your head. The effects of stimulation of the brain are unknown. Therefore, do not apply stimulation across the head and do not place electrodes on opposite sides of the head.
- Do not use the pads over or close to cancerous sores.
- Do not use this device while sleeping.
- Do not use if your back feels numb.
- 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.
- Never use the Stimulator without the belt.
- If you have ever had back surgery, consult your Physician before using this System.

Precautions for the safe use of this System

- Read every details of this User Manual before using this System for the first time.
- Keep this manual available whenever you use your System.
- This System is intended for individual person use.
- This system is not effective for pain associated with Central Pain Syndromes, such as headaches.
- This System is for low-back pain only, and should be placed only around your lower back and fastened in the front by your abdomen.
- The pain in low back may indicate that you have some other health problem. You should know the reason and source of your low back pain before using this system. Do not solely rely on the treatment of this system for your low back pain.
- The safety of using this System during pregnancy or birth has not been established.

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- The effectiveness of this system depends greatly upon the individually personal conditions. It may not be always effective for every user.
- If you have had medical or physical treatment for your back, consult with your treatment provider before using this System. You should contact your physician prior to using the device following recent surgical procedures on your back (e.g., disc surgery, spinal cages inserted, etc.) because stimulation may disrupt the healing process.

⚠ Use Caution and consult your Physician before using this 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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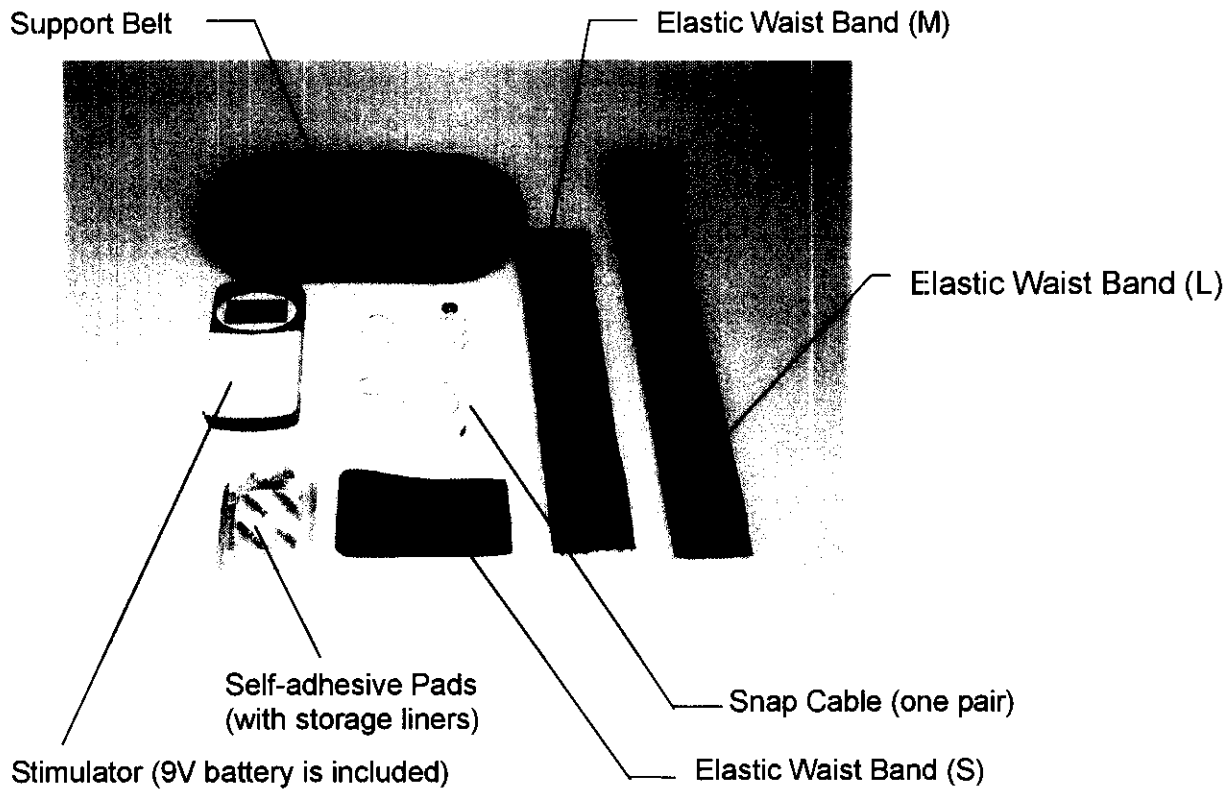
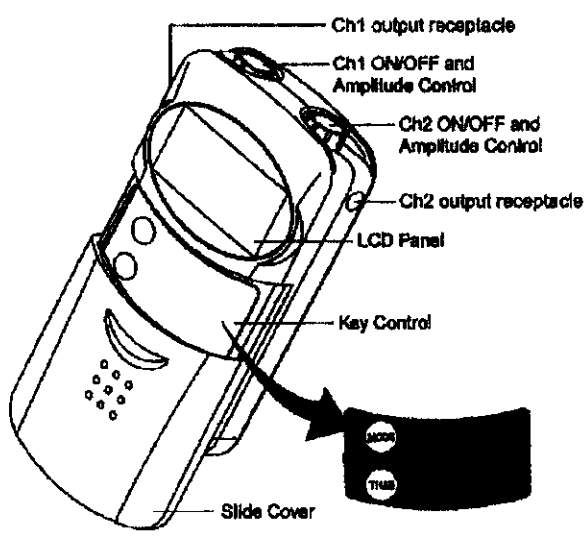
Introduction to your System

