Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

K150386

Premarket Notification 510(k) Submission
Traditional 510(k) Cover Letter

FDA CDRH DMC
FEB 18 2015
Received 69

Date of Submission: Feb.3.2015
Submitters Name: Tyece Ltd.
Contact Person: Parshid Falahati
Tel.: 852 2 3497456
Fax: 852 2 3499166
e-mail: sales@tyece.com

Official Correspondent: Guenter Ginsberg
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135
Tel 239 948 2001
Fax 239 948 2002
e-mail: g.ginsberg@mediatradecorp.net

The manufacturer is Savia Ltd. a medical device establishment in Shenzhen, China that manufactures medical devices. Their OTC TENS Device, Model SEM44 is the one now being submitted for a 510(k). We are submitting a traditional 510(k) application for the marketing of a class II medical device as defined by 21 CRF 868.5890. This device is a therapeutic device with many substantial equivalent devices on the US market and around the world.
This device is substantial equivalent to the predicate device from Counter Scientific Development Ltd., Model PTS-IV, K132993.
The Savia device has been evaluated according to IEC60601-1, IEC60601-1-2, IEC60601-2-10 and IEC60601-1-11 standards. It has been proven to be safe and effective to help patients with relief from pain associated with sore and aching muscles due to strain from exercise or normal household work activities.

We believe that this device should be classified under the category as follows:
Device: TENS Device (Transcutaneous Electric Nerve and Muscle Stimulator)
Regulation Number: 882.5890
Panel Review: Neurology
Product Code: NUH
Device Class: II
Thank you very much for your consideration or our 510(k) application and please contact me, the official correspondent, should any additional documentation be required.
Sincerely,
Guenter Ginsberg
Official Correspondent

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

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FDA CDRH DMC
FEB 18 2015
Received 69

MTC *Media Trade Corporation*

11820 Red Hibiscus Drive – Bonita Springs, FL 34135
Tel (239) 948-2001 – Fax (239) 948-2002
e-mail: mediatradecorp@gmx.net

eCopy Cover Letter

Date: Feb.7, 2015

To: US Food and Drug Administration

Center for Devices and Radiological Health
Document Control Center, WO66-G609
10903 New Hampshire Ave.
Silver Springs, MD 20993-0002

Re: **eCopy for Savia OTC TENS Device, Model SEM44**

We hereby state that **the eCopy is an exact duplicate of the paper copy provided**.

Thank you and with best regards,

Guenter Ginsberg
President MTC
Official Correspondent & US Agent
for Counter Scientific

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

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

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Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm	✓		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	✓		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			✓

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

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm			✓
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	✓		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm	✓		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm	✓		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm			✓
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm	✓		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm	✓		

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1-2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	✓		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			✓
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			✓
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf			✓
FORM FDA 3654, *Standards Data Report for 510(k)s* - *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	✓		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			

Last Updated: 9/3/08 – Brandi Stuart

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. 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. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
MEDIA TRADE CORP 11820 RED HIBISCUS DRIVE BONITA SPRINGS FL 34135 US	Guenter Ginsberg
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1779	2.1 E-MAIL ADDRESS g.ginsberg@gmx.net
	2.2 TELEPHONE NUMBER (include Area code) 239-9482001
	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 239-9482002

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

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

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

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

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

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

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

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[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

09-Feb-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
02.13.2015		

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Tyece Ltd.	Establishment Registration Number *(if known)*: 3007092044		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 852 2 3497456		
Street Address: Unit 801, Block A, Po Lung Centre, 11 Wang Chiu Rd., Kowloon Bay	FAX Number *(including area code)*: 852 2 3499166		
City: Kowloon, Hong Kong	State / Province: Hong Kong	ZIP/Postal Code:	Country: Hong Kong SAR
Contact Name: Parshid Falahati			
Contact Title: President	Contact E-mail Address: sales@tyece.com		

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

Company / Institution Name: Media Trade Corporation			
Division Name *(if applicable)*:	Phone Number *(including area code)*: 239 948 2001		
Street Address: 11820 Red Hibiscus Dr	FAX Number *(including area code)*: 239 948 2002		
City: Bonita Springs	State / Province: Florida	ZIP Code: 34135	Country: USA
Contact Name: Guenter Ginsberg			
Contact Title: President	Contact E-mail Address: g.ginsberg@mediatradecorp.net		

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

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

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

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

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

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

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

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

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

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

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

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

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

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

- [ ] Other Reason *(specify)*:

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

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NUH	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K132993	1	Counter TENS Device, Model PTS-IV	1	Counter Scientific Development Ltd.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

TENS

	Trade or Proprietary or Model Name for This Device		Model Number
1	Tyece OTC TENS Device	1	Model SEM44
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

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

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NUH	882.5890	[ ] Class I [x] Class II
Classification Panel: Neurology		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

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

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

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

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

Page 1 of 1 Released by FOIA Request # 2016-201, Released by CDRH on 03-15-2016

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	General requirements for basic safety and essential performance	2005+corr.1(2006) +corr.2(2007) +AMI (2012)	01/01/2012
2	60601-2-10	IEC	Basic safety and essential performance of nerve and muscle stimulators. (Neurology)	Edition 2.0 2012-08	01/01/2012
3	60601-1-2	IEC	Medical Electrical equipment part 1-2: General requirements for basic safety and essential performance - collateral standard: electro-magnetic disturbances - requirements and tests. (General II ES/EMC)	Edition 2007-03	01/01/2007
4	60601-1-11	IEC	General requirement for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical systems used in the home healthcare environment	First Edition: 2010	01/01/2010
5					
6					
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

Premarket Notification 510(k) Submission
Traditional 510(k) Cover Letter

Date of Submission: Feb.3.2015

Submitters Name: Tyece Ltd.
Contact Person: Parshid Falahati
Tel.: 852 2 3497456
Fax: 852 2 3499166
e-mail: sales@tyece.com

Official Correspondent: Guenter Ginsberg
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135
Tel 239 948 2001
Fax 239 948 2002
e-mail: g.ginsberg@mediatradecorp.net

The manufacturer is Savia Ltd. a medical device establishment in Shenzhen, China that manufactures medical devices. Their OTC TENS Device, Model SEM44 is the one now being submitted for a 510(k). We are submitting a traditional 510(k) application for the marketing of a class II medical device as defined by 21 CRF 868.5890. This device is a therapeutic device with many substantial equivalent devices on the US market and around the world.
This device is substantial equivalent to the predicate device from Counter Scientific Development Ltd., Model PTS-IV, K132993.
The Savia device has been evaluated according to IEC60601-1, IEC60601-1-2, IEC60601-2-10 and IEC60601-1-11 standards. It has been proven to be safe and effective to help patients with relief from pain associated with sore and aching muscles due to strain from exercise or normal household work activities.

We believe that this device should be classified under the category as follows:
Device: TENS Device (Transcutaneous Electric Nerve and Muscle Stimulator)
Regulation Number: 882.5890
Panel Review: Neurology
Product Code: NUH
Device Class: II
Thank you very much for your consideration or our 510(k) application and please contact me, the official correspondent, should any additional documentation be required.
Sincerely,
Guenter Ginsberg
Official Correspondent

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

93/42/EEC including 2007/47/EC
Annex I
Essential Requirements Checklist

93/42/EEC 包括 2007/47/EC
附录一　基本要求检查表

Product name:
产品名：
TENS

Type(s)/Model(s):
类型/型号
SEM44

Product group:
产品族
medical device

Issue date of Technical File:
技术文档发布日：
2014-4-30

Revision of Technical File:
(b)(4)

V2

Legal Manufacturer:
法定制造商

SAVIA ELECTRONICS （SHENZHEN）CO., LTD
Name 名字

FUYONG
Street 街道

518103
Postal code 邮编

4TH INDUSTRIAL DISTRICT, FENG HUANG VILLAGE, FU YONG COUNTY BAO AN DISTRICT SHENZHEN P.R. CHINA
Place 地点

CHINA
Country 国家

Accessories:
附件：

2014-4-30	**Engineer:** (b)(6)	(b)(6)
Date 日期	*Name draft and Experiences* (b)(4)	*Signature draft* (b)(6)
2014-4-30	**Project Manager:** (b)(6)	(b)(6)
Date 日期	*Name Reviewer and Experiences/审核人的名字与职位*	*Signature Reviewer* (b)(6)
2014-4-30	**General Manager** (b)(6)	(b)(6)
Date 日期	*Name Approver and Experiences* (b)(6)	*Signature Approver* (b)(6)

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

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
I.	**General Requirements** **通用要求**					
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. 器械的生产和设计必须保证：按照其预定用途和条件使用，器械不会损害临床条件、或患者安全、或操作者或其他人员的安全和健康；假设与器械预期用途相关的任何风险，与之给患者带来的益处相比，并与健康安全的保护程度相一致，则是可接受的。 This shall include: • reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and • consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 应包括： • 尽可能地降低由于器械的人体工学特征和器械预期使用的环境（为患者安全设计的）的错误使用而产生的风险， 和 • 考虑技术知识、经验、教育和培训，预期用户（为非专业人员、专业人员、伤残人员或其他人）的医疗和身体	A	EN 60601-1:2006/A1:2013 EN 60601-2-10:2012 EN 60601-1-6:2010 ISO 14971:2012	(b)(4) [redacted]		**Ok**

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	条件。					
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • Inform users of the residual risks due to any shortcomings of the protection measures adopted. 制造商采用的器械结构和设计方案，必须考虑在当前工艺技术条件下遵守安全原则。 在选择最合适方案时，制造商应按照以下顺序遵守原则： • 尽可能地降低或避免风险（固有的安全设计和结构） • 对无法避免的风险，如适用，采取适当的防护措施，包括必要的报警。 • 告知用户由于所提供防护措施的缺陷而带来的残留风险。	A	EN 60601-1:2006/A1:2013 ISO 14971:2012	(b)(4) [redacted]		Ok
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. 器械最后必须取得制造商期望获得的功能。器械设计、制	A	EN 60601-1:2006/A1:2013	(b)(4) [redacted]		Ok

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	造和包装应与第 1 条(2)(a)制造商所规定的一项或多项功能相适应。					
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. 在制造商确定的器械使用寿命期内，在正常使用可能出现的压力下，第 1，2，3 款指的各项特征和性能应不能影响临床条件、危害患者或其它人员的安全。	A	EN 60601-1:2006/A1:2013	(b)(4) [redacted]		Ok
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. 器械设计、生产和包装应当保证器械的特征和性能在运输和储存过程中，只要遵守制造商提供的有关说明和信息，就不会受到重大影响。	A	EN 60601-1:2006/A1:2013	(b)(4) [redacted]		Ok
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended. 副作用的大小同器械的预期性能相比，是可接受的风险。	A	EN 60601-1:2006/A1:2013	(b)(4) [redacted]		Ok
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A	EN 60601-1:2006/A1:2013	(b)(4) [redacted]		Ok

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	证明符合基本要求必须包括按照附录 X 的临床评估					
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION** 设计和结构的要求					
7.	Chemical, physical and biological properties 化学、物理和生物特征					
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the "General requirements". Particular attention must be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. • Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand. 器械的设计和生产必须保证达到本附录第 I 部分的通用要求，另外应特别注意： • 合理选择原料，特别是易燃物质和有毒物质的选择； • 从器械预定功能出发考虑所选材料同人体生物组织、细胞和体液的相容性。 • 如适用，事先已确认有效的生物物理学或模型研究的结果	A	(b)(4) [redacted]	(b)(4) [redacted]		**Ok**
7.2	The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the	A	(b)(4) [redacted]			**Ok**

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure. 器械的设计、制造和包装应当保证器械在运输、储存和使用过程中的污染和残留物对人体危害最低，应特别注意观察暴露于器械下的人体组织及其时间和频率。					
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use. 器械设计和生产必须保证在正常使用和常规过程中接触其它材料、物质和气体不会影响其安全使用；如果器械需要加载其它药品，器械的设计和生产必须保证同该药品相兼容，必须考虑法规对该药品的规定和限制，保证器械达到预定功能。	N/A				
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. 如果某种器械含有某种物质作为其组成部分，而且该物质单独使用时可被认为是 2001/83EC 第 1 条含义内的药品，并且它能够帮助该器械对人体产生辅助作用，这种物质的	N/A				

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	安全性、质量和有效性必须通过 2001/83/EC 指令附录 I 涉及的适用方法进行类推来确认。 For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004[1] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 对于第一段提到的物质，在考虑到该器械的预期用途时确认了该物质作为医疗器械一部分的有效性之后，公告机构应按 Regulation (EC) No 726/2004[1] 法规，就该物质的质量和安全性包括该物质与器械整合的临床受益/风险特性，向成员国指定的一个主管当局或欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或 EMEA 应考虑公告机构认定的关于该物质与器械整合有效性的生产过程和数据。 Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended	N/A				

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing this opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 如果某种器械含有人血制品作为其组成部分，在确认了该血制品作为医疗器械一部分的有效性，并考虑到该器械的预期用途的基础上，公告机构应就该制品的质量和安全性包括该制品与器械整合的临床受益/风险特性，向欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或EMEA应考虑公告机构认定的关于该物质与器械整合有效性的生产过程和数据。 Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. 如果器械整合的辅助物质发生了变更，特别是关系到其生产过程，公告机构应被通知并向相关的药品主管当局（也就是最初的咨询机构）咨询，以确认辅助物质的质量和安全性得以维持。主管当局应考虑公告机构认定的关于该物质与器械整合有效性的数据，以确保这种变更对已经建立的医疗器械中的增加物质的临床受益/风险特性没有负面影					

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	响。 When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. 当相关的药品主管当局（也就是最初的咨询机构）得到关于辅助物质对已经建立的医疗器械中的增加物质的临床受益/风险特性有影响的信息后，应向公告机构提出建议，该信息是否影响已经建立的医疗器械中增加物质的临床受益/风险特性。公告机构应考虑到更新的科学意见，以重新考虑对符合性评价程序的评价。					
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC[2] of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[3]. 器械的设计和制造，必须将源自器械的物质泄漏的风险降至最低。应当特别注意按1967年6月27日成员国法律中67/548/EEC[2]委员会指令附录I界定的致癌物、诱基因突变	N/A				

[2] Internal note: replaced by (EC) 1272/2008

[3] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
物和生殖毒性物质相关的危险物质[3]对分类、包装和标签的法律法规，行政条款的符合。 If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC[2], these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. 如果器械的一部分（或器械本身）预期用于对身体给药或除药、体液或其它物质，或预期用于运输或存储这些体液或物质，包含有按67/548/EEC[2]指令附录I界定的1类或2类致癌物、诱基因突变物或生殖毒性物质的邻苯二甲酸盐，该器械必须在自身和/或每台的包装上作出标识，及适当时在器械的销售包装上作出含有邻苯二甲酸盐的标识。 If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. 如果器械的预期用途包括对儿童、孕妇或哺乳期妇女的治疗，制造商必须在技术文档和使用说明书中提供具体的使用这些物质的理由，及关于对这些患者群的残留风险，如适用，和合适的防范措施等信息，以符合基本要求，特别	N/A				

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	是本条的要求。					
7.6	The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. 考虑到器械和预期使用的环境，器械的设计和生产必须保证，最大限度地降低由于异物进入而造成危害的可能性。	A	(b)(4) [redacted]			Ok
8.	Infection and microbial contamination 感染和微生物污染					
8.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use. 器械设计和制造工艺应当保证最大限度地降低甚至避免患者、使用者和其他人员之间交叉感染的可能性；器械应当操作简单，必要时，减少患者对器械、器械对患者的接触污染。	N/A				
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. 动物源组织必须从对按组织的预期用途被进行控制和监管的动物中取得。 Notified Bodies shall retain information on the geographical origin of the animals. 公告机构应保留动物的原生地的信息。	N/A				

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	Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. 对动物组织、细胞和其它动物源物质的加工、贮存、检验和处理，必须提供最可靠的安全保障。特别是病毒和其它传染物质的安全，在生产过程中有采取有效的消除方法或进行病毒灭活。					
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. 无菌器械的设计、生产和包装应采用一次性使用包装方式，并且在一定工作程序下保证器械上市时处于无菌状态，在贮藏、运输条件下只要包装不破损或开封，能够保持无菌状态。	N/A				
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. 无菌器械必须通过专门、有效的方法进行生产和灭菌。	N/A				
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions. 需要灭菌的器械在专门控制的环境下生产。	N/A				

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8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. 非灭菌器械的包装系统，应当保证产品达到规定的清洁度。如果器械需要在使用前灭菌，应减少器械灭菌前微生物污染的可能性。包装系统必须适合于制造商所指定的灭菌方式。	N/A				
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. 相同或相似的产品销售时处于无菌状态还是非无菌状态，器械必须具有不同的包装和/或标签。	N/A				
9.	Construction and environmental properties 结构和环境特征					
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use. 器械如果需要同其它器械或设备配合在一起使用，整个系统应保证安全，包括联接系统必须安全，不得改变器械的预定功能。必须在使用说明或标签上注明使用限制。	N/A				
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: 器械的设计和生产必须尽可能降低或避免:	A	(b)(4) [redacted]			**Ok**

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• the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features, 由于器械物理性能特性，如体积压力比、外观尺寸、人体工学，对人体造成伤害的可能性。 • risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure, and acceleration, 在合理的环境条件下，如电磁场、外部电子干扰，静电放射、大气压、气温以及压力变化和加速度等条件下，对人体造成伤害的可能性。 • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, 在治疗或试用时，同其它器械相互干扰对人体造成伤害的可能性。 • risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism. 如果无法维修或矫正(如植入人体后),由于材料老化、测试或控制机能精度不够，对人体造成伤害的可能性。					

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9.3	Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion. 器械的设计和生产必须保证，在正常使用情况下或单一故障的情况下，器械不至于起火或爆炸。对在暴露于易燃物质环境下使用的器械必须给予特别注意。	A	(b)(4) [redacted]			Ok
10.	Devices with a measuring function 具有测量功能的器械					
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer. 检测器械的设计和生产必须保证足够的精度和稳定性、符合器械预定功能的要求。制造商必须注明其精度范围。	N/A				
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device. 必须根据器械的预定功能，按照人体工学的原理设计器械的度量、监控和显示刻度。	N/A				
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC[4].	N/A				

[4] OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7. 12. 1989, p. 28).

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	测量器械必须使用法定度量单位，符合理事会法令 80/181/EEC[4] 的规定。					
11.	Protection against radiation 辐射保护					
11.1 11.1.1	*General* *原则* Devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. 器械的设计和生产必须保证在达到预定功能的情况下，尽量减少对患者、使用者和其它人员的辐射，但不限制为治疗和诊断疾病使用规定合理的剂量。	A	(b)(4) [redacted]	(b)(4) [redacted]		**Ok**
11.2 11.2.1	*Intended radiation* *预期的辐射* Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. 用于特定医疗目的，有的器械辐射危害人体健康的射线，这种器械对患者的治疗作用同射线相比可以为人们所接受。器械辐射剂量必须能够控制，(设计和生产时)必须考虑其可变参数的可重复性和容差。	N/A				

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11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions. 设计器械发射危害性射线，不论射线是否可见，都应根据实际需要安装可见的显示装置和发声的报警装置，指示射线的发射状态。	N/A				
11.3 11.3.1	*Unintended radiation* *非预期的辐射* Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is be reduced as far as possible. 器械的设计和制造应当保证，尽量减少对患者，使用者以及其它人员产生非预期的意外辐射。	A	(b)(4) [redacted]	(b)(4) [redacted]		Ok
11.4 11.4.1	*Instructions* *使用说明* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. 放射性医疗器械应详细说明辐射特性、对患者和操作者的保护措施、任何防止操作错误以及消除由于安装器械带来的潜在危险。	N/A				
11.5 11.5.1	*Ionising radiation* *电离辐射* Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure	N/A				

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	that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended uses. 电离辐射器械的设计和生产必须保证，可以改变和控制电离辐射的数量，形状和质量，满足预定使用功能的实际需要。					
11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user. 诊断用电离辐射器械的设计和生产必须保证，在获得清晰图象、提高输出质量、达到预定医疗目的的情况下，尽量减少对患者和使用者的照射。	N/A				
11.5.3	Devices emitting ionising radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation. 治疗用电离辐射器械的设计和生产必须保证，能够有效地监控照射剂量、离子束类型、能量大小以及离子束的质量。	N/A				
12.	Requirements for medical devices connected to or equipped with an energy source 连接或配备能源的医疗器械的要求					
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks	A	(b)(4) [redacted]	(b)(4) [redacted]		**Ok**

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	带有可编程系统的器械设计应保证其可重复性、可靠性、满足预定功能的需要。应当采取必要措施、减少因出现单一故障状态而造成危害的可能性。					
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. 对于合并软件使用的或本身是医疗软件的器械，软件必须考虑研发生命周期、风险管理、确认和验证的原则，按照当前的技术发展水平进行确认。	A	(b)(4) [redacted]			Ok
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply. 对维系患者安全的器械，内部供电时，应配有电源指示装置，表明电源的供电状况。	A	(b)(4) [redacted]	(b)(4) [redacted]		Ok
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure. 对维系患者安全的器械，外部供电时，应增加报警装置，报告电源中断。	N/A				
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. 监测患者临床数据的器械，必须配置相应的报警系统，提醒操作者可能导致患者死亡或病情严重恶化的情况。	N/A				
12.5	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or	A	(b)(4) [redacted]	(b)(4) [redacted]		

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	equipment in the usual environment. 器械的设计和生产必须保证，尽量减少由于产生电磁场，影响其它器械或设备的操作使用造成的危害。					
12.6	*Protection against electrical risks* *防止触电危险.* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly. 假定器械安装正确，器械的设计和生产必须尽量减少在正常使用和出现单一故障时，意外电击的危险。	N/A				
12.7 12.7.1	*Protection against mechanical and thermal risks* *高温和机械防护* Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. 器械的设计和生产必须保证患者、使用者不受机械部件造成的损伤，如阻力部件、稳定性部件和移动性部件造成的损伤。	A	(b)(4) [redacted]	(b)(4) [redacted]		
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制振动(特别是振动源)的措施，最大限度地降低器械振动造成的危害，除非所发出的振动是特定功能的需要。	A	(b)(4) [redacted]			
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks	A	(b)(4) [redacted]	(b)(4) [redacted]		

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	arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制噪音(特别是噪音源)的措施，最大限度地降低器械噪音造成的危害，除非所发出的声音是特定功能的需要。		(b)(4) [redacted]	(b)(4) [redacted]		
12.7.4	The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks. 操作者接触的电源、气动、气压端口和连接件，设计和生产必须考虑减少各种危险的可能性。	A	(b)(4) [redacted]			
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use. 在正常使用的情况下，人体可接触到的器械部件及其周围，温度不得过高，以免造成危险；但不包括专门用于提供热量或必须达到一定温度的部件和区域。	A	(b)(4) [redacted]			
12.8 12.8.1	Protection against the risks posed to the patient by energy supplies or substances 防止能源提供和物资供应造成对患者的危险 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user. 为患者提供能源或物质的器械设计和生产必须保证，器械可以控制流量，保证足够的精度，保证患者和使用者的安全。	A	(b)(4) [redacted]	(b)(4) [redacted]		

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12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. 器械必须配有专门装置，防止出现流量波动给患者带来危险，或出现问题时报警。 Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source. 器械必须配备适当的装置尽量避免能量和/或物质意外增加到危险的程度。	A	(b)(4) [redacted]	(b)(4) [redacted]		
12.9	The function of the controls and indicators must be clearly specified on the devices. 指示器和控制按钮、手柄等必须在器械上予以注明。 Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient. 如果器械通过可视系统提供操作说明，通过可视系统显示和修改各种参数，可视系统显示的信息必须能为操作者所理解，必要时患者也应看得懂。	A	(b)(4) [redacted]	(b)(4) [redacted]		
13.	Information supplied by the manufacturer 制造商提供的信息					
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. 考虑到对于潜在使用者的培训和认知，以及识别制造商，每个器械必须附带所需信息，以安全正确使用。 This information comprises the details on the label and the data in the instructions for use.	A	(b)(4) [redacted] (b)(4) [redacted]	(b)(4) [redacted]		

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	这些信息器械应在标签或使用说明书具体说明。 As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 根据实际需要，在器械上、在每个器械的包装上或在销售包装上都应注明安全使用所需要的操作信息。如果不可能对每个器械单独包装，则应随每一个器械或一定数量的器械提供活页说明。 Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions. 每个器械的包装中应附带使用说明，但 I 类或 IIa 类器械，如果不需要使用说明书也可以安全使用，可以除外。					
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device. 根据需要应通过使用标志说明操作信息。器械使用的标志或识别颜色应符合欧洲共同体协调标准。如果没有统一标准，标志和识别颜色的含义必须在器械附带的资料中说明。	A	(b)(4) [redacted] (b)(4) [redacted]	(b)(4) [redacted]		
13.3	The label must bear the following particulars: 器械标签必须具有下列内容： a) the name or trade name and address of the manufacturer. For devices imported into the	A	(b)(4) [redacted] (b)(4) [redacted]	(b)(4) [redacted] Label Instruction		

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community; (a)制造商的名称或商品名以及地址。为了在欧洲共同体内销售，如果制造商在欧共体内没有注册场地，则进口的器械标签、或外包装或使用说明书中应另外注明授权代表的名称和地址。 b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (b) 使用者识别器械和了解包装内容必需的信息； c) where appropriate, the word "STERILE"; (c)必要时，注明“已灭菌”字样； d) where appropriate, the batch code, preceded by the word "LOT", or the serial number; (d)必要时，注明批号或系列号，批号以“LOT”打头； e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; e) 必要时，注明器械安全使用的期限，以年和月表示。 f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; f) 必要时，注明器械属于一次性使用。制造商的一次性使用标识必须在欧共体内统一。					
g) if the device is custom made, the words "custom made device";	A	(b)(4) [redacted]	(b)(4) [redacted]		

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
	g) 如果属于定作器械，注明“定制器械”字样。 h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; h) 如果属于临床试用的器械，注明“专门用于临床研究”字样 i) any special storage and/or handling conditions; i) 特殊储存条件和/或管理要求； j) any special operating instructions; j) 特殊操作说明； k) any warnings and/or precautions to take; k) 任何警告和/或注意事项 l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; l) 有源器械的生产年份，如不为(e)项所含，则也可以包含在批号或系列号内。 m) where applicable, method of sterilisation. m) 如适用，注明灭菌方法。 n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative." n) 若器械涉及第一章 1(4a)条款，注明器械含有人血制品		(b)(4)	Label Instruction		
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. 如果器械的预定功能对操作者来说不是显而易见的，制造商在标签和说明书上应当加以清楚阐述。	A	(b)(4) (b)(4)	(b)(4)		

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. 当合理和可行时，器械和可拆卸部件必须加以识别，就批量而言，可以采取各种有效方法对器械和拆卸部件带来的潜在风险加以识别。	A	(b)(4) [redacted]			
13.6	Where appropriate, the instructions for use must contain the following particulars: 若适用，使用说明书必须包含以下说明： a) the details referred to in 13.3, with the exception of d) and e) a) 本附录第 13.3 款所指除(d)和(e)项以外的各项内容； b) the performances referred to in section 3 and any undesirable side effects; b) 本附录第 3 款所指使用性能及其可能带来的副作用。 c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; c) 如果必须同其它器械或设备一同安装或连接使用，应当详细说明配合使用的器械或设备的特性，以便取得预期的功能。 d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the	A	(b)(4) [redacted]			

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
devices operate properly and safely at all times; d) 鉴别器械是否正确安装所必要的技术信息，保证准确、安全使用；以及维护和校准器械所必须的技术指标或频率，保证器械长期准确、安全使用的所有信息。 e) where appropriate, information to avoid certain risks in connection with implantation of the device; e) 对植入人体的器械，如果需要，应加以特别说明，避免出现植入人体器械特有的危险。 f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; f) 在进行特定检查和治疗的过程中，器械产生相互干扰的危险性说明。 g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation g) 说明灭菌包装损坏后，器械如何进行处理；如果可能，说明重新灭菌的有效方法。 h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of he device to be resterilized, and any restriction on the number if reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I). If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could					

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; h) 可重复使用的器械，应说明准确使用的方法，包括清洁、消毒、包装以及，如适用，对需要再次灭菌器械进行灭菌的方法，重复使用的次数限制。 如果器械预期要在使用前灭菌，按照清洁和灭菌的使用说明书要求正确执行，器械仍符合第 1 部分的要求。 如果器械附带了一次性使用的标识，制造商已知的由于已知特性以及技术因素使器械重复使用带来风险的信息。如果按 13.1 部分的规定不需要使用说明书，则信息必须应使用者要求而提供。 i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.) i) 器械使用前如何进行处理，如灭菌、最后组装等； j) in the case of devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation j) 利用放射线治疗的器械，必须说明放射线的特性、类型、密度和分布 The instruction for use must also include details, allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: 使用说明书必须另外说明，医护人员如何向消患者说明禁忌症和注意事项，具体包括： k) precautions to be taken in the event of changes in the performance of the device; k)器械性能发生变化时的注意事项； l) precautions to be taken as regards exposure, in	N/A				

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准，其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足 (由公告机构填写)	Ok / Fail 符合 / 不符合
reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.; l) 在可预见的使用环境下，在电磁场、外界电流、静电放射、大气压以及大气压发生变化、加速度、热力源等作用下，应当采取的注意事项 m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; m) 应当详细说明器械加载的药品或其它物质的性能，包括其选择物质的限制范围； n) precautions to be taken against any special, unusual risks related to the disposal of the device; n)处置器械时防止出现特别、意外风险的注意事项。 o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; o)说明第 7.4 款所指同器械结合一体使用的药物或人血制品； p) degree of accuracy claimed for devices with a measuring function. p)具有测试功能的器械应说明声称的精度。 q) date of issue or the latest revision of the instructions for use. q) 使用说明书最新版本或修订日期					

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
TyeceOTC TENS Device, Model SEM44

Indications for Use *(Describe)*

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

510(k) SUMMARY

Date of Summary Prepared: 02/05/2015

1. Submitter's Name: Tyece Ltd.

Address: Unit 801, Block A, Po Lung Centre, 11 Wang Chiu Rd., Kowloon Bay, Kowloon, Hong Kong, SAR

Contact person: Parshid Falahati

Tel: 852- 2 - 3497456

Fax: 852 -2 - 3499166

E-mail sales@tyece.com

2. Proposed New Device:

Trade Name: Tyece OTC TENS Device, Model SEM44
Classification Name: TENS
Regulation Number: 882.5890
Product Code: NUH
Device Class: II

3. Predicate (cleared) Device:

Counter TENS Device, Model PTS-IV

510(k) Number: K132993

Manufacturer: Counter Scientific Development Ltd.

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

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4. Description of Proposed Device:

The SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 1 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under K070612.
The device has been tested to and meets the requirements of the following recognized consensus standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

5. Indication for Use:

This Savia OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

6. Environment of Use:

Clinics, Hospitals and home environments

7. Contraindications:

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

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

Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

8. Technological Characteristics Compared to the Predicate Device

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle and joint pain relief, Model PTS-IV, The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle and Joint Pain. Outputs are almost the identical, Each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500 Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both device are transiting pulses by the use of Electrode Pads. Both are portable devices. Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicate device. The differences that exist between the devices are insignificant in terms of safety or effectiveness.

Differences:
1. Device SEM44 has 15 preset programs, while the predicate device has 7.
2. Intensity levels of SEM44 are selectable from 1 to 50, while the predicate device is from 1 to 16,
3. All other parameters such as waveform, frequency, output current and voltage are very similar. However, the output of the SEM44 has a pulse width of 360µS, and the predicate device has 200µS.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Savia did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the SEM44 vs. the predicate. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

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

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IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

a. **EMC and electrical safety**

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

b. **Biocompatibility**

The electrode pads are the only body contacting parts. They have been FDA cleared under K070612.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Pain Therapy System can be cleaned by the use of the methods described in the Instruction Manual.

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

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e. **EMC and Electrical Safety**

Performance testing has established that, with respect to EMC and electrical safety in its intended operational environment, the device conforms to all applicable requirements of IEC 60601-1 and IEC 60601-1-2.

8. Conclusions:

The Tyece OTC TENS Device, Model SEM44 has the same intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the predicate device.

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

(b)(4) Third Party Information

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TYECE

Unit 801, Block A
Po Lung Centre
11 Wang Chiu Road
Kowloon Bay, Hong Kong

TRUTHFUL AND ACCURATE STATEMENT

(as Required by 21 CFR 807.87(K))

I certify, in my capacity as **Managing Director** of **Tyece Limited,** I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and no material fact has been omitted

TYECE LIMITED

Parshid Falahati

06 February, 2015

2

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

(b)(4) Third Party Information

(b)(4) Third Party Information

(b)(4) Third Party Information

Records processed under FOIA Request # 2016-301, Released by CDRH on 03-15-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Tyece Ltd.

2. Date of the Application/Submission Which This Certification Accompanies
02/13/2015

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
Unit 801, Block A, Po Lung Centre, 11 Wang Chiu Rd. Kowloon Bay

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Region
Kowloon, Hong Kong	Hong Kong

Country	ZIP or Postal Code
Hong Kong SAR	

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): 852 2 3497456
(Fax): 852 2 3499166

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Tyece OTC TENS Device, Model SEM44
TENS, Product Code: NUH
Neurology, Class II CFR 882.5890

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

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

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Guenter Ginsberg	President

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	11820 Red Hibiscus Dr
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Bonita Springs
State/Province/Region	Florida
Country	USA
ZIP or Postal Code	34135

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 239 948 2001

(Fax): 239 948 2002

14. Date of Certification

01/13/2015

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, 2005+corr.1(2006)+corr.2(2007)+AMI (2012) General requirement for safety and essential performance

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

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1, 2005+corr.1(2006)+corr.2(2007)+AMI (2012) General requirement for safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 1	General requirements for safety, 2005,2006,2007	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2 General requirement for safety and essential performance, collateral standard: electromagnetic disturbances - requirements and tests

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

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2 General requirement for safety and essential performance, collateral standard: electromagnetic disturbances - requirements and tests

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 1	General requirements for basic safety and essential performance	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
All Standards met

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 2	Collateral Standard: Electromagnetic Compatibility - Requirements and tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

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

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-10 Basic safety and essential performance of nerve and muscle stimulators. (Neurology)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 17-5		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-10 Basic safety and essential performance of nerve and muscle stimulators. (Neurology)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 2-10	Particular Requirements for the safety of nerve and muscle stimulators	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
All Standards were met

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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Department of Health and Human Services
Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-11 General requirement for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical systems used in the home healthcare environment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 19-7	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-11 General requirement for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical systems used in the home healthcare environment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 1-11	requirements for electrical equipment and medical systems used in the home	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
All Standards were met

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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EXECUTIVE SUMMARY

Date of Summary Prepared: 02/05/2015

1. Submitter's Name: Tyece Ltd.

Address: Unit 801, Block A, Po Lung Centre, 11 Wang Chiu Rd., Kowloon Bay, Kowloon, Hong Kong, SAR

Contact person: Parshid Falahati

Tel: 852- 2 - 3497456

Fax: 852 -2 - 3499166

E-mail sales@tyece.com

2. Proposed New Device:

Trade Name: Tyece OTC TENS Device, Model SEM44
Classification Name: TENS
Regulation Number: 882.5890
Product Code: NUH
Device Class: II

3. Predicate (cleared) Device:

Counter TENS Device, Model PTS-IV

510(k) Number: K132993

Manufacturer: Counter Scientific Development Ltd.

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4. Description of Proposed Device:

The SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 1 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under K070612.
The device has been tested to and meets the requirements of the following recognized consensus standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

5. Indication for Use:

This Savia OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

6. Environment of Use:

Clinics, Hospitals and home environments

7. Contraindications:

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

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Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

8. Technological Characteristics Compared to the Predicate Device

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle and joint pain relief, Model PTS-IV, The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle and Joint Pain. Outputs are almost the identical, Each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500 Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both device are transiting pulses by the use of Electrode Pads. Both are portable devices. Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicate device. The differences that exist between the devices are insignificant in terms of safety or effectiveness.

Differences:
1. Device SEM44 has 15 preset programs, while the predicate device has 7.
2. Intensity levels of SEM44 are selectable from 1 to 50, while the predicate device is from 1 to 16,
3. All other parameters such as waveform, frequency, output current and voltage are very similar. However, the output of the SEM44 has a pulse width of 360µS, and the predicate device has 200µS.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Savia did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the SEM44 vs. the predicate. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

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IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

a. **EMC and electrical safety**

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

b. **Biocompatibility**

The electrode pads are the only body contacting parts. They have been FDA cleared under K070612.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Pain Therapy System can be cleaned by the use of the methods described in the Instruction Manual.

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e. **EMC and Electrical Safety**

Performance testing has established that, with respect to EMC and electrical safety in its intended operational environment, the device conforms to all applicable requirements of IEC 60601-1 and IEC 60601-1-2.

8. Conclusions:

The Tyece OTC TENS Device, Model SEM44 has the same intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the predicate device.

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Device Description

This Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated
with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

Product Group	stimulator, nerve, transcutaneous, for pain relief for OTC use
Regulation Number Product Code Medical Specialty	882.5890 NUH Neurology
Short Name of product:	N.A.
Product Name List of Sizes/Models/Article No. Product name	Transcutaneous Electrical Nerve Stimulation (TENS) Model: SEM44 Tyece OTC TENS Device
Classification Rule	Class II

The SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 1 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under K070612.

1. Technical details:

Checksum: A24A
Output channel: 2 Channel
Output wave form: Biphasic rectangular pulse
Pulse length: 50-450 us
Pulse frequency: 1-150 Hz
Output voltage: max. 100Vpp (500 ohm)
Output current: max. 200mApp (500 ohm)
Voltage supply: 3 x AAA batteries
Treatment time: Adjustable from 5 to 100 minutes
Intensity: Adjustable from 0 to 50

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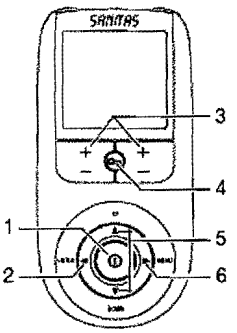
Program: Tens

2.

Buttons:
1 ON/OFF button ⏻
2 **ENTER** ◀ button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button ▲ **UP** and ▼ **DOWN**
6 **MENU** ▶ button



2. Auto shut-off function:
If the unit is turned "On" for 2 minutes and the intensity is not increased on either channel beyond level O, then the unit turns off automatically. This is to save battery life.
When the Timer counts down to 0 min, the unit turns off automatically.

3. Auto increased/de-creased function:
The intensity can be increased/decreased by pressing the intensity button CH1 + /- and CH2+/-. The intensity level changes at 2 steps per second while the key is pressed. When the program is changed, the intensity level drops to level 0. It stays at level 0 for 2 seconds before increasing two levels per second back to the previous intensity level. If at any time during the increase of the levels the user wishes to stop the rise in intensity, he can simply do so by pressing the down button on the corresponding channel.

4. ON/OFF function:
To turn "On" the unit, press the On/Off button once and to turn "Off" the unit press the On/Off button and hold down for 2 seconds.

5. Pause function testing of the machine:
Any Program can be paused by pressing the On/Off button once. To restart the program, press the On/Off button again.
When a Program is paused, the pause sign comes on and it flashes at 2 flashes per second. To restart, the intensity starts to rise to the original intensity level.

6. Memory function:
The unit stores the last Program and the times that were used when it is shut off and will be memorized as long as the batteries are not removed from the unit.

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127. Lock Function:
The buttons on the unit can be locked to prevent any accidental usage. This is done by holding the Program button down for 2 seconds. To cancel the key-lock, press and hold down the Program button for 2 seconds.

8. Program timer function:
Each program has a preset time which is displayed in the timer box. The timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

9. Open lead function testing:
Each program has a preset time which is displayed in the timer box. The timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

10. Low voltage check function testing:
When the battery voltage is low, a low battery sign will flash on the LCD at 2 flashes per second.

11. Output pulses from the device
When the intensity on either or both channels is increased to level 1 and up to level 20 the device delivers electrical pulses through the two output sockets located at the bottom of the unit. The output parameters of these electrical pulses are referred to in the Table (next page).

12. Technical Documentation (attached below)

13. Photos (attached below)

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

(b)(4) Third Party Technical Documentation

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Substantial Equivalence Discussion

Predicate Device Description:

The predicate device chosen is from Counter Scientific Development (GZ) Ltd.

Sponsor: Counter Scientific Development (GZ) Ltd.
2nd & 3rd Floor, Bld.6, DaPian Industrial Zone,
Tangxia Rd., Tianhe District,
Guangzhou 510665, China
Device: Counter TENS Device
Model: PTS-IV
510(k) No: K132993

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle and joint pain relief, Model PTS-IV, The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle and Joint Pain. Outputs are almost the identical, Each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both device are transiting pulses by the use of Electrode Pads. Both are portable devices.
More specific comparisons can be found in the following tables, graphs, photos, specifications etc.

Differences:

1. Device SEM44 has 15 preset programs, while the predicate device has 7.
2. Intensity levels of SEM44 are selectable from 1 to 50, while the predicate device from level 1 to 16,
3. All other parameters such as waveform, frequency, output current and voltage are very similar. However, the output of the SEM44 has a pulse width of 360μs, and the predicate device has 200μs.

Conclusion:

The comparison with the predicate device. Along with the non-clinical testing demonstrates that the PTS-IV device, model SEM44 is safe, effective and preforms as well as the predicate device and is therefore substantially equivalent to the predicate device.