Your System includes the following parts:



Parts of Stimulator



How Your System works

The main function of pain relief comes from the continuous stimulation 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.

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Conditions that may affect your System

Since the stimulator is a battery-operated electronic device, 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.

Quick operation guide

You may follow the following simple operation steps to operate this device.

Step 1. Inserting the 9-volt battery into your Stimulator.
Step 2. Preparing Your Support Belt.
Step 3. Applying Electrode Pads to the belt.
Step 4. Connecting snap cables.
Step 5. Choose and connect the elastic waist band.
Step 6. Putting on the support belt.
Step 7. Turning stimulator ON, adjusting appropriate stimulation strength.
Step 8. Adjust appropriate stimulation mode.
Step 9. Select the stimulation time.
Step 10. Enjoying the stimulation.
Step 11. Turning off the stimulator.

For the details of operation, please see the following description.

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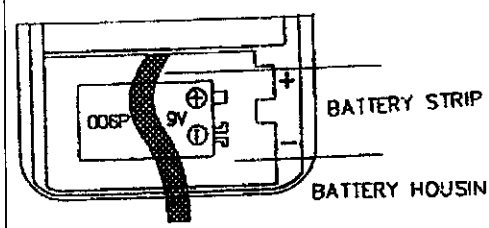
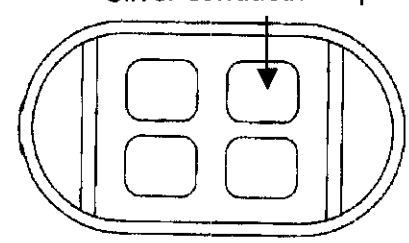
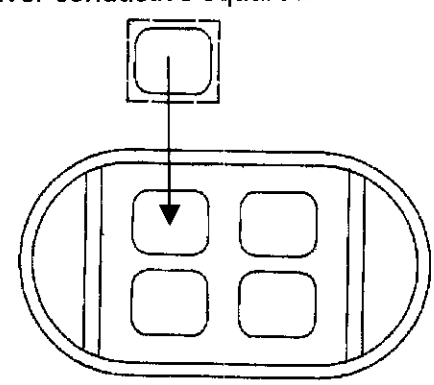
Operation Instruction