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Output Specifications:

Parameter		Your device	Predicate Device
Mode or Program Name		PAIN THERAPY DEVICE, SEM44	PAIN THERAPY DEVICE, PTS-IV
Waveform (e.g. positive-going, reverse, biphasic)		Positive-going, Reverse and Biphasic	Positive-going, Reverse and Biphasic
Shape(e.g., spike, rectangular, square ware)		Square ware	Square ware
Maximum Output Voltage (Volts)(+/-15%)		110vp p@500Ω	64vp p@500 Ω
		176vp p@1K Ω	68vp p@1K Ω
		246vp p@2K Ω	70vp p@2K Ω
Maximum Output Current (Volts)(+/-15%)		15mA@500 Ω	13mA@500 Ω
		7.5mA@1K Ω	8.5mA@1K Ω
		5mA@2K Ω	5mA@2K Ω
Duration of primary phase		50-360 μs	200 μs
Pulse Duration		50-360 μs	200 μs
Frequency		1-150Hz	1-136Hz
For multiphase waveforms only:	Symmetrical phases	N/A	N/A
	Pulse duration		
Net Charge (micro coulombs mC) (per pulse) (if zero, State method of achieving zero net charge)		0.003mC@500 Ω	0.0013mC@500 Ω
Maximum Phase Charge(mC)		0.040mC@500Ω	0.00135mC@500Ω
Maximum Current Density (mA/cm2, r.m.s)		0.360mA/cm2@500Ω	0.570mA/cm2@500Ω
Maximum Average Current(average absolute value), mA		4.0mA	2.9mA
Maximum Average Power Density, (W/cm2)(using smallest electrode conductive surface area)		0.195mW/cm2@500 Ω 1.0S	0.198mW/cm2@500Ω 1.0S
Burst Mode(i.e. pulse trains)	(a) Pulses per burst	180 μs	4/2
	(b) Bursts per second	10/80HZ	30/136Hz
	(c) Burst duration (seconds)	36ms	800 μS/400 μS
	(d) Duty Cycle	36ms/60ms	24ms/54.4ms
ON Time (seconds)		2s	0.5s

OFF Time (seconds)	2s	0.5s
Additional Features (specify, if applicable)	N/A	N/A
Electrode area:	20.25sqcm*4(81sqcm)	4.6sqcm*4(192sqcm)

Basic Unit Characteristics:

Parameter		**Your Device**	**Predicate Device**
510(k) Number		(to be assigned)	K132993
Device Name and Model		PAIN THERAPY DEVICE SEM44	PAIN THERAPY DEVICE PTS-IV
Manufacturer		SAVIA LTD.	COUNTER Scientific Development (GZ) Limited
Power Source		4.5V(batteries, 3x1.5V AAA)	3.7v Lithium (Power supply)
Method of Line Current Isolation		N/A	N/A
Patient Leakage Current		N/A	N/A
Normal Condition (μA)		N/A	N/A
Single Fault Condition (μA)		N/A	N/A
Average DC current through electrodes when device is on but no pulse are being applied (μA)		0μA	0μA
Numbers of Output Modes		15 Modes(01-15)	7 modes(A,B,C,D,E,F,ALL)
Number of Output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	PCB Insulation	Boost Isolation
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage
Software/firmware/microprocessor control?		Yes	Yes
Automatic overload trip?		No	No
Automatic no-load trip?		Yes	Yes
Automatic shut off?		Yes	Yes
Users override control?		Yes	Yes
Indicator display	On/off status?	Yes	Yes
	Low battery?	Yes	Yes
	Voltage/current level? Only voltage level display	Yes for voltage	Yes for voltage

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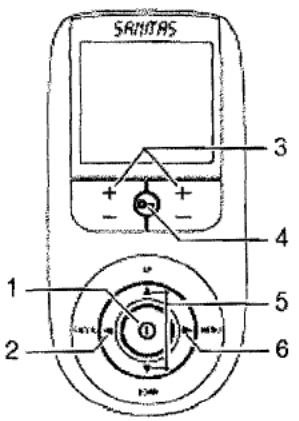
Timer range (minutes)	5-100min	20-40 min
Compliance with voluntary standards?	Yes	Yes
Compliance with 21CFR898-7?	Yes	Yes
Dimensions	L135xW65xT20mm	L120xW70xT18mm
Housing materials and construction	ABS	ABS

SEM44 Technical Specifications:

Output channel: 2 Channel
Output wave form: Biphasic rectangular pulse
Pulse length: 50-360 us
Pulse frequency: 1-150 Hz
Output voltage: max. 120Vpp (500 ohm)
Output current: max. 200mApp (500 ohm)
Voltage supply: 3 x AAA batteries
Treatment time: Adjustable from 5 to 100 minutes
Intensity: Adjustable from 0 to 50
Program: Tens
Buttons:

Buttons:
1 ON/OFF button ⏻
2 **ENTER** ◀ button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button ▲ **UP** and ▼ **DOWN**
6 **MENU** ▶ button



Operation:

Using the UP/DOWN buttons, select the desired program and confirm your selection with the ENTER button.

If you wish to return to the previous selection menu, press the MENU button. By holding down the ENTER button, you can skip individual setting steps and start directly with the stimulation treatment.

At the start of the stimulation treatment, the impulse intensity of and is set to 00 by default. No impulses are sent to the electrodes yet.

Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly. The impulse intensity of and can be set individually.

If the pulses are too weak, the intensity can be increased.

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If you wish to end the stimulation treatment early, press the ON/OFF button

Special Features:

1. Auto shut-off function:

If the unit is turned On for 2 minutes and the intensity is not increased on either channel beyond level O, then the unit turns Off automatically. This is to save battery life.
When the Timer counts down to 0 min, the unit turns off automatically.

2. Auto increased/de-creased function:

The intensity can be increased/decreased by pressing the intensity button CH1 + /- and CH2+/- and keep press it . The intensity level changes at 2 steps per second When the program is changed, the intensity level drops to level 0. It stays at level 0 for 2 seconds before increasing two levels per second back to the previous intensity level. If at any time during the increase of the levels the user wishes to stop the rise in intensity, he can simply do so by pressing the down button on the corresponding channel.

3. ON/OFF function:

To turn On the unit, press the On/Off button once and to turn Off the unit press the On/Off button and hold down for 2 seconds.

4. Pause function testing of the machine:

Any Program can be paused by pressing the On/Off button once. To restart the program, press the On/Off button again.
When a Program is Paused, the pause sign comes on and it flashes at 2 flashes per second . To restart, the intensity starts to rise to the original intensity level.

5. Memory function:

The unit stores the last Program and the times it was used when it is shut off (This is only dependant on the internal ROM of the MCU and will be valid as long as the batteries are not removed from the unit)

6. Lock Function:

The buttons on the unit can be locked to prevent any accidental usage. This is done by holding the Program button down for 2 seconds . To cancel the keylock, press and holddown the Program button button for 2 seconds.

7. Program timer function:

Each program has a preset time which is displayed in the timer box. When the timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

8. Open lead function testing:

Each program has a preset time which is displayed in the timer box. When the timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

9. Low voltage check function testing:

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When the battery voltage is low, a low battery sign will flash on the LCD at 2 flashes per second

10. Output pulses form the machine

When the intensity on either or both channels is increased to level 1 and upto level 20 the device delivers electrical pulses through the two output sockets located at the bottom of the unit. The output parameters of these electrical pulses are referred to in Table 2

Technical Specifications:

Channels:	Dual
Pulse Intensity:	
Output Voltage:	110V(at 500 Ω) 176V(at 1K Ω) 246V(at 2K Ω)
Frequency:	1-150Hz
Pulse Width:	50-360 us
Curve Shape:	Biphasic rectangular pulse
Programs:	15
Power Supply:	3 x 1.5V AAA batteries
Operating Conditions:	10°C-40°C(50°F-104°F) at a relative humidity of 30-85%
Storage Conditions:	-10°C-50°C(14°F-122°F) at a relative humidity of 10-95%
Key to symbols:	Warning! Read the safety information and all instructions to avoid serious injury.

Program	Pulse Intensity Max.	Pulse Width	Frequency	Mode
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

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SEM44 parameter and waveform(300 Ohm load)

Program	Description	Training Frequency (HZ)	Running Times(Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times(Min)	Waveform
1	Phase 1	(b)(4) [redacted]							As shown in picture 1
2	Phase1								As shown in picture 2
3	Phase1								As shown in picture 3.4
4	Phase1								As shown in picture 5.6
5	Phase1								As shown in picture 7.8
6	Phase1								As shown in picture 9.10
	Phase2								As shown in picture 11.12
7	Phase1								As shown in picture 13.14
	Phase2								As shown in picture 15.16
8	Phase1								As shown in picture 17.18
	Phase2								As shown in picture 19.20
9	Phase1								As shown in picture 21.22
10	Phase1								As shown in picture 23
11	Phase1								As shown in picture 24.25
12	Phase1								As shown in picture 26.27
13	Phase1								As shown in picture 28.29
14	Phase1								As shown in picture 30.31
15	Phase1								As shown in picture 32

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SEM44 parameter and waveform(500 Ohm load)

Program	Description	Training Frequency (HZ)	Running Times(Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times(Min)	Waveform
1	Phase 1	(b)(4) [redacted]							As shown in picture 1
2	Phase1								As shown in picture 2
3	Phase1								As shown in picture 3.4
4	Phase1								As shown in picture 5.6
5	Phase1								As shown in picture 7.8
6	Phase1								As shown in picture 9.10
	Phase2								As shown in picture 11.12
7	Phase1								As shown in picture 13.14
	Phase2								As shown in picture 15.16
8	Phase1								As shown in picture 17.18
	Phase2								As shown in picture 19.20
9	Phase1								As shown in picture 21.22
10	Phase1								As shown in picture 23
11	Phase1								As shown in picture 24.25
12	Phase1								As shown in picture 26.27
13	Phase1								As shown in picture 28.29
14	Phase1								As shown in picture 30.31
15	Phase1								As shown in

Questions? [redacted] 796-6118

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SEM44 parameter and waveform(1k Ohm load)

Program	Description	Training Frequency (HZ)	Running Times(Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times(Min)	Waveform
1	Phase 1	(b)(4) [redacted]							As shown in picture 1
2	Phase1								As shown in picture 2
3	Phase1								As shown in picture 3.4
4	Phase1								As shown in picture 5.6
5	Phase1								As shown in picture 7.8
6	Phase1								As shown in picture 9.10
	Phase2								As shown in picture 11.12
7	Phase1								As shown in picture 13.14
	Phase2								As shown in picture 15.16
8	Phase1								As shown in picture 17.18
	Phase2								As shown in picture 19.20
9	Phase1								As shown in picture 21.22
10	Phase1								As shown in picture 23
11	Phase1								As shown in picture 24.25
12	Phase1								As shown in picture 26.27
13	Phase1								As shown in picture 28.29
14	Phase1								As shown in picture 30.31
15	Phase1								As shown in picture 32

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SEM44 parameter and waveform(2K Ohm load)

Program	Description	Training Frequency (HZ)	Running Times(Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times(Min)	Waveform
1	Phase 1	(b)(4) [redacted]							As shown in picture 1
2	Phase1								As shown in picture 2
3	Phase1								As shown in picture 3.4
4	Phase1								As shown in picture 5.6
5	Phase1								As shown in picture 7.8
6	Phase1								As shown in picture 9.10
	Phase2								As shown in picture 11.12
7	Phase1								As shown in picture 13.14
	Phase2								As shown in picture 15.16
8	Phase1								As shown in picture 17.18
	Phase2								As shown in picture 19.20
9	Phase1								As shown in picture 21.22
10	Phase1								As shown in picture 23
11	Phase1								As shown in picture 24.25
12	Phase1								As shown in picture 26.27
13	Phase1								As shown in picture 28.29
14	Phase1								As shown in picture 30.31
15	Phase1								As shown in picture 32

Questions? [redacted] 796-8118

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

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PTS-IV:

Program	Description	Training Frequency (Hz)	Running time (min)	Voltage (V)	Pulse Duration (μs)	Output method	Intensity level	Total Running time (Min)	Waveform
A	1	(b)(4) [redacted]							As shown in picture 3、4、
	2								As shown in picture 3、4
	3								As shown in picture 3、4
	4								As shown in picture 1、2
	5								As shown in picture 1、2
	6								As shown in picture 1、2
	7								As shown in picture 1、2
Program	Description								Waveform
B	1								As shown in picture 3、4
	2								As shown in picture 3、4
	3								As shown in picture 3、4
	4								As shown in picture 3、4
	5								As shown in picture

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(b)(4)

		[redacted]	3、4
	6	[redacted]	As shown in picture 3、4
	7	[redacted]	As shown in picture 3、4
	8	[redacted]	As shown in picture 3、4
	9	[redacted]	As shown in picture 3、4
Program	Description	[redacted]	Waveform
C	1	[redacted]	As shown in picture 1、2
	2	[redacted]	As shown in picture 1、2
	3	[redacted]	As shown in picture 1、2
	4	[redacted]	As shown in picture 1、2
	5	[redacted]	As shown in picture 1、2
	6	[redacted]	As shown in picture 1、2
Program	Description	[redacted]	Waveform
D	1	[redacted]	As shown in picture 1、2
	2	[redacted]	As shown in picture 1、2
	3	[redacted]	As shown

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(b)(4)

		[redacted]	in picture 1、2
	4	[redacted]	As shown in picture 1、2
	5	[redacted]	As shown in picture 1、2
Program	Description	[redacted]	Waveform
E	1	[redacted]	As shown in picture 1
	2	[redacted]	As shown in picture 1
	3	[redacted]	As shown in picture 1
	4	[redacted]	As shown in picture 1
	5	[redacted]	As shown in picture 1
	6	[redacted]	As shown in picture 1
Program	Description	[redacted]	Waveform
F	1	[redacted]	As shown in picture 1
	2	[redacted]	As shown in picture 1
	3	[redacted]	As shown in picture 1
Program	Description	[redacted]	Waveform
ALL	1	[redacted]	As shown in picture 4、5
	2	[redacted]	As shown in picture 4、5
	3	[redacted]	As shown in picture

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(b)(4)

		[redacted]	4、5
	4		As shown in picture 1、2
	5		As shown in picture 1、2
	6		As shown in picture 1、2
	7		As shown in picture 1、2

PTS-IV parameter and waveform（300Ω load）

(b)(4)

[redacted]

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

(b)(4) Parameter and Waveform Pictures

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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

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(b)(4) Testing

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SANITAS

SEM 44

GB IE CY **Instructions for use**
Digital EMS/TENS unit 3

GR CY **Οδηγίες χρήσης**
Ψηφιακή συσκευή EMS/TENS 20

NL **Gebruiksaanwijzing**
Digitaal EMS/TENS-apparaat 39

Electromagnetic Compatibility Information 57

Service Hotline:
GB Tel.: 02030 249 050
GR Τηλ.: 00800 44144962
NL Tel.: 0202 008 466
IE Tel.: 01932 461 312
CY Τηλ.: 800 92440

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SANITAS

CE 0483

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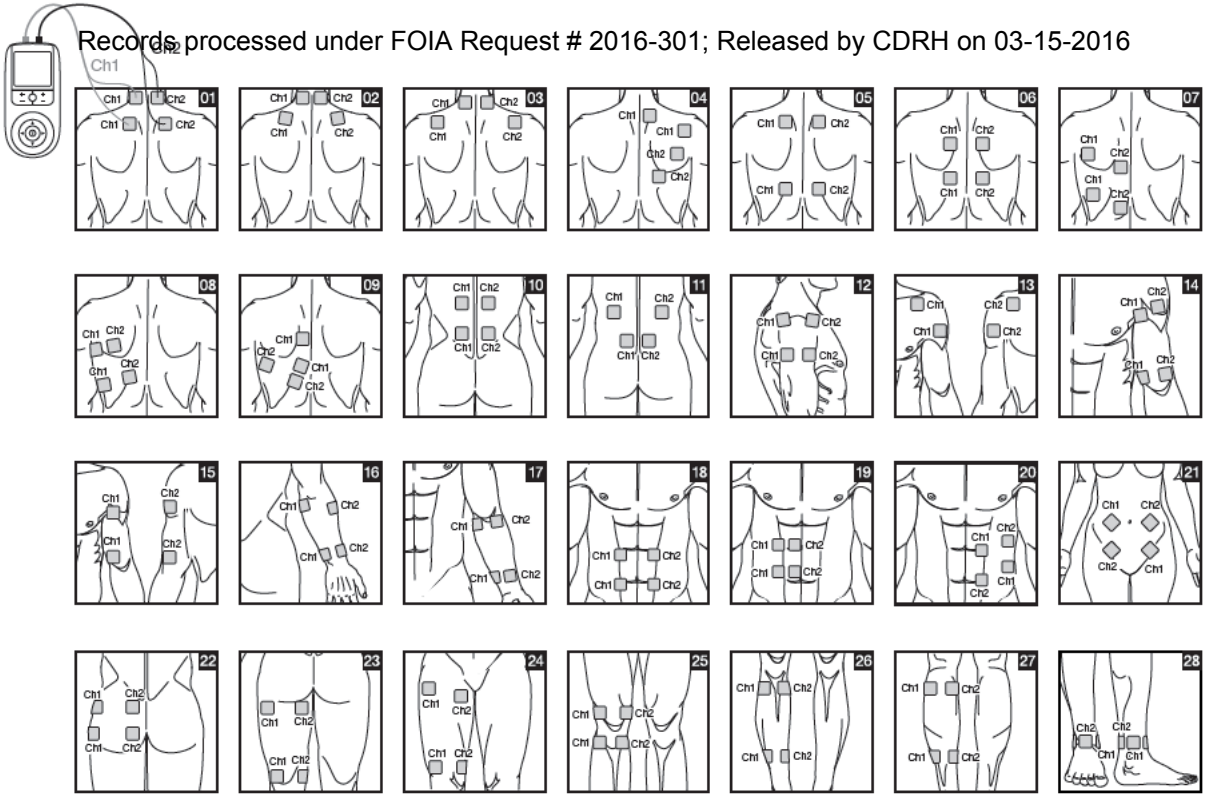

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Please read these instructions for use carefully and keep them for later. Be sure to make them accessible to other users and observe the notes they contain.

Signs and symbols

	WARNING Warning instruction indicating a risk of injury or damage to health
	IMPORTANT Safety note indicating possible damage to the unit/ accessory.
	Note Note on important information
	Observe the instructions for use
	Protect from moisture
SN	Serial number
	Application part, type BF
	Disposal in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment)
	CE conformity marking

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	Medical device
	The device can emit effective output values above 10 mA, averaged over every five second interval

1. Getting to know your instrument

1.1 What is a digital EMS/TENS unit and what can it do?

Digital EMS/TENS units fall into the electrostimulation device category. They provide three basic functions suitable for combined operation:

1. Electrical stimulation of nerve tracts (TENS)
2. Electrical stimulation of muscle tissue (EMS)
3. A massage effect triggered by electrical signals

The unit also features two independent stimulation channels and four self-adhesive electrodes. It offers a wide range of functions for increasing general well-being, pain relief, maintaining physical fitness, relaxation, muscle revitalisation and combating tiredness. For these purposes, you can either choose from pre-set programs or specify your own to suit your individual needs.

The principle of electrostimulation units is based on the imitation of impulses in our bodies that are transferred to nerve and muscle fibres with electrodes via our skin. The electrodes can be applied to many parts of the body; the electrical impulses are completely harmless and virtually painless. In certain applications you will merely notice a slight tingling or vibrating sensation. The electrical impulses that are sent into the tissue influence the transmission of stimulation into nerves, nerve centres and muscle groups in the application area.

Electrostimulation usually only has an effect after regular applications. With regard to muscles, electrostimulation does not replace regular training. However, it is a sensible, supplementary training element.

TENS, or transcutaneous electrical nerve stimulation, relates to the electrical stimulation of the nerves via the skin. TENS is an effective non-pharmacological method of treating different types of pain that have a variety of causes. It has no side-effects if administered correctly. The method has been clinically tested and approved and can be used for simple self-treatment. The pain-relieving or pain-suppressing effect is achieved by inhibiting the transference of pain to nerve fibres (caused mainly by high-frequency impulses) and by increasing the secretion of endorphins in the body. Their effect on the central nervous system reduces the sensation of pain. The method is scientifically substantiated and approved as a form of medical treatment.

Any symptoms that could be relieved using TENS must be checked by your doctor. Your doctor will also give you instructions on how to carry out a TENS self-treatment regime.

TENS is clinically tested and approved to treat the following complaints:

- Back pain, particularly in the lumbar/cervical spine area
- Sore joints (e.g. knee, hip and shoulder joints)
- Neuralgia
- Menstrual cramps in women
- Pain resulting from injury to the musculoskeletal system
- Pain caused by circulatory disorders
- Chronic pain with various causes.

Electrical muscle stimulation (EMS) is a widespread and generally recognised method and has been used in sports medicine and rehabilitation for years. In sports and fitness, EMS is used to complement conventional muscle training, to increase the performance of muscle groups and to adjust physical proportions to achieve the desired aesthetic results. There are two different types of EMS application: one is for targeted strengthening of the muscles (activating application), and the other is to achieve a relaxing, restful effect (relaxing application).

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The activating application involves:

- Muscle training to increase endurance and fitness
- Muscle training to support the strengthening of specific muscles or muscle groups, and to achieve the desired changes to physical proportions

The relaxing application involves:

- Muscle relaxation for easing muscle tension
- Improving symptoms of muscular fatigue
- Acceleration of muscle regeneration after high muscle performance (e.g. after a marathon)

Thanks to **integrated massage technology**, digital EMS/TENS units are also able to relieve muscle tension and combat fatigue with a program based on the sensation and effects of a real massage.

The positioning suggestions and program tables in these instructions for use allow you to quickly and simply determine the corresponding application (depending on the affected area of the body) and set the unit to achieve the desired effects.

Thanks to the two separately adjustable channels, the digital EMS/TENS unit offers you the advantage of being able to set the intensity of the impulses independently from each other for two treatment areas on the body, for example to cover both sides of your body or to evenly stimulate larger areas of tissue. The option to individually set the intensity of each channel also enables you to treat two separate areas of the body simultaneously instead of having to treat the individual areas in turn, which saves you time.

1.2 Included in the delivery

- 1 x digital EMS/TENS unit (including belt clip)
- 2 x connection cables
- 4 x adhesive electrodes (45 x 45 mm)
- 3 x AAA batteries
- These instructions for use

Replacement items

8 x adhesive electrodes (45 x 45 mm), item no.: 661.22
4 x adhesive electrodes (50 x 100 mm), item no.: 661.21

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2. Important notes

The device is not a substitute for medical consultation and treatment. Consult your doctor first if you are experiencing any pain or are suffering from an illness.