Description of operation	Diagram Indication
Step 1 – Inserting the 9-volt battery into your Stimulator	
Make sure both power knobs on the stimulator are turned OFF. To insert the battery, slide the front cover downward until the cover pops off by pressing gently on the arrow and pulling, and insert a 9-volt battery according to the diagram in the battery compartment. Close the cover on the stimulator by sliding from the bottom up.	
Step 2 – Preparing Your Support Belt	Sliver conductive square
Lay your Support Belt open on a flat surface, with the electrode applying side facing up. You will see four silver conductive squares marked for the support belt.	 This side being faced upward.
Step 3 – Applying Electrode Pads to the belt	Four electrode pads, attached to the silver conductive squares.
Electrode Pads help deliver continuously the stimulation pulses through your skin and into the nerves in your lower back. The pads are designed to fit within the four silver squares on the Support Belt. Open the package of four electrode Pads. Remove the plastic liner from the patterned side and then place the pad with the pattern side down. Repeat this process with the other three pads. IMPORTANT: Leave the other plastic liners with electrode pads until step 5. IMPORTANT: Each electrode pad shall be placed exactly on the silver conductive square, and be pressed firmly on the belt. IMPORTANT: Always use all four pads on the support belt when using the system.	

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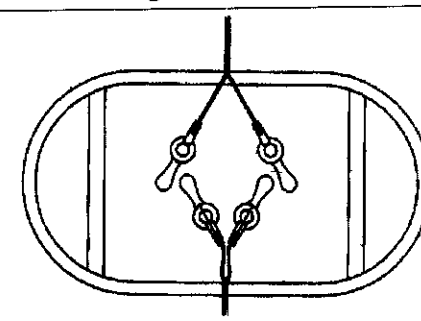
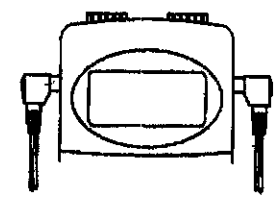
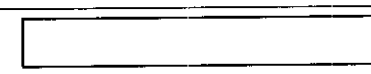
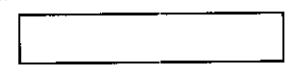
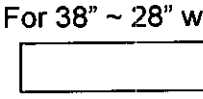
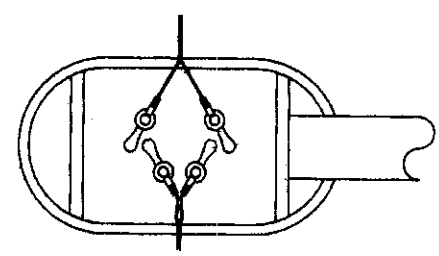
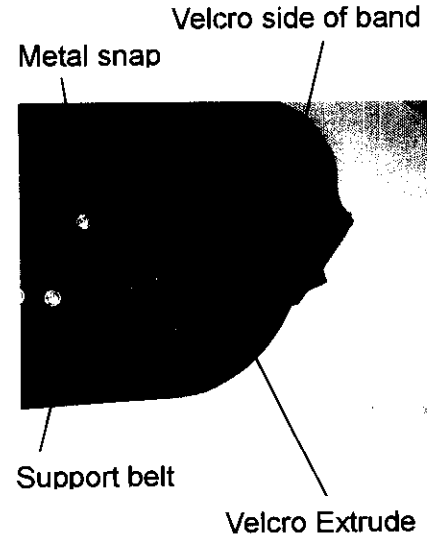
Description of operation	Diagram Indication
Step 4 – Connecting snap cables	
Turn the support belt over, with the electrode pads facing down. The belt should be lying horizontally in front of you. Under this placement you'll see four metal snaps, and Velcro extrude in two sides. Take one cable, and snap two connectors onto the metal snaps (facing upward). Repeat with second cable onto the other snaps (facing downward). Then plug each cable into one socket on the top of the stimulator. It does not matter which cable goes to which socket. IMPORTANT: Make sure both channel 1and channel 2 are turned "OFF" prior to plugging in the load cables.	Channel 1 Channel 2 
Step 5 – Choose and connect the elastic waist band	 L: For 46" ~ 38" waist size  M: For 38" ~ 28" waist size  L: For 28" ~ 20" waist size
For this device, three different size of elastic waist bands are provided for the wearing of support belt to the treatment location. Those bands are made of elastic material with Velcro connection to fit for the Velcro on two sides of support belt. Your may choose "L" size for 46" ~ 38" waist, "M" for 38" ~ 28" waist, and "S" for 28" ~ 20" waist. Connect waist band at one side of support belt as indication of drawing. The connection of belt and hand is done through putting the Velcro side of band onto the connecting extrude area of support belt. For the connection of waist band and support belt, please see the indication of photo.	 Velcro side of band Metal snap  Support belt Velcro Extrude