⚠ *WARNING!*

To avoid damage to health, we strongly advise against using the digital EMS/TENS unit in the following situations:

- With implanted electrical devices (such as a pacemaker)
- In the case of metal implants
- If you use an insulin pump
- If you have a high temperature (e.g. > 39°C)
- If you have a known or acute cardiac arrhythmia, or disorders of the heart's impulse and conduction system
- If you suffer from a seizure disorder (e.g. epilepsy)
- If you are pregnant
- If you have cancer
- After an operation, if strong muscle contractions could affect the healing process
- The device must never be used near to the heart. The stimulation electrodes must not be placed on any part of the front ribcage (where the ribs and breastbone are located), especially not on the two large pectorals. This can increase the risk of ventricular fibrillation and induce cardiac arrest.

- On the skeletal skull structure, or around the mouth, throat or larynx
- In the neck/carotid artery area
- In the genital area
- On acutely or chronically diseased (injured or irritated) skin (e.g. inflamed skin – whether painful or not, reddened skin, rashes, e.g. allergies, burns, bruises, swellings, both open and healing wounds, and post-operative scars where the healing process has not yet ended)

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- In humid environments (e.g. in the bathroom) or when bathing or showering
- Do not use after consuming alcohol
- Do not use if connected to a high-frequency surgical device

Before using the device, consult your doctor if any of the following applies to you:

- Serious illnesses, in particular if you suspect or have been diagnosed with high blood pressure, a blood coagulation disorder, propensity to thrombo-embolic conditions or recurrent malignant growths
- Any skin conditions
- Unexplained chronic pain in any part of the body
- Diabetes
- Any sensory impairment that reduces the feeling of pain (e.g. metabolic disorders)
- If you are receiving medical treatment
- In the event of complaints linked to stimulation treatment
- If you suffer from persistently irritated skin due to long-term stimulation at the same electrode site

⚠ *IMPORTANT!*

Only use digital EMS/TENS units:

- On people
- For the intended purpose and as specified in these instructions for use. Improper use can be dangerous.
- For external use
- With the original accessories supplied, which can be re-ordered. Failure to do so invalidates the warranty.

PRECAUTIONS:

- Always pull firmly on electrodes to remove them from the skin to prevent injuries in the unusual case of highly sensitive skin.
- Keep the device away from sources of heat and do not use it in close proximity (approx. 1 m) to shortwave or microwave devices (e.g. mobile phones), as doing so can result in unpleasant current peaks.
- Do not expose the device to direct sunlight or high temperatures.
- Protect the device from dust, dirt and humidity. Never immerse the device in water or other liquids.
- The device is suitable for self-treatment.
- For hygiene reasons, the electrodes may only be used on one person.
- If the device does not work properly, or you feel unwell or experience pain, stop using it immediately.
- Switch off the unit or the respective channel first before removing or relocating electrodes to prevent unintentional stimulation.
- Do not modify electrodes (e.g. by cutting them). This increases the current intensity, which is potentially hazardous (max. recommended output value for the electrodes is 9 mA/cm^2, an effective current intensity beyond 2 mA/cm^2 requires increased awareness).
- Do not use the device whilst asleep, driving a vehicle or operating machinery.
- Do not use whilst undertaking any activity where an unexpected reaction (e.g. strong muscle contractions even at low intensity) could be dangerous.
- Ensure that no metallic objects (e.g. belt buckles or necklaces) come into contact with the electrodes during stimulation. If you are wearing jewellery or have piercings in the area to be treated (e.g. a navel piercing), these must be removed before using the device. Failure to do so could result in spot burns.
- Keep the device away from children.
- Make sure not to confuse the electrode cables including contacts with your headphones or other devices and do not connect the electrodes to other devices.
- Do not use the device whilst using other devices that transmit electrical impulses into your body.
- Do not use in the vicinity of highly flammable substances, gases or explosives.
- Do not use rechargeable batteries and always use the same battery types.
- During the initial few minutes use the device while sitting or lying down to minimise the risk of injuries as a consequence of isolated cases of vagal responses (feeling of faintness). If you feel faint,

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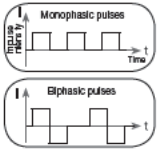
immediately switch off the device, lie down and support the legs in an elevated position (approx. 5 – 10 min).
- Treatment of the skin with moisturising lotions or ointments beforehand is not recommended as this considerably increases the electrode wear and may cause unpleasant current peaks.

Damage
- If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
- Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
- Switch the device off immediately if it is faulty or not working properly.
- Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
- The manufacturer is not liable for damage resulting from improper or careless use.

3. Current parameters

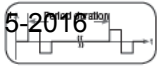
Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

3.1 Impulse form



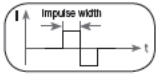
This describes the time function of the electrical impulse.
It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.
The digital EMS/TENS unit only provides biphasic pulse currents as these relieve muscles, cause little muscle fatigue and provide safer applications.

3.2 Impulse frequency



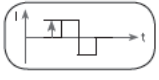
The frequency determines the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards. Impulses of approx. 45 – 70 Hz are linked with constant tension in the muscles and quicker fatigue. Higher impulse frequencies are therefore favourable in strength and maximum power training.

3.3 Impulse width



This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.

3.4 Impulse intensity



Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided.
During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

3.5 Cycled impulse parameter variation

In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the digital EMS/TENS unit, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This

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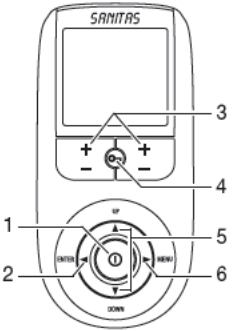
also prevents individual muscle groups at the site of application being affected by fatigue.
The digital EMS/TENS unit provides sensible default current parameter settings. With this, you can change the impulse intensity at any time during use. For 6 programs you can also set various parameters for stimulation yourself.

4. Unit description

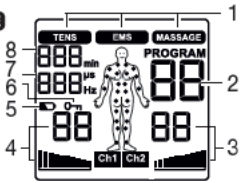
Buttons:

1 ON/OFF button ⏻
2 **ENTER** ◀ button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button ▲ **UP** and ▼ **DOWN**
6 **MENU** ▶ button



Display (full screen):

1 Menu TENS / EMS / MASSAGE
2 Program number
3 Impulse intensity channel 2 (Ch2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (µs) or pause time
8 Timer function (remaining time display) or working time



Accessories:

- 1 x connection cables
- 4 x adhesive electrodes (45 x 45 mm)
- 1 x belt clip

Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF ⏻

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP ▲ and DOWN ▼

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU ▶

(1) Navigation between the TENS, EMS and MASSAGE menus.
(2) Return to program selection screen or menu selection.

ENTER ◀

(1) Menu selection
(2) Confirmation of a selection made using **UP ▲ / DOWN ▼**, except channel intensity

Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)

Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.

1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

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5. Initial use

1. Remove the belt clip (if it is attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).

ⓘ The electrodes feature clip closures to make connection particularly easy.

7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).

ⓘ Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

Fig. 1

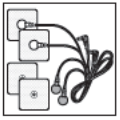


Fig. 2

Fig. 3

Fig. 4

6. Program overview

6.1 Fundamentals

The digital EMS/TENS unit features a total of over 70 programs:

- 15 TENS programs
- 35 EMS programs
- 20 MASSAGE programs

In all programs you can set the impulse intensity of both channels individually.

You can also set various parameters in the TENS programs 13 – 15 and the EMS programs 33 – 35 to adjust the stimulating effect to the application area.

6.2 Information regarding the positioning of electrodes

The following information relates to the correct application of electrodes for stimulation applications that electrodes are positioned sensibly.

We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

The figure on the display is intended as an initial aid to help you position the electrodes. Please refer to the inside of the cover for more detailed information on how to position the electrodes.

The following applies to the selection of electrode positions:

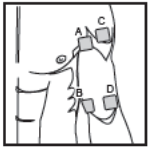
Electrode distance

The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:

- Sensible distance: approx. 5– 15 cm
- At distances below 5 cm, the unit primarily stimulates surface structures intensively
- At distances in excess of 15 cm, large areas and deep structures are stimulated very weakly

Relation between electrodes and muscle fibre structures



Adapt the current flow direction to the fibre structure of the muscle according to the muscle layer you would like to treat. If you are targeting superficial muscles, position the electrodes in parallel to the fibre structure (A–B / C–D) and if you are targeting deeper layers of tissue, position the electrodes across the fibre structure. You can do this by positioning electrodes across (or diagonally), such as A–D / B–C.

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As part of pain relief treatment (TENS) using the digital EMS/TENS unit and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2–3 cm.

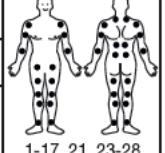
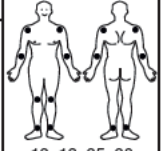
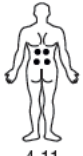
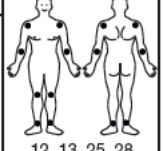
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses.

Tip for the massage function: always use all four electrodes for optimum treatment.

Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

6.3 TENS program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Pain relief – acute pain	1	30	 1-17, 21, 23-28
2	Pain relief – chronic pain (pulse width modulated)	1	30	
3	Endorphin effect (burst)	1	30	
4	Chronic pain in the lower back	1	30	10, 11
5	Pain in the lower back	1	30	
6	Knee, ankle, joint pain	1	5	 12, 13, 25, 28
		2	15	
7	Back pain	1	20	 4-11
		2	20	
8	Arthritis	1	15	 12, 13, 25, 28
		2	10	

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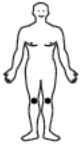
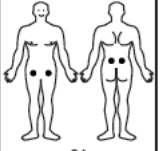
Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
9	Osteoarthritis of the knee joint	1	30	 25
10	Neck pain	1	30	1-3
11	Menstrual cramps	1	30	 21
12	Menstrual cramps	1	30	

TENS programs 13–15 can be set individually, see section 7.3.2 (p. 14).

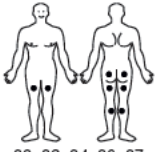
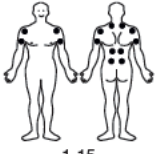
Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.

To relieve joint pain, surround the joint with electrodes at the front and back as well as on the left and right of the joint, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 5 cm or exceed 15 cm.

Please note Figures 25 and 28, which apply to the knee and ankle joints.

Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

6.4 EMS program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Capillarisation	1	20	1-28
2	Warming up	1	10	
3	Cooling down after training/match	1	20	
4	Maximum power of lower limbs	1	05	 22, 23, 24, 26, 27
		2	15	
		3	05	
5	Maximum power of lower limbs	1	05	
		2	20	
		3	05	
6	Explosive force of the lower limbs	1	05	
		2	12	
		3	05	
7	Maximum force at the upper limbs and on the back	1	05	 1-15
		2	15	
		3	05	
8	Endurance at the upper limbs and on the back	1	05	
		2	12	
		3	05	
9	Elasticity at the upper limbs and on the back	1	05	
		2	12	
		3	05	

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Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
10	Vascularisation at the lower limbs	1	40	22, 23, 24, 26, 27
11	Lymphatic drainage at the lower limbs	1	40	
12	Strengthening of lower limbs	1	20	
		2	10	
13	Toning of lower limbs	1	20	
		2	10	
14	Shaping of the lower limbs	1	20	
		2	20	
15	Accompanying muscle build-up on the lower limbs	1	15	
16	Lymphatic drainage of stomach muscles	1	40	18, 19, 20
17	Lipolysis of stomach muscles	1	40	
18	Toning of stomach muscles	1	20	
		2	10	
19	Strengthening of stomach muscles	1	20	
		2	10	
20	Shaping of stomach muscles	1	20	
		2	20	
21	Lymphatic drainage at the upper limbs and on the back	1	20	1-15
		2	10	
22	Strengthening of the upper limbs and back	1	20	
		2	10	
23	Toning the upper limbs and back	1	20	
		2	20	
24	Shaping the upper limbs and back	1	15	
25	Accompanying muscle build-up on the upper limbs and back			

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
26	Strengthening thighs and hips 1	1	20	20, 23, 24
		2	10	
27	Strengthening thighs and hips 2	1	20	
		2	10	
28	Toning the thighs and hips	1	20	
		2	10	
29	Shaping the thighs and hips	1	20	
		2	10	
30	Strengthening of gluteal muscles	1	20	22
		2	10	
31	Toning of gluteal muscles	1	20	
		2	10	
32	Shaping of gluteal muscles	1	20	
		2	20	

EMS programs 33 – 35 can be set individually, see section 7.3.3 (p. 15).

6.5 MASSAGE program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Muscle strain relief 1	1	20	1-28
2	Muscle strain relief 2	1	20	
3	Relaxing massage 1	1	25	
4	Relaxing massage 2	1	25	
5	Invigorating massage 1	1	20	
6	Invigorating massage 2	1	20	

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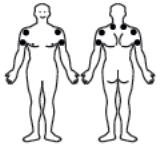
Progr. no.	Area of application, Indication	Phase	Running time (min)	Possible electrode positions
7	Shoulder massage 1	1	15	 1-3, 12, 13
8	Shoulder massage 2	1	15	
9	Tapping and jet massage 1	1	15	1-28
10	Tapping and jet massage 2	1	15	
11	Vibrating massage 1	1	20	
12	Vibrating massage 2	1	20	
13	Warm up massage 1	1	20	
14	Warm up massage 2	1	10	
15	Warm up massage 3	1	10	
16	Warm up massage 4	1	10	
17	Pressure massage 1	1	20	
18	Pressure massage 2	1	20	
19	Kneading and pressure massage 1	1	20	
20	Kneading and pressure massage 2	1	20	

Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 15 cm.

Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.

7. Use

7.1 Information regarding application

- The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the menu selection and the most recently used menu flashes.
- A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
- You can pause the stimulation at any time by briefly pressing the ON/OFF button ⏻. To continue the stimulation, briefly press the ON/OFF button ⏻ again and set the desired impulse intensity again.

7.2 Procedure for TENS programs 1 – 12, EMS programs 1 – 32 and MASSAGE programs 1 – 20 (quick start)

- Select a suitable program from the program tables (p. 10 – 12).
- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device.
- The figure on the display is intended as an additional aid to help you position the electrodes.

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Selecting a program

- Press the ON/OFF button ⏻ to switch on the device.
- Press the **MENU** button to navigate through the TENS / EMS / MASSAGE menus (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.

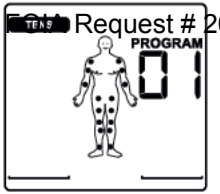

Fig. 1

- Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).

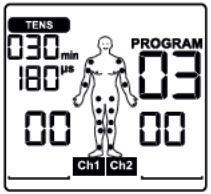

Fig. 2

General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down the **ENTER** button, you can skip individual setting steps and start directly with the stimulation treatment.

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

- Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.

Fig. 3

- If the program is in a pause phase, the intensity cannot be increased.
- If you wish to end the stimulation treatment early, press the ON/OFF button ⏻.

7.3 Setting your own parameters for individual programs

7.3.1 Setting the treatment duration

(TENS programs 13 – 15 and EMS programs 33 – 35 only)

Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treatment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

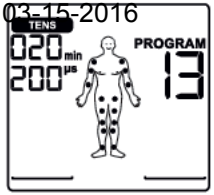

Fig. 4

The stimulation treatment starts and the display of the selected basic function (TENS / EMS / MASSAGE) starts flashing.

7.3.2 Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.

- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device. Select the TENS 13 program, as described in section 7.2 “Selecting a program” (p. 13).
- Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).

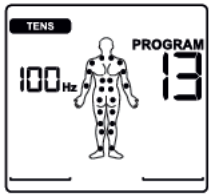

Fig. 1

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- Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 2, example shows an impulse width of 200 µs).
- Select the desired treatment time, as described in 7.3.1 “Setting the treatment time” (p. 14).
- Select the desired impulse intensity, as described in 7.2 “Setting the impulse intensity” (p. 14).

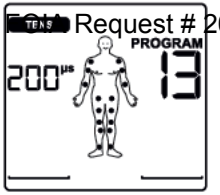

Fig. 2

Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.

- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device. Select the TENS 14 program, as described in section 7.2 “Selecting a program” (p. 13).
- Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
- Select the desired treatment time, as described in 7.3.1 “Setting the treatment time” (p. 14).
- Select the desired impulse intensity, as described in 7.2 “Setting the impulse intensity” (p. 13).

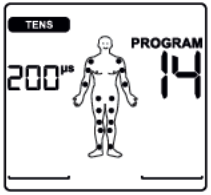

Fig. 1

Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.

- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device. Select the TENS 15 program, as described in section 7.2 “Selecting a program” (p. 13).
- Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
- Select the desired treatment time, as described in 7.3.1 “Setting the treatment time” (p. 14).
- Select the desired impulse intensity, as described in 7.2 “Setting the impulse intensity” (p. 13).

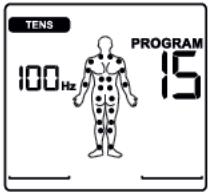

Fig. 1

7.3.3 Setting individual EMS programs

Procedure for the EMS 33 program

EMS 33 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 100 Hz and the impulse width to between 50 and 320 µs.

- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device. Select EMS program 33, as described in section 7.2 “Selecting a program” (p. 13).
- Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 30 Hz).

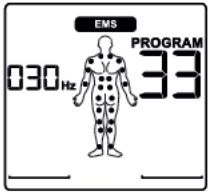

Fig. 1

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- Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 2, example shows an impulse width of 250 µs).
- Select the desired treatment time, as described in 7.3.1 “Setting the treatment time” (p. 14).
- Select the desired impulse intensity, as described in 7.2 “Setting the impulse intensity” (p. 13).

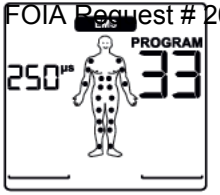

Fig. 2

Procedure for the EMS 34 program

EMS 34 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 100 Hz. The impulse width changes automatically during the stimulation treatment.

- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device. Select EMS program 34, as described in section 7.2 “Selecting a program” (p. 13).

- Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 30 Hz).
- Select the desired treatment time, as described in 7.3.1 “Setting the treatment time” (p. 14).
- Select the desired impulse intensity, as described in 7.2 “Setting the impulse intensity” (p. 13).

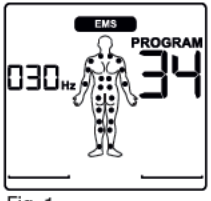

Fig. 1

Procedure for the EMS 35 program

EMS 35 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 100 Hz. You can also set the working time and pause time for the program to between 1 and 30 seconds each.

- Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 2) and connect them to the device. Select EMS program 35, as described in section 7.2 “Selecting a program” (p. 13).

- Select the desired working time using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows a working time of 2 seconds).

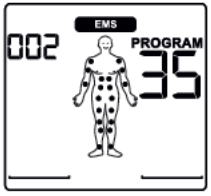

Fig. 1

- Select the desired pause time using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 2, example shows a pause time of 10 seconds).

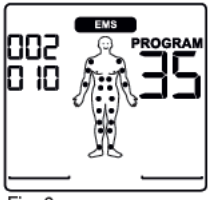

Fig. 2

- Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 3, example shows an impulse frequency of 30 Hz).

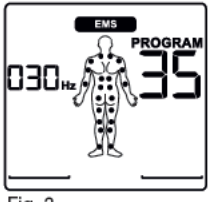

Fig. 3

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- Select the desired treatment time, as described in 7.3.1 “Setting the treatment time” (p. 12).
- Select the desired impulse intensity, as described in 7.2 “Setting the impulse intensity” (p. 13).

7.4 Changing the settings

Changing the intensity (during treatment)

- **Ch1 +/- and Ch2 +/-**: changes the intensity of each channel

Interrupting stimulation

Press the ON/OFF button ⏻.

Changing application (completely or individual parameters)

- ON/OFF ⏻: interrupt stimulation
- Setting the programs, see 7.2; setting your own parameters, see 7.3.

7.5 Doctor’s function

The Doctor’s function is a special setting to allow you to access your personal program even more easily and directly.
Your individual program settings are instantly recalled and activated when the device is switched on.
You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor’s function

- Select your program and the corresponding settings as described in 7.2 and 7.3.
- At the start of the stimulation treatment, the impulse intensity of **Ch1** and **Ch2** is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the **Ch2** button for 5 seconds. Storage in the Doctor’s function is confirmed with a long acoustic signal.
  If you switch on the device again, the program you saved using the Doctor’s function is automatically opened directly.

Deleting the Doctor’s function

To clear the device again and to re-allow access to other programs, press and hold the **Ch2** button again for approx. 5 seconds. To do this, the impulse intensity of **Ch1** and **Ch2** must be set to 00. Deletion of the Doctor’s function is confirmed with a long acoustic signal.

8. Cleaning and storage

Adhesive electrodes

- To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
  ⓘ Before cleaning with water, remove the connection cables from the electrodes.
- Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

- Remove the batteries from the device before cleaning.
- Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
- Do not use any chemical or abrasive cleaning agents.

⚠ Ensure that no water enters the device.

Storage

- Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.
- Do not make sharp bends in the connection cables and electrodes.
- Disconnect the connection cables from the electrodes.
- Reapply the electrodes to the carrier foil after use.
- Store the device and accessories in a cool, well-ventilated space.
- Never place any heavy objects on the device.

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9. Disposal

The empty, completely flat batteries should be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.

Note: The codes below are printed on batteries containing harmful substances: Pb = Battery contains lead, Cd = Battery contains cadmium, Hg = Battery contains mercury.

Please dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

10. Problems/solutions

The device does not switch when the ON/OFF button ⏻ is pressed. How to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.
(2) Replace batteries, if applicable.
(3) Contact Customer Services.

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lint-free cloth. Replace the electrodes if they still do not adhere securely.
(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button ⏻ to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.
(2) Ensure the connection plug is firmly connected to the device.
(3) Press the ON/OFF button ⏻ to restart the program.
(4) Check electrode positions and ensure that adhesive electrodes do not overlap.
(5) Gradually increase the impulse intensity.
(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow.

However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

11. Technical specifications

Name and model	SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries
Treatment time	Adjustable from 5 to 100 minutes

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Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (including belt clip)
Weight	101 g (including belt clip, without batteries), 127 g (including belt clip and batteries)

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!

We reserve the right to make technical changes to improve and develop the product.

This device complies with European standards EN60601-1 and EN60601-1-2 and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

More details can be requested from the stated Customer Services address or found at the end of the instructions for use.

This device meets the requirements of European Directive 93/42/EC for medical devices, as well as those of the Medical Devices Act.

12. Warranty/Service centre

We provide a 3-year warranty covering faults in materials or manufacture of the product from the purchase date.
The warranty does not cover:

- Damage resulting from improper use.
- Wear parts.
- Defects that were known to the customer at the time of purchase.
- Damage for which the customer was responsible.

This warranty does not affect the customer's legal rights.

The customer must provide proof of purchase in order for any warranty claims within the warranty period to be honoured.
Claims under the warranty within a period of 3 years from the date of purchase are honoured by

Hans Dinslage GmbH, Riedlinger Straße 28, 88524 Uttenweiler, Germany

GB Tel.: 02030 249 050; IE Tel.: 0152 451 32; CY Tel.: 800 92440

In the event of a warranty claim, the customer has the right to have the goods repaired by our own workshop or a workshop authorised by use. The device must not be opened for any reason. Opening or modifying the device invalidates the warranty.
This warranty does not grant any additional rights to the customer.
In many cases the reason for complaints is operating errors. They can be easily corrected by telephone. Please contact the service hotline.

GB Tel.: 02030 249 050; IE Tel.: 0152 451 32; CY Tel.: 800 92440

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Tyece OTC TENS Device
Model SEM 44

Instructions for Use

Please read these instructions carefully before use

Indication for Use:

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household activities.

Rev: 02.10.15

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

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Warning:

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities
- Metals Implants or Electronic Auxiliary Devices
- Diabetes or Abnormal High Blood Pressure
- A tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

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User Instructions

Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Tyece OTC TENS Device, SEM44".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
Danger	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
Warning	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol
Refers to prohibitive action in the proper use of the unit. The specific forbidden

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content is indicated inside the circle.	The left picture means no dismantling.
	Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. The left picture means general compulsion.
	BF Isolated Applied Part

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

2. Precautions

1) Do not use the muscle stimulator during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over areas of the skin which lack normal sensation.
5) Do not use the products near the heart; it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) The TENS Device, SEM44 must be kept out of the reach of children.
8) The TENS Device, SEM44 should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the TENS Device, SEM44 and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical shock, do not connect two pads to each other
12) Do not apply pads to the same spot for over 40 minutes at a time.
13) Do not use the TENS Device, SEM44 while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.
17) Never use this product near a microwave oven, or other high frequency equipment.
18) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

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3. Contraindication

1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions

1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application of electrical 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your pain, consult with your physician before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Device, SEM44.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The upper neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic pad sheet provided.
Place the pads at least 5 cm (1 inch) apart on your skin. The pads should never touch each other.
Always place clean pads in accordance with illustrations provided. Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin.
Do not place on your spine or backbone.
Pads should not touch any metal object, such as a belt buckle or necklace.
Pads should not be placed simultaneously on the soles of both feet.
Pads should not be placed simultaneously on the calves of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads attached to the skin after treatment.

CAUTION WHILE USING UNIT

If the unit is not functioning properly or you feel discomfort, immediately stop using the device.

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

Do not use for any other purpose except for what it is intended for.
Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
Do not pull on the electrode cord during treatment.
Do not use the device while wearing electronic devices such as watches as this may damage the device.
Do not use near a cell phone as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, hold the plug and pull.
Replace the cord when broken or damaged.
Do not throw the batteries into a fire. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
Using pads that are too small or incorrectly applied, could result in discomfort or skin burns

General Precautions

• The long-term effects of electrical stimulation are unknown.
• Apply stimulation to only normal, intact, clean, dry, and healthy skin.
• TENS is not effective in treating the original source or cause of the pain, including headache.
• TENS is not a substitute for pain medications and other pain management therapies.
• TENS devices do not cure disease or injuries.
• TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your phycician
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
Keep unit out of the reach of young children. The electrode cord can cause strangulation.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

What is it?

The Tyece OTC TENS Device, Model SEM44 is a multi-program, portable device designed for adults only. It is designed to reduce and relieve muscle and joint pain, stiffness and numbness in the arms, legs and foot by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.

How does it work?

Scientific theory suggests that electrical stimulation therapy may work in several ways:
1. The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.
2. The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
3. Furthermore, it is thought that the electrical stimulation improves blood circulation as well.

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

Symbols

Symbol	Meaning
	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Direct current
	Class II equipment
	Re-back label
	Indoor use only

Included in the delivery

– 1 x digital TENS unit (including belt clip)
– 2 x connection cables
– 4 x adhesive electrodes (50x 50 mm)
– 3 x AAA batteries
– These instructions for use

Replacement items

8 x adhesive electrodes (50 x 50 mm), item no.: 661.22
4 x adhesive electrodes (50 x 100 mm), item no.: 661.21

Damage

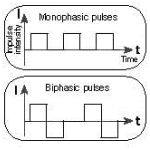
• If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
• Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
• Switch the device off immediately if it is faulty or not working properly.
• Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
• The manufacturer is not liable for damage resulting from improper or careless use.

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

Current parameters

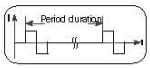
Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

Impulse form



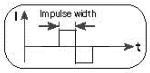
This describes the time function of the electrical impulse.
It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.

Impulse frequency



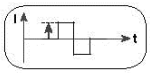
The frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards.

Impulse width



This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.

Impulse intensity



Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided. During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

Cycled impulse parameter variation

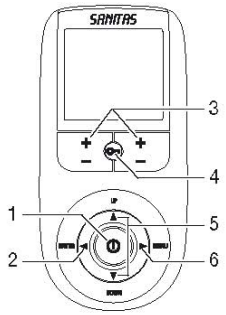
In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the TENS Device SEM44, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This also prevents individual muscle groups at the site of application being affected by fatigue.
The TENS Device SEM44 unit provides sensible default current parameter settings. With this, you can change the impulse intensity at any time during use. For 6 programs you can also set various parameters for stimulation yourself.

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

Unit description

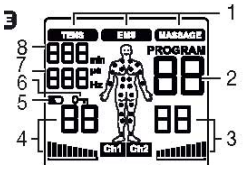
Buttons:

1 ON/OFF button
2 ENTER button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button UP and DOWN
6 MENU button



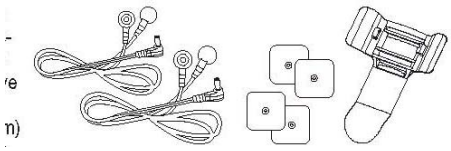
Display (full screen):

1 TENS
2 Program number
3 Impulse intensity channel 2 (CH2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (µs) or pause time
8 Timer function (remaining time display) or working time



Accessories:

• 2 x connection cables
• 4 x adhesive electrodes (45 x 45 mm)
• 1 x belt clip



Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP and DOWN

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU

(1) Navigation between the , and MENUs.
(2) Return to program selection screen or MENU selection.

ENTER

(1) MENU selection
(2) Confirmation of a selection made using UP / DOWn , except channel intensity

Intensity setting buttons (+/- left, +/- right) Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.
1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

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

Initial use

1. Remove the belt clip from the unit (if attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5 V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).
   The electrodes feature clip closures to make connection particularly easy.
7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).
   Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

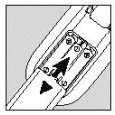


Fig. 1

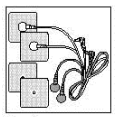


Fig. 2

Fig. 3

Program overview
Fundamentals

The TENS Device SEM44 features a total of 15 programs.

In all programs you can set the impulse intensity of both channels individually.
You can also set various parameters in the TENS programs 13 – 15 to adjust the stimulating effect to the application area.

Information regarding the positioning of electrodes

It is fundamental to the intended success of electrostimulation applications that electrodes are positioned sensibly. We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

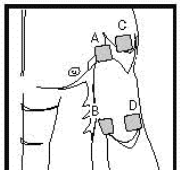
The figures displayed are intended as an initial aid to help you position the electrodes.

The following applies to the selection of electrode positions:

Electrode distance
The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:
• Sensible distance: approx. 2-6 inches
• At distances below 2 in, the unit primarily stimulates surface structures intensively
• At distances in excess of 6 in, large areas and deep structures are stimulated very weakly

Relation between electrodes and muscle fibre structures
Adapt the current flow direction to the fibre structure of the muscle according to the muscle layer you would like to treat. If you are targeting superficial muscles, position the electrodes in parallel to the fibre structure (A – B / C – D) and if you are targeting deeper layers of tissue, position the electrodes across the fibre structure. You can do this by positioning electrodes as crosses (i.e. diagonally), such as A – D / B – C.



As part of pain relief treatment using the digital Tyece OTC TENS Device and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2 in.
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses.

ⓘ Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

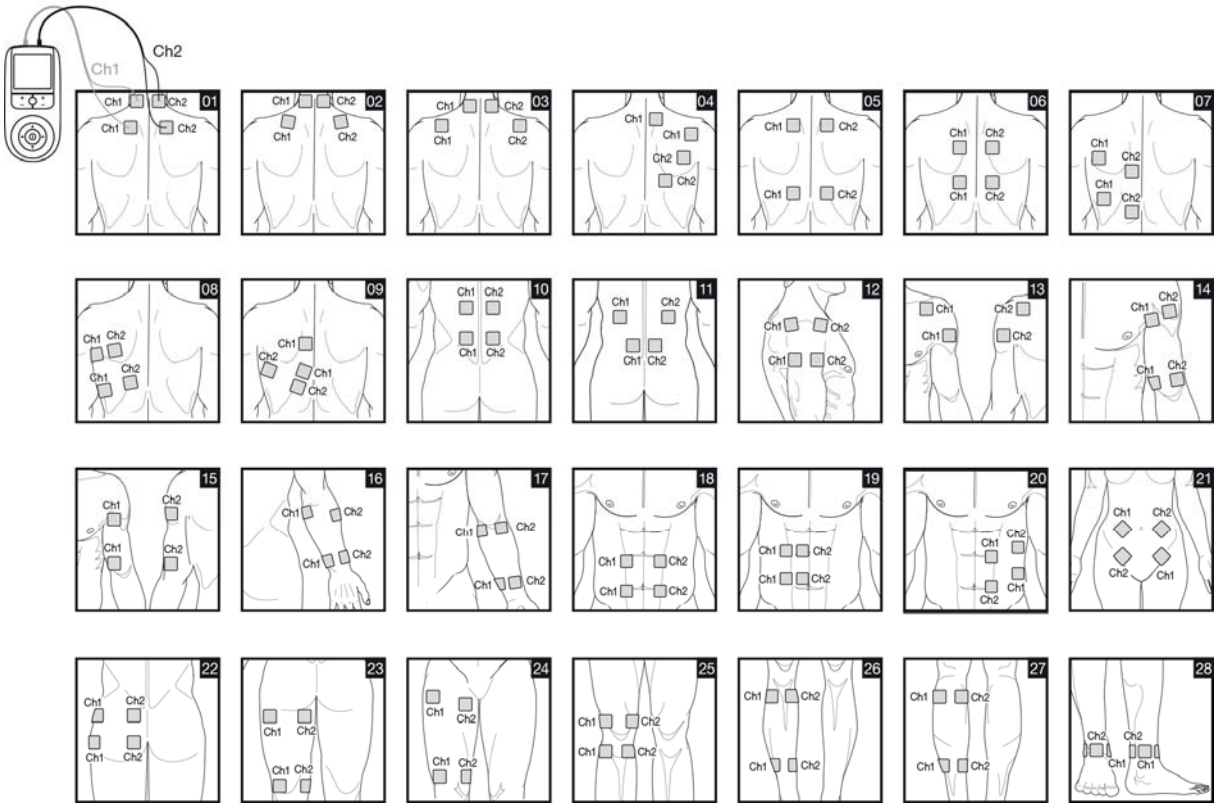
ⓘ If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

ⓘ TENS programs 13 – 15 can be set individually, see pages 12-13

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve joint pain, surround the joint with electrodes at the front and back as well as on the left and right of the joint, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Please note Figures 25 and 28, which apply to the knee and ankle joints.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.

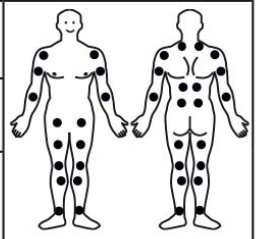
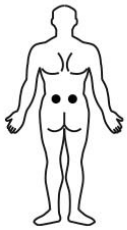
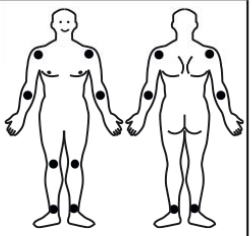
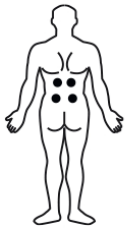
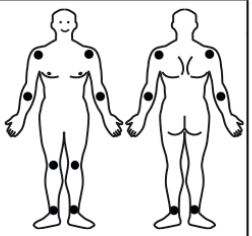
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.



Suggested Electrode Pad placements

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

TENS program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Pain relief – acute pain	1	30	 1-17, 21, 23-28
2	Pain relief – chronic pain (pulse width modulated)	1	30	
3	Endorphin effect (burst)	1	30	
4	Chronic pain in the lower back	1	30	 10, 11
5	Pain in the lower back	1	30	
6	Knee, ankle, joint pain	1	5	 12, 13, 25, 28
		2	15	
7	Back pain	1	20	 4-11
		2	20	
8	Arthritis	1	15	 12, 13, 25, 28
		2	10	

Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).
Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.

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

Use
Information regarding application

• The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the MENU selection and the most recently used MENU flashes.
• A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
• You can pause the stimulation at any time by briefly pressing the ON/OFF button . To continue the stimulation, briefly press the ON/OFF button again and set the desired impulse intensity again.

Procedure for TENS programs 1 – 12,

• Select a suitable program from the program tables (page 11).
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions (page 10) and connect them to the device.
• The figure on the display is intended as an additional aid to help you position the electrodes.

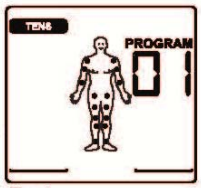
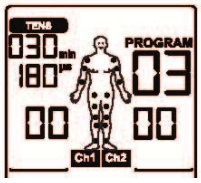


Fig. 1

Selecting a program

• Press the ON/OFF button to switch on the device.
• Press the **MENU** button to activate the TENS program (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.
• Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).



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General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

• Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.
• If the program is in a pause phase, the intensity cannot be increased.
• If you wish to end the stimulation treatment early, press the ON/OFF button.

Fig. 3

Setting your own parameters for individual programs
Setting the treatment duration

(TENS programs 13 – 15 only).
Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treat-ment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

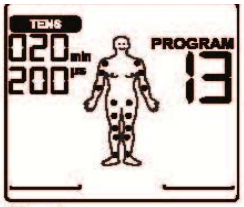
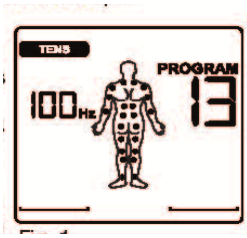


Fig. 4

Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, page 10) and connect them to the device. Select the TENS 13 program, as described in section “Selecting a program” (p. 12).



• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER**

button to confirm (Fig. 2, example shows an impulse width of 200 µs).
• Select the desired treatment time, as described in “Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).

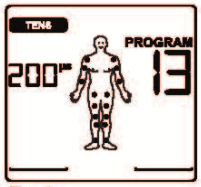
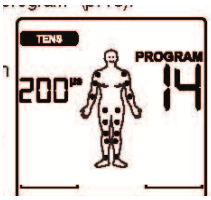


Fig. 2

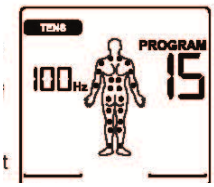
Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 14 program, as described in section“Selecting a program” (p. 11).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
• Select the desired treatment time, as described in “Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).



Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 15 program, as described in section “Selecting a program” (p. 11).
• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired treatment time, as described in“Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).



Changing the settings

Changing the intensity (during treatment)

• Ch1 +/- and Ch2 +/-: changes the intensity of each channel

Interrupting stimulation.

Press the ON/OFF button.

Changing application (completely or individual parameters)

• ON/OFF : interrupt stimulation
• Setting the programs, see page 12; setting your own parameters, see page 12.

Doctor’s function

The Doctor’s function is a special setting to allow you to access your personal program even more easily and directly. Your individual program settings are instantly recalled and activated when the device is switched on.
You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor’s function

• Select your program and the corresponding settings as described on page 12.
• At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the Ch2 - button for 5 seconds. Storage in the Doctor’s function is confirmed with a long acoustic signal.
If you switch on the device again, the program you saved using the Doctor’s function is automatically opened directly.

Deleting the Doctor’s function

To clear the device again and to re-allow access to other programs, press and hold the Ch2 - button again for approx. 5 seconds. To do this, the impulse intensity of Ch1 and Ch2 must be set to 00. Deletion of the Doctor’s function is confirmed with a long acoustic signal.

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

Cleaning and storage

Adhesive electrodes

• To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
ⓘ Before cleaning with water, remove the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

• Remove the batteries from the device before cleaning.
• Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
• Do not use any chemical or abrasive cleaning agents.
⚠ Ensure that no water ENTERs the device.

Storage

• Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.
• Do not make sharp bends in the connection cables and electrodes.
• Disconnect the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil after use.
• Store the device and accessories in a cool, well-ventilated space.
• Never place any heavy objects on the device.

Disposal

Warning!

Danger of explosion if wrong type of battery is used as replacement! Replace only with the same or equivalent type recommended by the manufacturer.

DO NOT dispose of batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e.g. to the collecting points for disposal of batteries).

Problems/solutions

The device does not switch when the On/OFF button is pressed. how to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.
(2) Replace batteries, if applicable.
(3) Contact Customer Services.

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lintfree cloth. Replace the electrodes if they still do not adhere securely.
(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.
(2) Ensure the connection plug is firmly connected to the device.
(3) Press the ON/OFF button to restart the program.
(4) Check electrode positions and ensure that adhesive electrodes do not overlap.
(5) Gradually increase the impulse intensity.
(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

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

You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow. However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

Technical specifications

Name and model	SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries (3 x 1.5 V)
Treatment time	Adjustable from 5 to 100 minutes
Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (5.2 x 2.5 x1.2 inches, including belt clip)
Weight	101 g (3.5 oz, including belt clip, without batteries), 127 g (4.5 oz, including belt clip and batteries)
Product Life	5 years
Electrode Pads, Size	50 x 50 mm (2 x 2 in)

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!
We reserve the right to make technical changes to improve and develop the product.
This device complies with US and European standards and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

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

ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5) Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the OTC TENS Device SEM44 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer of the user of the OTC TENS Device SEM44 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	OTC TENS Device SEM44 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The OTC TENS Device SEM44 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 is intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level IEC60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OTC TENS Device SEM44 requires continued operation during power mains interruptions, it is recommended that the OTC TENS Device SEM44 be powered from an uninterruptible power supply or a battery.

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

	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the OTC TENS Device SEM44 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OTC TENS Device SEM44 is used exceeds the applicable RF compliance level above, the OTC TENS Device SEM44 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OTC TENS Device SEM44.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the OTC TENS Device SEM44.

The OTC TENS Device SEM44 *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OTC TENS Device SEM44 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OTC TENS Device SEM44 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Limited Lifetime Warranty for Original Purchaser

Your TYECE OTC TENS Device SEM44, excluding all enclosed accessories as these require routine maintenance, is warranted to be free from defects in materials and workmanship for the life of the product under normal conditions of intended use and service. This warranty extends only to the original retail purchaser and does not extend to retailers or subsequent owners.

We will, at our option, repair or replace the OTC TENS Device SEM44, without charge, for any part or parts covered by these written warranties. No refunds will be given. Repair or replacement is our only responsibility and your only remedy under this written warranty. If replacement parts for defective materials are not available, Tyece reserves the right to make product substitutions in lieu of repair or replacement.

For warranty service contact our customer service department at **info@tyece.com** to provide a description of the problem. If the problem is deemed to be within the scope of the limited lifetime warranty, you will be asked to mail the product at your costs in its original package with proof of purchase, your name, address and phone number. If the problem is not deemed to be within the scope of the limited lifetime warranty, we will provide quotation for repair, respectively, replacement and return shipping fee.

This warranty does not cover damage caused by misuse or abuse; accident; failures of the atomizer, tubing, or accessories; parts or cleaning solutions; the attachment of unauthorized accessories; alteration to the product; improper installation; misapplication; lack of reasonable care with respect to the product; unauthorized repairs or modifications; improper use of electrical/power supply; normal wear; loss of power; dropped product; malfunction or damage of an operating part as a result of failure to comply with instructions for use or to provide

manufacturer's recommended maintenance; transit damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of Tyece. This warranty is void if the product is ever used in a commercial or business environment. The maximum liability of Tyece under this warranty is limited to the purchase price actually paid by the customer for the product covered by the warranty, as confirmed by proof of purchase, regardless of the amount of any other direct or indirect damage suffered by the customer.