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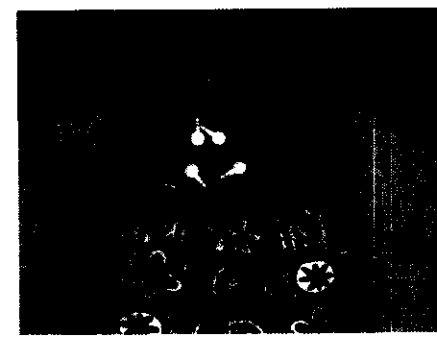
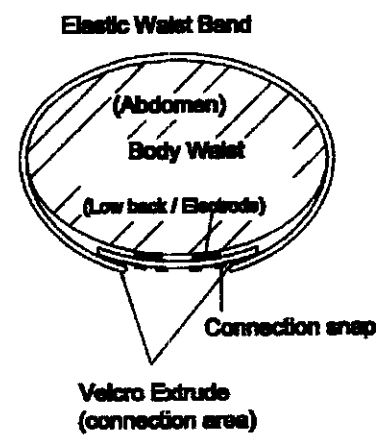
Description of operation	Diagram Indication
Step 6 – Putting on the support belt	
Now, remove the remaining plastic liners from the pads. (Your system includes two large storage liners to cover each set of pads after use.) You may now put on the belt according to the following orders: 1> Choose and place the support belt to the intended treatment as the following two instructions. 2> If your low-back pain is closer to your waist level than it is to the bottom of your back, place the support belt so that the middle of the belts rests at your waist. 3> If you feel pain closer to the lower part of your back, place the support belt so that the middle of the belt rests an inch or two below your waist. 4> Once you have the support belt in the position you want, fasten the elastic band firmly around your torso with both side of Velcro connected with both end of elastic band. 5> You can tighten or loosen the elastic band to adjust the fasten tension of elastic band so as to attach the support belt firmly belt adjusting the ends of the black tension strap on the outside of the belt and fastening them with their Velcro parches.	 Putting on the support belt. **Diagram of wearing support belt** 

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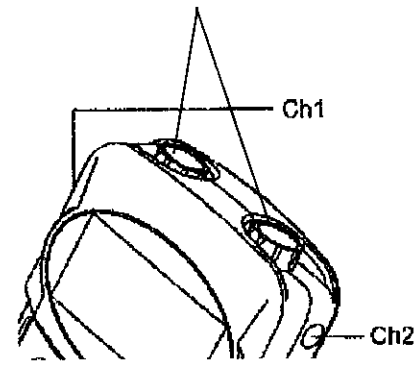
Step 7 – Turning stimulator ON, adjusting appropriate stimulation strength	
Turn both knobs on the top of stimulator to such a position that you can feel the stimulation coming from each channel, and the strength of stimulation could make you feel very comfortable. As soon as the stimulation is switch ON, the LED indicator will become flash so as to indicate that there is stimulation output coming from that channel. The strength of stimulation may be adjusted depending upon the individual condition of user. For the suitable adjustment of output, you may feel strong or weak sensation, but with no muscle contractions.	Amplitude Adjustment Knob 
Step 8 – Adjust appropriate stimulation mode	
The stimulation effect could be different due to the different stimulation mode. For this device you may select stimulation mode by following the instruction described below: MODE = Therapy mode selection / setting. With this key you can select the seven preset modes. With each depression of the key, you switch to the next mode. The selected mode will be blinking. For the operation mode, they may be chosen from pushing "MDDE" key. The stimulation characteristics of different operation modes, are described hereafter. A: Cycle Burst. 2Burst/sec, 9 pulses/Bursts, 100Hz, width is adjustable. (Also known as "B" mode) B: Continuous mode. Pulse rate, pulse width and intensity are adjustable. (Also known as "C" mode)	