This warranty is effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adaptation to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THE WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. ANY IMPLIED WARRANTIES, OBLIGATIONS, OR LIABILITES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS APPLICABLE WRITTEN WARRANTY. Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL TYECE BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES FOR BREACH OF THIS OR ANY OTHER WARRANTY, EXPRESS, IMPLIED OR ANY OTHER THEORY OF LIABILITY, WHATSOEVER. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

Tyece does not authorize anyone, including, but not limited to, retailers, the subsequent consumer purchaser of the product from a retailer or remote purchaser, to obligate Tyece in any way beyond the terms set forth herein.

This warranty does not extend to the purchase of opened, used, repaired, repackaged and/or resealed products, including but not limited to sale of such products on Internet auction sites and/or products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate in connection with any products or parts thereof which are repaired, replaced, altered, or modified, without the prior explicitly written consent of Tyece.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state.

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H

Tyece OTC TENS Device
Model SEM 44

Instructions for Use

Warning Copy

Please read these instructions carefully before use

Indication for Use:

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household activities.

Rev: 02.10.15 update

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Warning:

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities
- Metals Implants or Electronic Auxiliary Devices
- Diabetes or Abnormal High Blood Pressure
- A tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

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User Instructions

Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Tyece OTC TENS Device, SEM44".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
Danger	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
Warning	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol	
	Refers to prohibitive action in the proper use of the unit. The specific forbidden

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content is indicated inside the circle. The left picture means no dismantling.	
	Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. The left picture means general compulsion.
	BF Isolated Applied Part

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

underline "trigger" words

2. Precautions

1) Do not use the ~~muscle stimulator~~ TENS device during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over areas of the skin which lack normal sensation.
5) Do not use the products near the heart; it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) The TENS Device, SEM44 must be kept out of the reach of children.
8) The TENS Device, SEM44 should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the TENS Device, SEM44 and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical shock, do not connect two pads to each other
12) Do not apply pads to the same spot for over 40 minutes at a time.
13) Do not use the TENS Device, SEM44 while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.
17) Never use this product near a microwave oven, or other high frequency equipment.
18) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

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3. Contraindication

1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions

1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application of electrical 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your pain, consult with your physician before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Device, SEM44.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The upper neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic pad sheet provided.
Place the pads at least 5 cm (1 inch) apart on your skin. The pads should never touch each other.
Always place clean pads in accordance with illustrations provided. Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin.
Do not place on your spine or backbone.
Pads should not touch any metal object, such as a belt buckle or necklace.
Pads should not be placed simultaneously on the soles of both feet.
Pads should not be placed simultaneously on the calves of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads attached to the skin after treatment.

CAUTION WHILE USING UNIT

If the unit is not functioning properly or you feel discomfort, immediately stop using the device.

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Do not use for any other purpose except for what it is intended for.
Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
Do not pull on the electrode cord during treatment.
Do not use the device while wearing electronic devices such as watches as this may damage the device.
Do not use near a cell phone as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, hold the plug and pull.
Replace the cord when broken or damaged.
Do not throw the batteries into a fire. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
Using pads that are too small or incorrectly applied, could result in discomfort or skin burns

⚠ **General Precautions**

• The long-term effects of electrical stimulation are unknown.
• Apply stimulation to only normal, intact, clean, dry, and healthy skin.
• TENS is not effective in treating the original source or cause of the pain, including headache.
• TENS is not a substitute for pain medications and other pain management therapies.
• TENS devices do not cure disease or injuries.
• TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your phycician
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
Keep unit out of the reach of young children. The electrode cord can cause strangulation.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

What is it?

The Tyece OTC TENS Device, Model SEM44 is a multi-program, portable device designed for adults only. It is designed to reduce and relieve muscle and joint pain, stiffness and numbness in the arms, legs and foot by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.

add: no to be used as an EMS device

How does it work?

Scientific theory suggests that electrical stimulation therapy may work in several ways:
1. The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.
2. The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
3. Furthermore, it is thought that the electrical stimulation improves blood circulation as well.

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Symbols

Symbol	Meaning
	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Direct current
	Class II equipment
	Re-back label
	Indoor use only

Included in the delivery

- 1 x digital TENS unit (including belt clip)
- 2 x connection cables
- 4 x adhesive electrodes (50x 50 mm)
- 3 x AAA batteries
- These instructions for use

Replacement items

8 x adhesive electrodes (50 x 50 mm), item no.: 661.22
4 x adhesive electrodes (50 x 100 mm), item no.: 661.21

Damage

• If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
• Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
• Switch the device off immediately if it is faulty or not working properly.
• Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
• The manufacturer is not liable for damage resulting from improper or careless use.

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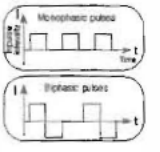
Current parameters

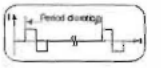
Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

Impulse form



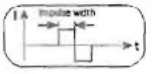
This describes the time function of the electrical impulse.
It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.

Impulse frequency



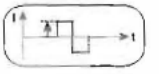
The frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards.

Impulse width



This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.

Impulse intensity



Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided. During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

Cycled impulse parameter variation

In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the TENS Device SEM44, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This also prevents individual muscle groups at the site of application being affected by fatigue.
The TENS Device SEM44 unit provides sensible default current parameter settings. With this, you can change the impulse intensity at any time during use. For 6 programs you can also set various parameters for stimulation yourself.

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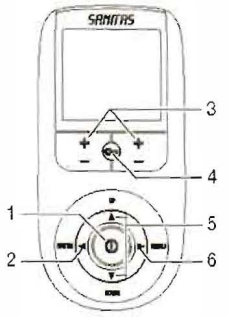
Unit description

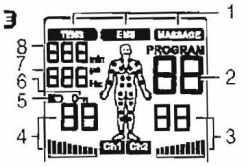
Buttons:

1 ON/OFF button
2 ENTER button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button UP and DOWN
6 MENU button



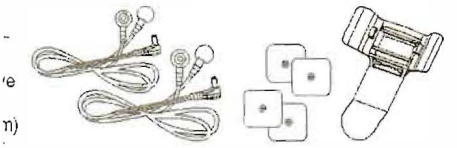
Display (full screen):

1 TENS
2 Program number
3 Impulse intensity channel 2 (CH2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (μs) or pause time
8 Timer function (remaining time display) or working time



Accessories:

- 2 x connection cables
- 4 x adhesive electrodes (45 x 45 mm)
- 1 x belt clip



Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP and DOWN

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU

(1) Navigation between the , and MENUs.
(2) Return to program selection screen or MENU selection.

ENTER

(1) MENU selection
(2) Confirmation of a selection made using UP / DOWn , except channel intensity

Intensity setting buttons (+/- left, +/- right) Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.
1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

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Initial use

1. Remove the belt clip from the unit (if attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5 V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).
   The electrodes feature clip closures to make connection particularly easy.
7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).
   Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

Fig. 1

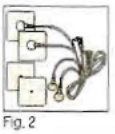


Fig. 2

Fig. 3

Program overview
Fundamentals

The TENS Device SEM44 features a total of 15 programs.

In all programs you can set the impulse intensity of both channels individually.
You can also set various parameters in the TENS programs 13 – 15 to adjust the stimulating effect to the application area.

Information regarding the positioning of electrodes

It is fundamental to the intended success of electrostimulation applications that electrodes are positioned sensibly. We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

The figures displayed are intended as an initial aid to help you position the electrodes.

The following applies to the selection of electrode positions:

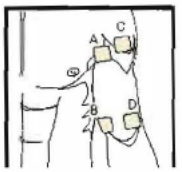
Electrode distance

The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:
- Sensible distance: approx. 2-6 inches
- At distances below 2 in, the unit primarily stimulates surface structures intensively
- At distances in excess of 6 in, large areas and deep structures are stimulated very weakly

Relation between electrodes and muscle fibre structures

Adapt the current flow direction to the fibre structure of the muscle according to the muscle layer you would like to treat. If you are targeting superficial muscles, position the electrodes in parallel to the fibre structure (A – B / C – D) and if you are targeting deeper layers of tissue, position the electrodes across the fibre structure. You can do this by positioning electrodes as crosses (i.e. diagonally), such as A – D / B – C.



As part of pain relief treatment using the digital Tyece OTC TENS Device and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2 in.
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses.

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ⓘ Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

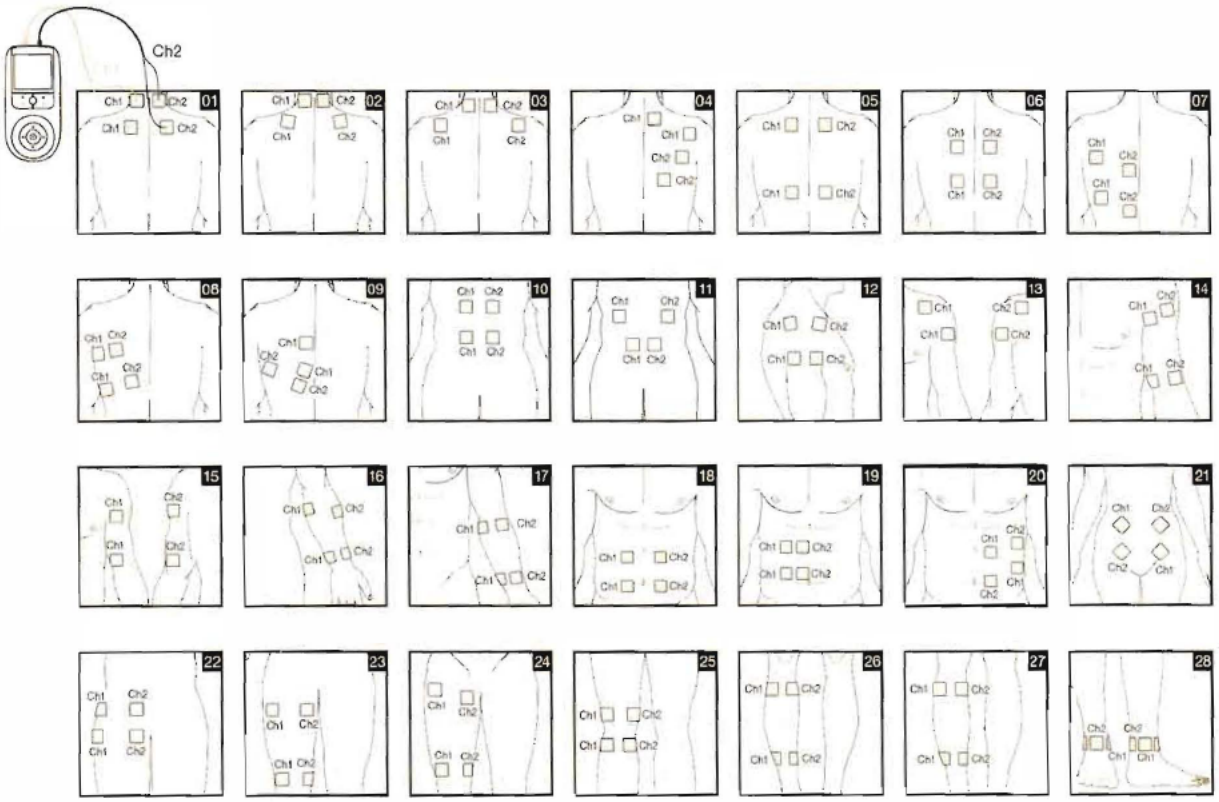
ⓘ If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

ⓘ TENS programs 13 – 15 can be set individually, see pages 12-13

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve joint pain, surround the joint with electrodes at the front and back as well as on the left and right of the joint, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Please note Figures 25 and 28, which apply to the knee and ankle joints.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.

Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.



Suggested Electrode Pad placements

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

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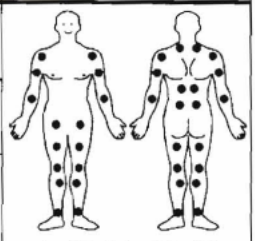
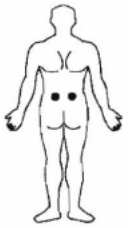
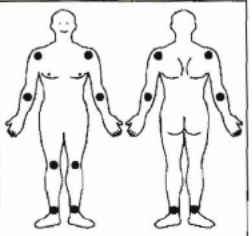
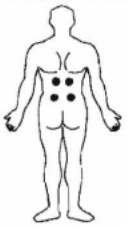
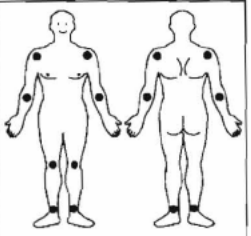
TENS program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Pain relief – acute pain	1	30	 1-17, 21, 23-28
2	Pain relief – chronic pain (pulse width modulated)	1	30	
3	Endorphin effect (burst)	1	30	
4	Chronic pain in the lower back	1	30	 10, 11
5	Pain in the lower back	1	30	
6	Knee, ankle, joint pain	1	5	 12, 13, 25, 28
		2	15	
7	Back pain	1	20	 4-11
		2	20	
8	Arthritis	1	15	 12, 13, 25, 28
		2	10	

Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).
Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.

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

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Use
Information regarding application

• The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the MENU selection and the most recently used MENU flashes.
• A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
• You can pause the stimulation at any time by briefly pressing the ON/OFF button . To continue the stimulation, briefly press the ON/OFF button again and set the desired impulse intensity again.

Procedure for TENS programs 1 – 12,

• Select a suitable program from the program tables (page 11).
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions (page 10) and connect them to the device.
• The figure on the display is intended as an additional aid to help you position the electrodes.

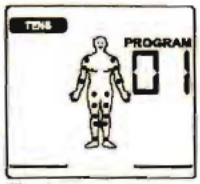
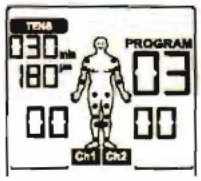


Fig. 1

Selecting a program

• Press the ON/OFF button to switch on the device.
• Press the **MENU** button to activate the TENS program (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.
• Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).



General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

• Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.
• If the program is in a pause phase, the intensity cannot be increased.
• If you wish to end the stimulation treatment early, press the ON/OFF button.

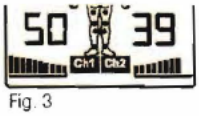


Fig. 3

Setting your own parameters for individual programs
Setting the treatment duration

(TENS programs 13 – 15 only).
Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treat-ment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

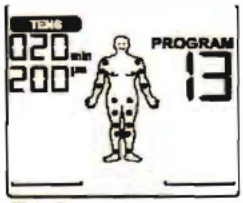
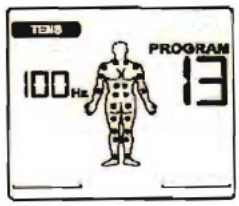


Fig. 4

Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, page 10) and connect them to the device. Select the TENS 13 program, as described in section "Selecting a program" (p. 12).



• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER**

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button to confirm (Fig. 2, example shows an impulse width of 200 µs).
• Select the desired treatment time, as described in "Setting the treatment time" (p. 12).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 12).

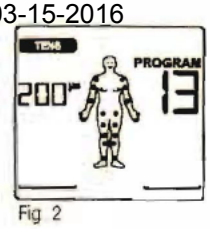
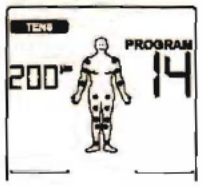


Fig 2

Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.

• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 14 program, as described in section"Selecting a program" (p. 11).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
• Select the desired treatment time, as described in "Setting the treatment time" (p. 12).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 12).



Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.

• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 15 program, as described in section "Selecting a program" (p. 11).
• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired treatment time, as described in"Setting the treatment time" (p. 12).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 12).

Changing the settings

Changing the intensity (during treatment)

• Ch1 +/- and Ch2 +/-: changes the intensity of each channel

Interrupting stimulation.

Press the ON/OFF button.

Changing application (completely or individual parameters)

• ON/OFF : interrupt stimulation
• Setting the programs, see page 12; setting your own parameters, see page 12.

Doctor's function

The Doctor's function is a special setting to allow you to access your personal program even more easily and directly. Your individual program settings are instantly recalled and activated when the device is switched on.
You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor's function

• Select your program and the corresponding settings as described on page 12.
• At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the Ch2 - button for 5 seconds. Storage in the Doctor's function is confirmed with a long acoustic signal.
If you switch on the device again, the program you saved using the Doctor's function is automatically opened directly.

Deleting the Doctor's function

To clear the device again and to re-allow access to other programs, press and hold the Ch2 - button again for approx. 5 seconds. To do this, the impulse intensity of Ch1 and Ch2 must be set to 00. Deletion of the Doctor's function is confirmed with a long acoustic signal.

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Cleaning and storage

Adhesive electrodes

• To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.

ⓘ Before cleaning with water, remove the connection cables from the electrodes.

• Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

• Remove the batteries from the device before cleaning.

• Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.

• Do not use any chemical or abrasive cleaning agents.

⚠ Ensure that no water ENTERs the device.

Storage

• Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.

• Do not make sharp bends in the connection cables and electrodes.

• Disconnect the connection cables from the electrodes.

• Reapply the electrodes to the carrier foil after use.

• Store the device and accessories in a cool, well-ventilated space.

• Never place any heavy objects on the device.

Disposal

Warning!

Danger of explosion if wrong type of battery is used as replacement! Replace only with the same or equivalent type recommended by the manufacturer.

DO NOT dispose of batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e.g. to the collecting points for disposal of batteries).

Problems/solutions

The device does not switch when the On/OFF button is pressed. how to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.

(2) Replace batteries, if applicable.

(3) Contact Customer Services.

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lintfree cloth. Replace the electrodes if they still do not adhere securely.

(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.

(2) Ensure the connection plug is firmly connected to the device.

(3) Press the ON/OFF button to restart the program.

(4) Check electrode positions and ensure that adhesive electrodes do not overlap.

(5) Gradually increase the impulse intensity.

(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

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You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow. However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

Technical specifications

Name and model	SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries (3 x 1.5 V)
Treatment time	Adjustable from 5 to 100 minutes
Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (5.2 x 2.5 x1.2 inches, including belt clip)
Weight	101 g (3.5 oz, including belt clip, without batteries), 127 g (4.5 oz, including belt clip and batteries)
Product Life	5 years
Electrode Pads, Size	50 x 50 mm (2 x 2 in)

Battery life — add

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!
We reserve the right to make technical changes to improve and develop the product.
This device complies with US and European standards and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

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

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ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5) Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the OTC TENS Device SEM44 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer of the user of the OTC TENS Device SEM44 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	OTC TENS Device SEM44 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The OTC TENS Device SEM44 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 is intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level IEC60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OTC TENS Device SEM44 requires continued operation during power mains interruptions, it is recommended that the OTC TENS Device SEM44 be powered from an uninterruptible power supply or a battery.

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

	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the OTC TENS Device SEM44 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OTC TENS Device SEM44 is used exceeds the applicable RF compliance level above, the OTC TENS Device SEM44 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OTC TENS Device SEM44.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the OTC TENS Device SEM44.

The OTC TENS Device SEM44 *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OTC TENS Device SEM44 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OTC TENS Device SEM44 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Limited Lifetime Warranty for Original Purchaser

Your TYECE OTC TENS Device SEM44, excluding all enclosed accessories as these require routine maintenance, is warranted to be free from defects in materials and workmanship for the life of the product under normal conditions of intended use and service. This warranty extends only to the original retail purchaser and does not extend to retailers or subsequent owners.

We will, at our option, repair or replace the OTC TENS Device SEM44, without charge, for any part or parts covered by these written warranties. No refunds will be given. Repair or replacement is our only responsibility and your only remedy under this written warranty. If replacement parts for defective materials are not available, Tyece reserves the right to make product substitutions in lieu of repair or replacement.

For warranty service contact our customer service department at **info@tyece.com** to provide a description of the problem. If the problem is deemed to be within the scope of the limited lifetime warranty, you will be asked to mail the product at your costs in its original package with proof of purchase, your name, address and phone number. If the problem is not deemed to be within the scope of the limited lifetime warranty, we will provide quotation for repair, respectively, replacement and return shipping fee.

This warranty does not cover damage caused by misuse or abuse; accident; failures of the atomizer, tubing, or accessories; parts or cleaning solutions; the attachment of unauthorized accessories; alteration to the product; improper installation; misapplication; lack of reasonable care with respect to the product; unauthorized repairs or modifications; improper use of electrical/power supply; normal wear; loss of power; dropped product; malfunction or damage of an operating part as a result of failure to comply with instructions for use or to provide

manufacturer's recommended maintenance; transit damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of Tyece. This warranty is void if the product is ever used in a commercial or business environment. The maximum liability of Tyece under this warranty is limited to the purchase price actually paid by the customer for the product covered by the warranty, as confirmed by proof of purchase, regardless of the amount of any other direct or indirect damage suffered by the customer.

This warranty is effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adaptation to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THE WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. ANY IMPLIED WARRANTIES, OBLIGATIONS, OR LIABILITES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS APPLICABLE WRITTEN WARRANTY. Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL TYECE BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES FOR BREACH OF THIS OR ANY OTHER WARRANTY, EXPRESS, IMPLIED OR ANY OTHER THEORY OF LIABILITY, WHATSOEVER. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

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This warranty does not extend to the purchase of opened, used, repaired, repackaged and/or resealed products, including but not limited to sale of such products on Internet auction sites and/or products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate in connection with any products or parts thereof which are repaired, replaced, altered, or modified, without the prior explicitly written consent of Tyece.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state.

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Tyece OTC TENS Device
Model SEM 44

Instructions for Use

Please read these instructions carefully before use

Indication for Use:

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household activities.

Rev: 02.13.15

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

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Warning:

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities
- Metals Implants or Electronic Auxiliary Devices
- Diabetes or Abnormal High Blood Pressure
- A tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

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User Instructions

Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Tyece OTC TENS Device, SEM44".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
Danger	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
Warning	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol
Refers to prohibitive action in the proper use of the unit. The specific forbidden

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content is indicated inside the circle.	The left picture means no dismantling.
	Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. The left picture means general compulsion.
	BF Isolated Applied Part

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

2. Precautions

1) Do not use the TENS device during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over areas of the skin which lack normal sensation.
5) Do not use the products near the heart; it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) The TENS Device, SEM44 must be kept out of the reach of children.
8) The TENS Device, SEM44 should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the TENS Device, SEM44 and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical shock, do not connect two pads to each other
12) Do not apply pads to the same spot for over 40 minutes at a time.
13) Do not use the TENS Device, SEM44 while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.
17) Never use this product near a microwave oven, or other high frequency equipment.
18) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

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3. Contraindication

1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions

1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application of electrical 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your pain, consult with your physician before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Device, SEM44.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The upper neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic pad sheet provided.
Place the pads at least 5 cm (1 inch) apart on your skin. The pads should never touch each other.
Always place clean pads in accordance with illustrations provided. Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin.
Do not place on your spine or backbone.
Pads should not touch any metal object, such as a belt buckle or necklace.
Pads should not be placed simultaneously on the soles of both feet.
Pads should not be placed simultaneously on the calves of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads attached to the skin after treatment.

CAUTION WHILE USING UNIT

If the unit is not functioning properly or you feel discomfort, immediately stop using the device.

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

Do not use for any other purpose except for what it is intended for.
Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
Do not pull on the electrode cord during treatment.
Do not use the device while wearing electronic devices such as watches as this may damage the device.
Do not use near a cell phone as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, hold the plug and pull.
Replace the cord when broken or damaged.
Do not throw the batteries into a fire. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
Using pads that are too small or incorrectly applied, could result in discomfort or skin burns

General Precautions

• The long-term effects of electrical stimulation are unknown.
• Apply stimulation to only normal, intact, clean, dry, and healthy skin.
• TENS is not effective in treating the original source or cause of the pain, including headache.
• TENS is not a substitute for pain medications and other pain management therapies.
• TENS devices do not cure disease or injuries.
• TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your phycician
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
Keep unit out of the reach of young children. The electrode cord can cause strangulation.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

What is it?

The Tyece OTC TENS Device, Model SEM44 is a multi-program, portable device designed for adults only. It is designed to reduce and relieve muscle and joint pain, stiffness and numbness in the arms, legs and foot by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.
Not to be used as an EMS device (Electrical Muscle Stimulator)

How does it work?

Scientific theory suggests that electrical stimulation therapy may work in several ways:
1. The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.
2. The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
3. Furthermore, it is thought that the electrical stimulation improves blood circulation as well.

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

Symbols

Symbol	Meaning
	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Direct current
	Class II equipment
	Re-back label
	Indoor use only

Included in the delivery

– 1 x digital TENS unit (including belt clip)
– 2 x connection cables
– 4 x adhesive electrodes (50x 50 mm)
– 3 x AAA batteries
– These instructions for use

Replacement items

8 x adhesive electrodes (50 x 50 mm), item no.: 661.22
4 x adhesive electrodes (50 x 100 mm), item no.: 661.21

Damage

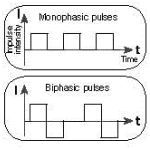
• If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
• Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
• Switch the device off immediately if it is faulty or not working properly.
• Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
• The manufacturer is not liable for damage resulting from improper or careless use.

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

Current parameters

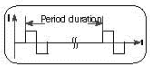
Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

Impulse form



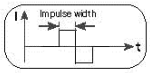
This describes the time function of the electrical impulse.
It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.

Impulse frequency



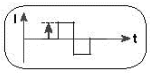
The frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards.

Impulse width



This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.

Impulse intensity



Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided. During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

Cycled impulse parameter variation

In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the TENS Device SEM44, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This also prevents individual muscle groups at the site of application being affected by fatigue.
The TENS Device SEM44 unit provides sensible default current parameter settings. With this, you can change the impulse intensity at any time during use. For 6 programs you can also set various parameters for stimulation yourself.

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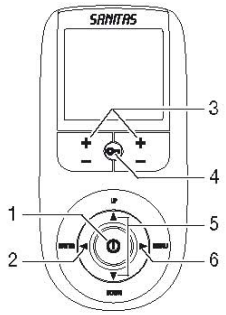
Unit description

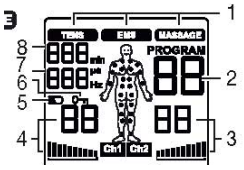
Buttons:

1 ON/OFF button
2 ENTER button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button UP and DOWN
6 MENU button



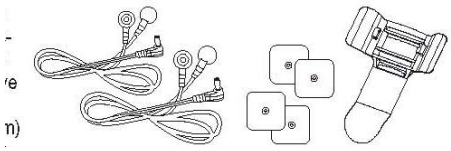
Display (full screen):

1 TENS
2 Program number
3 Impulse intensity channel 2 (CH2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (µs) or pause time
8 Timer function (remaining time display) or working time



Accessories:

• 2 x connection cables
• 4 x adhesive electrodes (45 x 45 mm)
• 1 x belt clip



Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP and DOWN

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU

(1) Navigation between the , and MENUs.
(2) Return to program selection screen or MENU selection.

ENTER

(1) MENU selection
(2) Confirmation of a selection made using UP / DOWn , except channel intensity

Intensity setting buttons (+/- left, +/- right) Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.
1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

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

Initial use

1. Remove the belt clip from the unit (if attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5 V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).
   The electrodes feature clip closures to make connection particularly easy.
7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).
   Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

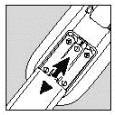


Fig. 1

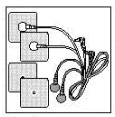


Fig. 2

Fig. 3

Program overview
Fundamentals

The TENS Device SEM44 features a total of 15 programs.

In all programs you can set the impulse intensity of both channels individually.
You can also set various parameters in the TENS programs 13 – 15 to adjust the stimulating effect to the application area.

Information regarding the positioning of electrodes

It is fundamental to the intended success of electrostimulation applications that electrodes are positioned sensibly. We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

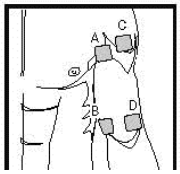
The figures displayed are intended as an initial aid to help you position the electrodes.

The following applies to the selection of electrode positions:

Electrode distance
The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:
• Sensible distance: approx. 2-6 inches
• At distances below 2 in, the unit primarily stimulates surface structures intensively
• At distances in excess of 6 in, large areas and deep structures are stimulated very weakly

Relation between electrodes and muscle fibre structures
Adapt the current flow direction to the fibre structure of the muscle according to the muscle layer you would like to treat. If you are targeting superficial muscles, position the electrodes in parallel to the fibre structure (A – B / C – D) and if you are targeting deeper layers of tissue, position the electrodes across the fibre structure. You can do this by positioning electrodes as crosses (i.e. diagonally), such as A – D / B – C.



As part of pain relief treatment using the digital Tyece OTC TENS Device and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2 in.
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses.

ⓘ Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

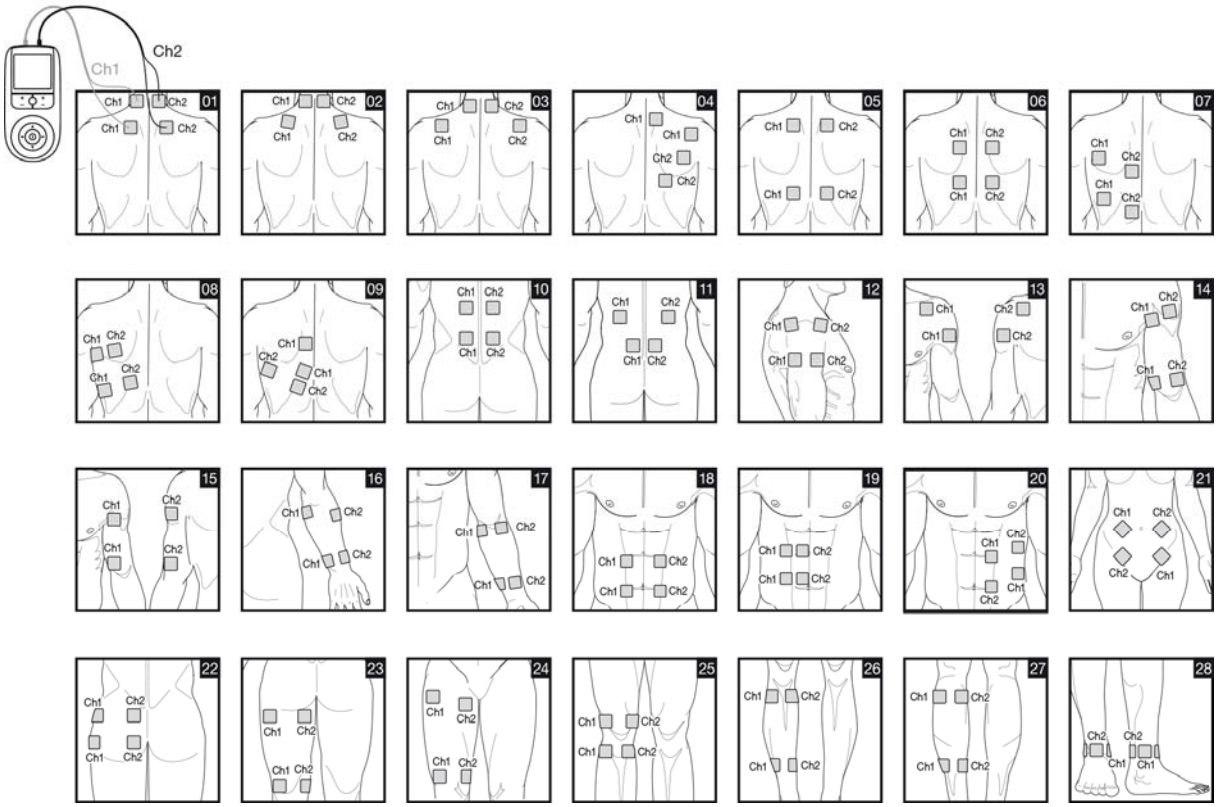
ⓘ If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

ⓘ TENS programs 13 – 15 can be set individually, see pages 12-13

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve joint pain, surround the joint with electrodes at the front and back as well as on the left and right of the joint, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Please note Figures 25 and 28, which apply to the knee and ankle joints.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.

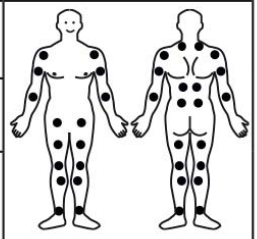
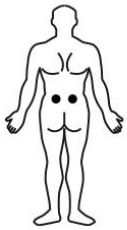
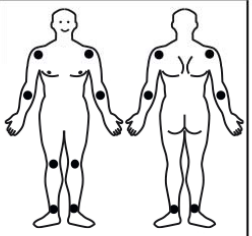
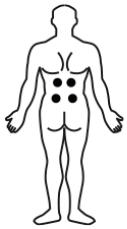
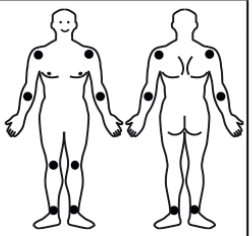
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.



Suggested Electrode Pad placements

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

TENS program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Pain relief – acute pain	1	30	 1-17, 21, 23-28
2	Pain relief – chronic pain (pulse width modulated)	1	30	
3	Endorphin effect (burst)	1	30	
4	Chronic pain in the lower back	1	30	 10, 11
5	Pain in the lower back	1	30	
6	Knee, ankle, joint pain	1	5	 12, 13, 25, 28
		2	15	
7	Back pain	1	20	 4-11
		2	20	
8	Arthritis	1	15	 12, 13, 25, 28
		2	10	

Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).
Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.

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

Use
Information regarding application

• The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the MENU selection and the most recently used MENU flashes.
• A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
• You can pause the stimulation at any time by briefly pressing the ON/OFF button . To continue the stimulation, briefly press the ON/OFF button again and set the desired impulse intensity again.

Procedure for TENS programs 1 – 12,

• Select a suitable program from the program tables (page 11).
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions (page 10) and connect them to the device.
• The figure on the display is intended as an additional aid to help you position the electrodes.

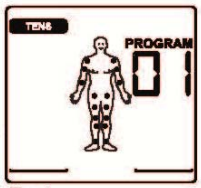
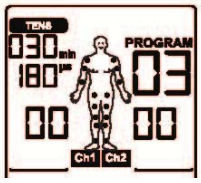


Fig. 1

Selecting a program

• Press the ON/OFF button to switch on the device.
• Press the **MENU** button to activate the TENS program (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.
• Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).



.

General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

• Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.
• If the program is in a pause phase, the intensity cannot be increased.
• If you wish to end the stimulation treatment early, press the ON/OFF button.

Fig. 3

Setting your own parameters for individual programs
Setting the treatment duration

(TENS programs 13 – 15 only).
Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treat-ment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

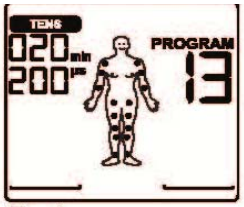
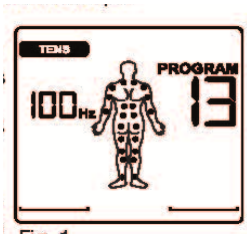


Fig. 4

Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, page 10) and connect them to the device. Select the TENS 13 program, as described in section “Selecting a program” (p. 12).



• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER**

button to confirm (Fig. 2, example shows an impulse width of 200 µs).
• Select the desired treatment time, as described in “Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).

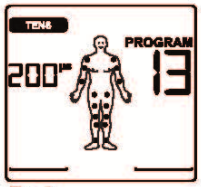
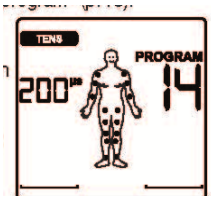


Fig. 2

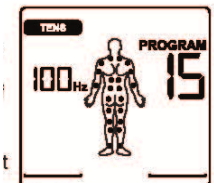
Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 14 program, as described in section“Selecting a program” (p. 11).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
• Select the desired treatment time, as described in “Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).



Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 15 program, as described in section “Selecting a program” (p. 11).
• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired treatment time, as described in“Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).



Changing the settings

Changing the intensity (during treatment)

• Ch1 +/- and Ch2 +/-: changes the intensity of each channel

Interrupting stimulation.

Press the ON/OFF button.

Changing application (completely or individual parameters)

• ON/OFF : interrupt stimulation
• Setting the programs, see page 12; setting your own parameters, see page 12.

Doctor’s function

The Doctor’s function is a special setting to allow you to access your personal program even more easily and directly. Your individual program settings are instantly recalled and activated when the device is switched on.
You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor’s function

• Select your program and the corresponding settings as described on page 12.
• At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the Ch2 - button for 5 seconds. Storage in the Doctor’s function is confirmed with a long acoustic signal.
If you switch on the device again, the program you saved using the Doctor’s function is automatically opened directly.

Deleting the Doctor’s function

To clear the device again and to re-allow access to other programs, press and hold the Ch2 - button again for approx. 5 seconds. To do this, the impulse intensity of Ch1 and Ch2 must be set to 00. Deletion of the Doctor’s function is confirmed with a long acoustic signal.

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

Cleaning and storage

Adhesive electrodes

• To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
ⓘ Before cleaning with water, remove the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

• Remove the batteries from the device before cleaning.
• Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
• Do not use any chemical or abrasive cleaning agents.
⚠ Ensure that no water ENTERs the device.

Storage

• Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.
• Do not make sharp bends in the connection cables and electrodes.
• Disconnect the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil after use.
• Store the device and accessories in a cool, well-ventilated space.
• Never place any heavy objects on the device.

Disposal

Warning!

Danger of explosion if wrong type of battery is used as replacement! Replace only with the same or equivalent type recommended by the manufacturer.

DO NOT dispose of batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e.g. to the collecting points for disposal of batteries).

Problems/solutions

The device does not switch when the On/OFF button is pressed. how to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.
(2) Replace batteries, if applicable.
(3) Contact Customer Services.

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lintfree cloth. Replace the electrodes if they still do not adhere securely.
(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.
(2) Ensure the connection plug is firmly connected to the device.
(3) Press the ON/OFF button to restart the program.
(4) Check electrode positions and ensure that adhesive electrodes do not overlap.
(5) Gradually increase the impulse intensity.
(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

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

You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow. However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

Technical specifications

Name and model	SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries (3 x 1.5 V)
Treatment time	Adjustable from 5 to 100 minutes
Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (5.2 x 2.5 x1.2 inches, including belt clip)
Weight	101 g (3.5 oz, including belt clip, without batteries), 127 g (4.5 oz, including belt clip and batteries)
Product Life	5 years
Electrode Pads, Size	50 x 50 mm (2 x 2 in)
Battery Life:	approx. 30 x 30 minute sessions (15 hrs)

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!
We reserve the right to make technical changes to improve and develop the product.
This device complies with US and European standards and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

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

ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5) Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the OTC TENS Device SEM44 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer of the user of the OTC TENS Device SEM44 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	OTC TENS Device SEM44 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The OTC TENS Device SEM44 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 is intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level IEC60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OTC TENS Device SEM44 requires continued operation during power mains interruptions, it is recommended that the OTC TENS Device SEM44 be powered from an uninterruptible power supply or a battery.

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

	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the OTC TENS Device SEM44 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OTC TENS Device SEM44 is used exceeds the applicable RF compliance level above, the OTC TENS Device SEM44 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OTC TENS Device SEM44.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the OTC TENS Device SEM44.

The OTC TENS Device SEM44 *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OTC TENS Device SEM44 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OTC TENS Device SEM44 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Limited Lifetime Warranty for Original Purchaser

Your TYECE OTC TENS Device SEM44, excluding all enclosed accessories as these require routine maintenance, is warranted to be free from defects in materials and workmanship for the life of the product under normal conditions of intended use and service. This warranty extends only to the original retail purchaser and does not extend to retailers or subsequent owners.

We will, at our option, repair or replace the OTC TENS Device SEM44, without charge, for any part or parts covered by these written warranties. No refunds will be given. Repair or replacement is our only responsibility and your only remedy under this written warranty. If replacement parts for defective materials are not available, Tyece reserves the right to make product substitutions in lieu of repair or replacement.

For warranty service contact our customer service department and provide a description of the problem. If the problem is deemed to be within the scope of the limited lifetime warranty, you will be asked to mail the product at your costs in its original package with proof of purchase, your name, address and phone number. If the problem is not deemed to be within the scope of the limited lifetime warranty, we will provide quotation for repair, respectively, replacement and return shipping fee.

This warranty does not cover damage caused by misuse or abuse; accident; failures of the atomizer, tubing, or accessories; parts or cleaning solutions; the attachment of unauthorized accessories; alteration to the product; improper installation; misapplication; lack of reasonable care with respect to the product; unauthorized repairs or modifications; improper use of electrical/power supply; normal wear; loss of power; dropped product; malfunction or damage of an operating part as a result of failure to comply with instructions for use or to provide

manufacturer's recommended maintenance; transit damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of Tyece. This warranty is void if the product is ever used in a commercial or business environment. The maximum liability of Tyece under this warranty is limited to the purchase price actually paid by the customer for the product covered by the warranty, as confirmed by proof of purchase, regardless of the amount of any other direct or indirect damage suffered by the customer.

This warranty is effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adaptation to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THE WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. ANY IMPLIED WARRANTIES, OBLIGATIONS, OR LIABILITES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS APPLICABLE WRITTEN WARRANTY. Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL TYECE BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES FOR BREACH OF THIS OR ANY OTHER WARRANTY, EXPRESS, IMPLIED OR ANY OTHER THEORY OF LIABILITY, WHATSOEVER. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

Tyece does not authorize anyone, including, but not limited to, retailers, the subsequent consumer purchaser of the product from a retailer or remote purchaser, to obligate Tyece in any way beyond the terms set forth herein.

This warranty does not extend to the purchase of opened, used, repaired, repackaged and/or resealed products, including but not limited to sale of such products on Internet auction sites and/or products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate in connection with any products or parts thereof which are repaired, replaced, altered, or modified, without the prior explicitly written consent of Tyece.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state.

Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895
Customer Service Center: **1-800-645-3867** e-mail: **cvs@product-info.us**

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

Tyece OTC TENS Device
Model SEM 44

Instructions for Use

Please read these instructions carefully before use

Indication for Use:

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household activities.

Rev: 02.13.15

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

Warning:

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities
- Metals Implants or Electronic Auxiliary Devices
- Diabetes or Abnormal High Blood Pressure
- A tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

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User Instructions

Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Tyece OTC TENS Device, SEM44".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
Danger	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
Warning	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol
Refers to prohibitive action in the proper use of the unit. The specific forbidden

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content is indicated inside the circle.	The left picture means no dismantling.
	Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. The left picture means general compulsion.
	BF Isolated Applied Part

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

2. Precautions

1) Do not use the TENS device during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over areas of the skin which lack normal sensation.
5) Do not use the products near the heart; it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) The TENS Device, SEM44 must be kept out of the reach of children.
8) The TENS Device, SEM44 should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the TENS Device, SEM44 and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical shock, do not connect two pads to each other
12) Do not apply pads to the same spot for over 40 minutes at a time.
13) Do not use the TENS Device, SEM44 while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.
17) Never use this product near a microwave oven, or other high frequency equipment.
18) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

3. Contraindication

1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions

1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application of electrical 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your pain, consult with your physician before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Device, SEM44.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The upper neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic pad sheet provided.
Place the pads at least 5 cm (1 inch) apart on your skin. The pads should never touch each other.
Always place clean pads in accordance with illustrations provided. Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin.
Do not place on your spine or backbone.
Pads should not touch any metal object, such as a belt buckle or necklace.
Pads should not be placed simultaneously on the soles of both feet.
Pads should not be placed simultaneously on the calves of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads attached to the skin after treatment.