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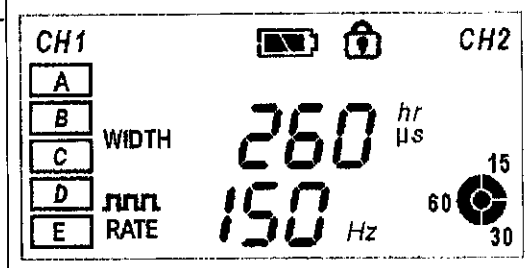
Description of operation	Diagram Indication
D: Strength-Duration and Rate modulation. SDR consists of alternating modulated intensity (amplitude) and pulse rate so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse rate increase 45% from the modulated rate to the setting value and return to the modulated rate. Total cycle time is 6 seconds. Rate, width and intensity are adjustable. (Also known as "SDR" mode) E: Strength Duration and Width modulation. SDW consists of Alternating modulated intensity (amplitude) and pulse width so that one parameter is always increasing while the other is decreasing and vice-versa. The stimulation intensity decreases 20% from the intensity control setting and returns to the setting value; the pulse width increase 54% from the modulated width to the setting value and return to the modulated width. Total cycle time is 6secinds. Rate, width and intensity are adjustable. (Also known as "SDW" mode) For the adjustment of stimulation mode, you may pull down the slide cover, and adjust the switching knobs to the intended setting depending upon the individual condition of user. Basically the different stimulation mode will not cause too much significant difference on the therapy result. The different stimulation mode will not cause too much significant difference on the therapy result. The therapy result may be greatly affected by the strength of stimulation output. The providing of different output waveform is to prevent the user from losing sensation feeling if he use a single stimulation only for a long period of time. Based on this, we suggest you to change the operation mode so as to have different stimulation output waveform. In general it is not matter for you to start from any mode and/or change to any mode, as long as you feel comfortable and effective.	

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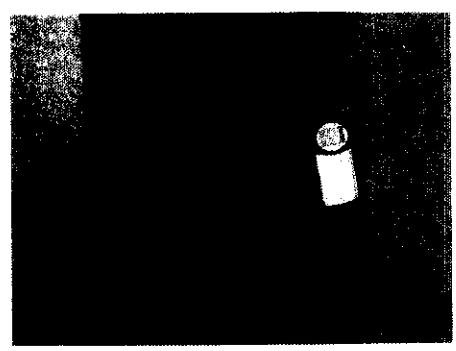
Description of operation	Diagram Indication
Step 9 – Select the stimulation time	
On the stimulator, the "Timer" switch is provided for the setting of stimulation time. It may be chosen between 15min, 30min, 60min and continuous operation. For the operation. TIME = Therapy time selection / setting. After switch on the device, time is set as last operation memory. With the key, you set the therapy time that will be shown in 15, 30, 60 minutes or continuous. The stimulation will be continued until the expiration of setting time. Before the end of expiration of setting time, the LED indicator will be flashed to indicate that the stimulator is operated to generate the stimulation output according to the combination of setting parameters.	
Step 10 – Enjoying the stimulation	
After completing the setting of stimulation, you may put on your dress first, and then clip the stimulator to the support belt or your clothing, and enjoy portable, hands-free pain relief. Try the stimulator for every different setting combination, and see if it relieve your pain. Everyone is different. For some people, the stimulator may begin to feel less effective if it is used for hours on the same settings. The pain may begin to return. Thus can happen if your body becomes used to the intensity or wave form setting of stimulation. You can prevent this by changing the setting of parameters and/or amplitude on your stimulator during extended use.	

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Description of operation	Diagram Indication
Remember to follow Step 7, 8, and 9 instructions. IMPORTANT: While stimulating, the pads must always cover all four metal snaps.	
Step 11 – Turning off the stimulator	
When you are finished using your stimulator, turn OFF both power knobs (Counter clockwise) before removing your support belt to avoid unpleasant stimulation.	

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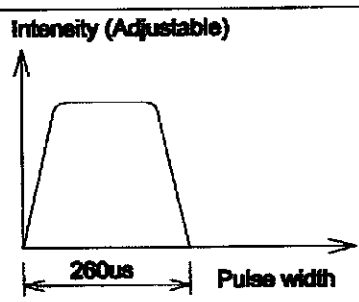
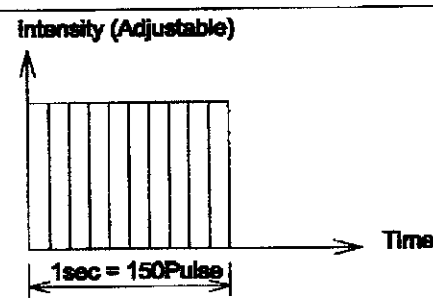
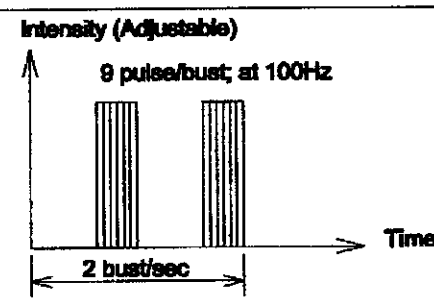
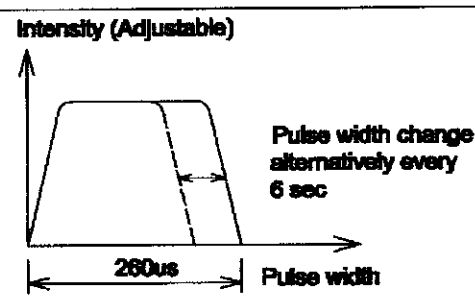
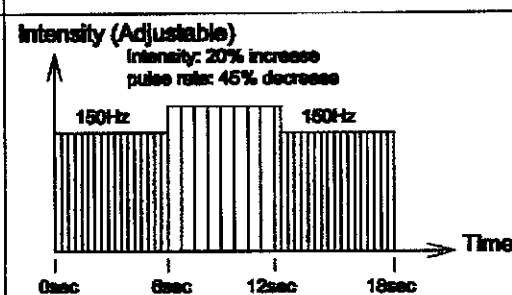
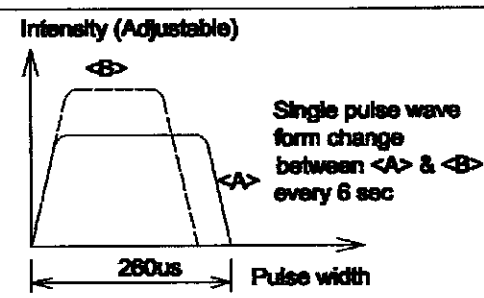
Diagram for the Explanation of Wave Form

This diagram is provided for general reference only.

Operation Mode	Single pulse Wave Form	Long time Wave Form
A		
B	Identical to that of A Mode	
C		Identical to that of A Mode
D	Identical to that of A Mode	
E		Identical to that of A Mode

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How to clean Your System

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 a clothes dryer.

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.

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 large amounts of water.

Maintaining Your System

1. Your Stimulator uses a standard 9-volt battery. If the stimulation seems to be weakening, or the stimulator will not turn on, check the battery. To replace the battery, make sure both power knobs are turned OFF. Side the stimulator cover open by pressing gently on the arrow and pulling downward until the cover pops off. Remove the old battery. Insert a 9-volt 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 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 System

1. Store your 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.
For the ordering of new pads, you may call our service center at THERATECH, 1109 Myatt Blvd. Madison, TN 37115. TEL: 615-865-4000 / 800-788-1705
FAX: 800-485-2626.

Check the System before using

Before using your 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 device carries a one year warranty from the date of purchase.
The warranty applies to the device 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.

Manufacturer
Well-Life Healthcare Inc.
1FL., No.16, Lane 454, Jungjeng Rd., Yunghe City,
Taipei County, Taiwan, R.O.C.

Distributor

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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.

Troubleshooting Guide

If you have a problem using your System, 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 a new 9-volt battery, but will not turn on.	Call Customer Service +886-2-2928-2112.
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-2403 Stimulator Technical Specifications

Features	*WL-2403*
510(k) Number	K030537
Manufacturer	Well-Life
Classification	Class II
Basic Specification Comparison	
Waveform	Asymmetrical Biphasic Square
Channels	Dual
Power supply	9 volt battery
Circuit designed	Digital
Software	Yes
Amplitude (mA)	0-80 (Adjustable)
Pulse rate (Hz)	150 (fix)
Width (μs)	260 (fix)
Power ON indicator	LCD
Timer (min)	15-60
Weight (grams) (batt. Include)	142
Size (mm)	110×62×27
Prescription or OTC	OTC
Indication for use	All models as above mentioned 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.

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