CAUTION WHILE USING UNIT

If the unit is not functioning properly or you feel discomfort, immediately stop using the device.

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

Do not use for any other purpose except for what it is intended for.
Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
Do not pull on the electrode cord during treatment.
Do not use the device while wearing electronic devices such as watches as this may damage the device.
Do not use near a cell phone as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, hold the plug and pull.
Replace the cord when broken or damaged.
Do not throw the batteries into a fire. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
Using pads that are too small or incorrectly applied, could result in discomfort or skin burns

General Precautions

• The long-term effects of electrical stimulation are unknown.
• Apply stimulation to only normal, intact, clean, dry, and healthy skin.
• TENS is not effective in treating the original source or cause of the pain, including headache.
• TENS is not a substitute for pain medications and other pain management therapies.
• TENS devices do not cure disease or injuries.
• TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your phycician
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
Keep unit out of the reach of young children. The electrode cord can cause strangulation.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

What is it?

The Tyece OTC TENS Device, Model SEM44 is a multi-program, portable device designed for adults only. It is designed to reduce and relieve muscle and joint pain, stiffness and numbness in the arms, legs and foot by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.
Not to be used as an EMS device (Electrical Muscle Stimulator)

How does it work?

Scientific theory suggests that electrical stimulation therapy may work in several ways:
1. The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.
2. The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
3. Furthermore, it is thought that the electrical stimulation improves blood circulation as well.

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

Symbols

Symbol	Meaning
	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Direct current
	Class II equipment
	Re-back label
	Indoor use only

Included in the delivery

– 1 x digital TENS unit (including belt clip)
– 2 x connection cables
– 4 x adhesive electrodes (50x 50 mm)
– 3 x AAA batteries
– These instructions for use

Replacement items

8 x adhesive electrodes (50 x 50 mm), item no.: 661.22
4 x adhesive electrodes (50 x 100 mm), item no.: 661.21

Damage

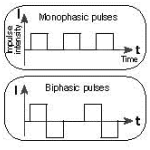
• If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
• Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
• Switch the device off immediately if it is faulty or not working properly.
• Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
• The manufacturer is not liable for damage resulting from improper or careless use.

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

Current parameters

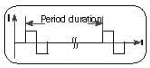
Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

Impulse form



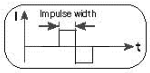
This describes the time function of the electrical impulse.
It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.

Impulse frequency



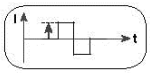
The frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards.

Impulse width



This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.

Impulse intensity



Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided. During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

Cycled impulse parameter variation

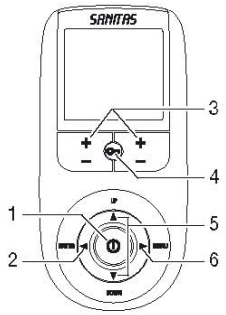
In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the TENS Device SEM44, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This also prevents individual muscle groups at the site of application being affected by fatigue.
The TENS Device SEM44 unit provides sensible default current parameter settings. With this, you can change the impulse intensity at any time during use. For 6 programs you can also set various parameters for stimulation yourself.

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

Unit description

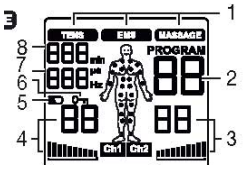
Buttons:

1 ON/OFF button
2 ENTER button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button UP and DOWN
6 MENU button



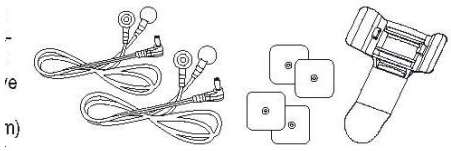
Display (full screen):

1 TENS
2 Program number
3 Impulse intensity channel 2 (CH2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (µs) or pause time
8 Timer function (remaining time display) or working time



Accessories:

• 2 x connection cables
• 4 x adhesive electrodes (45 x 45 mm)
• 1 x belt clip



Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP and DOWN

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU

(1) Navigation between the , and MENUs.
(2) Return to program selection screen or MENU selection.

ENTER

(1) MENU selection
(2) Confirmation of a selection made using UP / DOWn , except channel intensity

Intensity setting buttons (+/- left, +/- right) Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.
1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

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

Initial use

1. Remove the belt clip from the unit (if attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5 V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).
   The electrodes feature clip closures to make connection particularly easy.
7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).
   Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

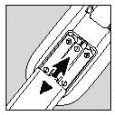


Fig. 1

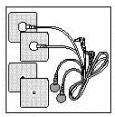


Fig. 2

Fig. 3

Program overview
Fundamentals

The TENS Device SEM44 features a total of 15 programs.

In all programs you can set the impulse intensity of both channels individually.
You can also set various parameters in the TENS programs 13 – 15 to adjust the stimulating effect to the application area.

Information regarding the positioning of electrodes

It is fundamental to the intended success of electrostimulation applications that electrodes are positioned sensibly. We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

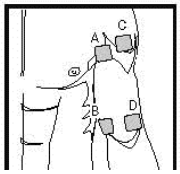
The figures displayed are intended as an initial aid to help you position the electrodes.

The following applies to the selection of electrode positions:

Electrode distance
The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:
• Sensible distance: approx. 2-6 inches
• At distances below 2 in, the unit primarily stimulates surface structures intensively
• At distances in excess of 6 in, large areas and deep structures are stimulated very weakly

Relation between electrodes and muscle fibre structures
Adapt the current flow direction to the fibre structure of the muscle according to the muscle layer you would like to treat. If you are targeting superficial muscles, position the electrodes in parallel to the fibre structure (A – B / C – D) and if you are targeting deeper layers of tissue, position the electrodes across the fibre structure. You can do this by positioning electrodes as crosses (i.e. diagonally), such as A – D / B – C.



As part of pain relief treatment using the digital Tyece OTC TENS Device and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2 in.
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses.

ⓘ Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

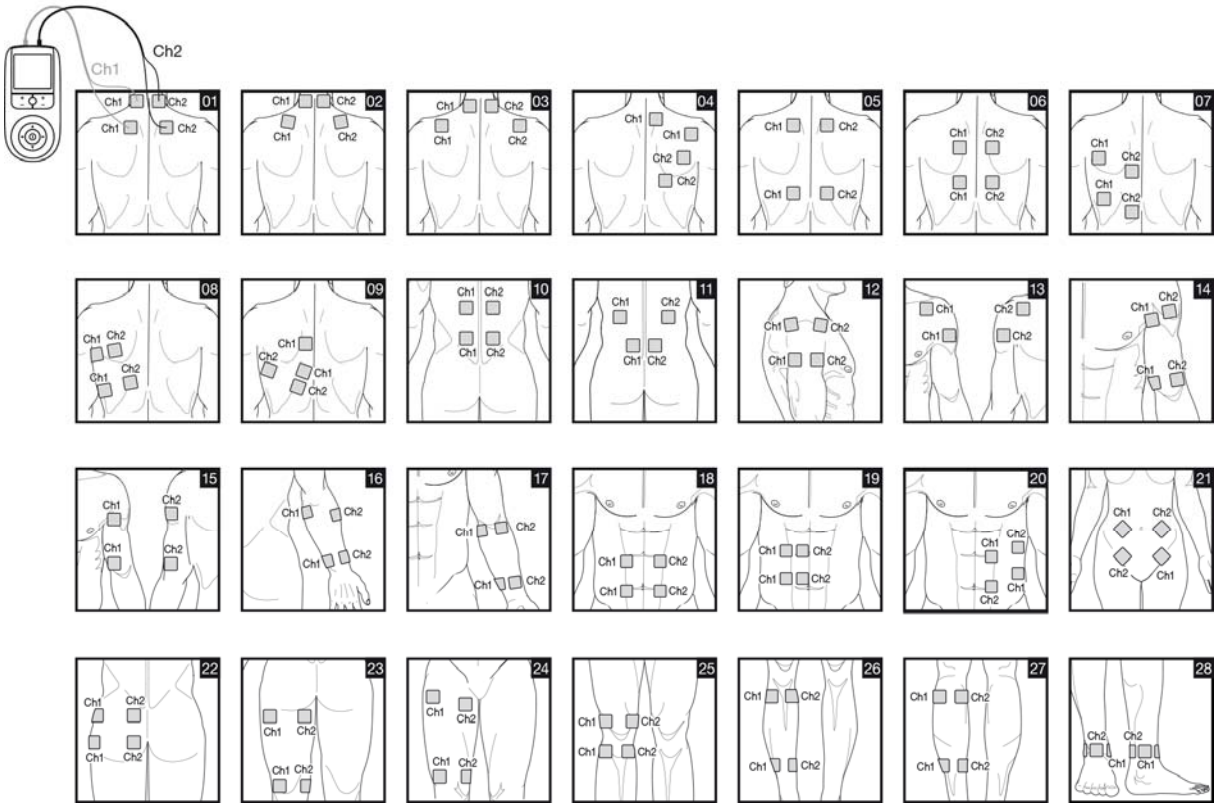
ⓘ If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

ⓘ TENS programs 13 – 15 can be set individually, see pages 12-13

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve joint pain, surround the joint with electrodes at the front and back as well as on the left and right of the joint, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Please note Figures 25 and 28, which apply to the knee and ankle joints.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.

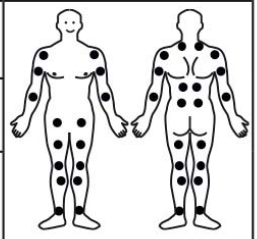
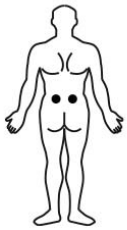
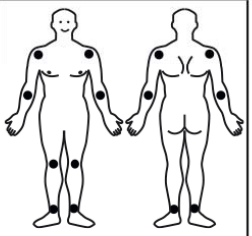
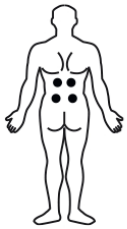
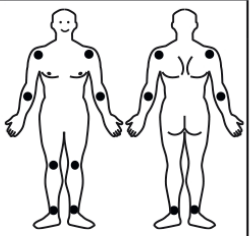
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.



Suggested Electrode Pad placements

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

TENS program table

Progr. no.	Area of application, indications	Phase	Running time (min)	Possible electrode positions
1	Pain relief – acute pain	1	30	 1-17, 21, 23-28
2	Pain relief – chronic pain (pulse width modulated)	1	30	
3	Endorphin effect (burst)	1	30	
4	Chronic pain in the lower back	1	30	 10, 11
5	Pain in the lower back	1	30	
6	Knee, ankle, joint pain	1	5	 12, 13, 25, 28
		2	15	
7	Back pain	1	20	 4-11
		2	20	
8	Arthritis	1	15	 12, 13, 25, 28
		2	10	

Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).
Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.
Do not apply the electrodes to the front wall of the chest, i.e. do not massage the large left and right pectoral muscles.

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

Use
Information regarding application

• The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the MENU selection and the most recently used MENU flashes.
• A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
• You can pause the stimulation at any time by briefly pressing the ON/OFF button . To continue the stimulation, briefly press the ON/OFF button again and set the desired impulse intensity again.

Procedure for TENS programs 1 – 12,

• Select a suitable program from the program tables (page 11).
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions (page 10) and connect them to the device.
• The figure on the display is intended as an additional aid to help you position the electrodes.

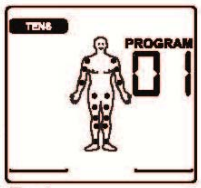
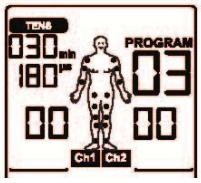


Fig. 1

Selecting a program

• Press the ON/OFF button to switch on the device.
• Press the **MENU** button to activate the TENS program (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.
• Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).



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General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

• Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.
• If the program is in a pause phase, the intensity cannot be increased.
• If you wish to end the stimulation treatment early, press the ON/OFF button.

Fig. 3

Setting your own parameters for individual programs
Setting the treatment duration

(TENS programs 13 – 15 only).
Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treat-ment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

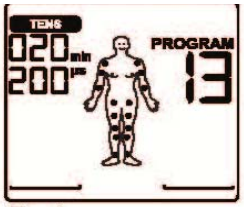
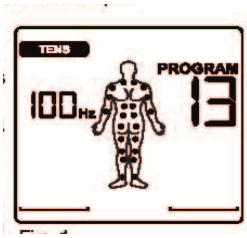


Fig. 4

Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, page 10) and connect them to the device. Select the TENS 13 program, as described in section “Selecting a program” (p. 12).



• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER**

button to confirm (Fig. 2, example shows an impulse width of 200 µs).
• Select the desired treatment time, as described in “Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).

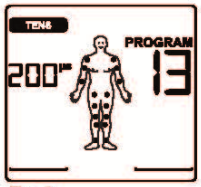
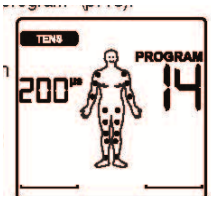


Fig. 2

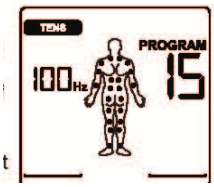
Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 14 program, as described in section“Selecting a program” (p. 11).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
• Select the desired treatment time, as described in “Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).



Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 15 program, as described in section “Selecting a program” (p. 11).
• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired treatment time, as described in“Setting the treatment time” (p. 12).
• Select the desired impulse intensity, as described in “Setting the impulse intensity” (p. 12).



Changing the settings

Changing the intensity (during treatment)

• Ch1 +/- and Ch2 +/-: changes the intensity of each channel

Interrupting stimulation.

Press the ON/OFF button.

Changing application (completely or individual parameters)

• ON/OFF : interrupt stimulation
• Setting the programs, see page 12; setting your own parameters, see page 12.

Doctor’s function

The Doctor’s function is a special setting to allow you to access your personal program even more easily and directly. Your individual program settings are instantly recalled and activated when the device is switched on.
You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor’s function

• Select your program and the corresponding settings as described on page 12.
• At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the Ch2 - button for 5 seconds. Storage in the Doctor’s function is confirmed with a long acoustic signal.
If you switch on the device again, the program you saved using the Doctor’s function is automatically opened directly.

Deleting the Doctor’s function

To clear the device again and to re-allow access to other programs, press and hold the Ch2 - button again for approx. 5 seconds. To do this, the impulse intensity of Ch1 and Ch2 must be set to 00. Deletion of the Doctor’s function is confirmed with a long acoustic signal.

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

Cleaning and storage

Adhesive electrodes

• To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
ⓘ Before cleaning with water, remove the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

• Remove the batteries from the device before cleaning.
• Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
• Do not use any chemical or abrasive cleaning agents.
⚠ Ensure that no water ENTERs the device.

Storage

• Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.
• Do not make sharp bends in the connection cables and electrodes.
• Disconnect the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil after use.
• Store the device and accessories in a cool, well-ventilated space.
• Never place any heavy objects on the device.

Disposal

Warning!

Danger of explosion if wrong type of battery is used as replacement! Replace only with the same or equivalent type recommended by the manufacturer.

DO NOT dispose of batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e.g. to the collecting points for disposal of batteries).

Problems/solutions

The device does not switch when the On/OFF button is pressed. how to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.
(2) Replace batteries, if applicable.
(3) Contact Customer Services.

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lintfree cloth. Replace the electrodes if they still do not adhere securely.
(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.
(2) Ensure the connection plug is firmly connected to the device.
(3) Press the ON/OFF button to restart the program.
(4) Check electrode positions and ensure that adhesive electrodes do not overlap.
(5) Gradually increase the impulse intensity.
(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

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

You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow. However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

Technical specifications

Name and model	SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries (3 x 1.5 V)
Treatment time	Adjustable from 5 to 100 minutes
Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (5.2 x 2.5 x1.2 inches, including belt clip)
Weight	101 g (3.5 oz, including belt clip, without batteries), 127 g (4.5 oz, including belt clip and batteries)
Product Life	5 years
Electrode Pads, Size	50 x 50 mm (2 x 2 in)
Battery Life:	approx. 30 x 30 minute sessions (15 hrs)

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!
We reserve the right to make technical changes to improve and develop the product.
This device complies with US and European standards and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

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

ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5) Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the OTC TENS Device SEM44 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer of the user of the OTC TENS Device SEM44 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	OTC TENS Device SEM44 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The OTC TENS Device SEM44 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 is intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level IEC60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OTC TENS Device SEM44 requires continued operation during power mains interruptions, it is recommended that the OTC TENS Device SEM44 be powered from an uninterruptible power supply or a battery.

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

	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer or the user of OTC TENS Device SEM44 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the OTC TENS Device SEM44 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OTC TENS Device SEM44 is used exceeds the applicable RF compliance level above, the OTC TENS Device SEM44 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OTC TENS Device SEM44.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the OTC TENS Device SEM44.

The OTC TENS Device SEM44 *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OTC TENS Device SEM44 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OTC TENS Device SEM44 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

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For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Limited Lifetime Warranty for Original Purchaser

Your TYECE OTC TENS Device SEM44, excluding all enclosed accessories as these require routine maintenance, is warranted to be free from defects in materials and workmanship for the life of the product under normal conditions of intended use and service. This warranty extends only to the original retail purchaser and does not extend to retailers or subsequent owners.

We will, at our option, repair or replace the OTC TENS Device SEM44, without charge, for any part or parts covered by these written warranties. No refunds will be given. Repair or replacement is our only responsibility and your only remedy under this written warranty. If replacement parts for defective materials are not available, Tyece reserves the right to make product substitutions in lieu of repair or replacement.

For warranty service contact our customer service department and provide a description of the problem. If the problem is deemed to be within the scope of the limited lifetime warranty, you will be asked to mail the product at your costs in its original package with proof of purchase, your name, address and phone number. If the problem is not deemed to be within the scope of the limited lifetime warranty, we will provide quotation for repair, respectively, replacement and return shipping fee.

This warranty does not cover damage caused by misuse or abuse; accident; failures of the atomizer, tubing, or accessories; parts or cleaning solutions; the attachment of unauthorized accessories; alteration to the product; improper installation; misapplication; lack of reasonable care with respect to the product; unauthorized repairs or modifications; improper use of electrical/power supply; normal wear; loss of power; dropped product; malfunction or damage of an operating part as a result of failure to comply with instructions for use or to provide

manufacturer's recommended maintenance; transit damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of Tyece. This warranty is void if the product is ever used in a commercial or business environment. The maximum liability of Tyece under this warranty is limited to the purchase price actually paid by the customer for the product covered by the warranty, as confirmed by proof of purchase, regardless of the amount of any other direct or indirect damage suffered by the customer.

This warranty is effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adaptation to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THE WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. ANY IMPLIED WARRANTIES, OBLIGATIONS, OR LIABILITES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS APPLICABLE WRITTEN WARRANTY. Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL TYECE BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES FOR BREACH OF THIS OR ANY OTHER WARRANTY, EXPRESS, IMPLIED OR ANY OTHER THEORY OF LIABILITY, WHATSOEVER. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

Tyece does not authorize anyone, including, but not limited to, retailers, the subsequent consumer purchaser of the product from a retailer or remote purchaser, to obligate Tyece in any way beyond the terms set forth herein.

This warranty does not extend to the purchase of opened, used, repaired, repackaged and/or resealed products, including but not limited to sale of such products on Internet auction sites and/or products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate in connection with any products or parts thereof which are repaired, replaced, altered, or modified, without the prior explicitly written consent of Tyece.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state.

Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895
Customer Service Center: **1-800-645-3867** e-mail: **cvs@product-info.us**

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

CVS/pharmacy®

TENS

TENS Digital

• TENS technology for the alleviation of pain • 2 channels • 12 fixed and 3 changeable programs • Timer function • Keylock•/ Safety switch-off • Limited Lifetime Warranty

Art.-Nr. 662.71

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CVS/pharmacy®

TENS

TENS Digital

Utilizes Transcutaneous Electrical Nerve Stimulation (TENS) technology used by physical therapists and medical professionals for more than 30 years.

- 12 fixed and 3 changeable programs
- Displays the position of electrodes
- 2 channels
- 4 electrodes included
- Timer function

4 electrodes

Useable on many different body parts

Displays the position of electrodes

Complete Instructions enclosed
Read instructions carefully before use

We're Here to Help! Call toll free 1-866-464-6184 or visit www.cvs.com for more information.

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

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Risk Analysis

(b)(4) Risk Analysis

[redacted]

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

(b)(4) Risk Analysis

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Device Classification Name	Electrode, Cutaneous
510(K) Number	K070612
Device Name	TOP-RANK ADHESIVE ELECTRODE
Original Applicant	TOP-RANK HEALTH CARE EQUIPMENT CO., LTD. Dongguan St. Shangyu City, CN 312352
Original Contact	Uwe Degenhardt
Regulation Number	882.1320
Classification Product Code	GXY
Date Received	03/05/2007
Decision Date	05/07/2007
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Statement	Statement
Type	Traditional
Reviewed By Third Party	Yes
Combination Product	No

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

(b)(4) Third Party Testing

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K150386/S001

FDA CDRH DMC
APR 08 2015
Received

MTC *Media Trade Corporation*

11820 Red Hibiscus Drive – Bonita Springs, FL 34135
Tel (239) 948-2001 – Fax (239) 948-2002
e-mail: mediatradecorp@gmx.net

eCopy Cover Letter

Date: Apr.4, 2015

To: US Food and Drug Administration

Center for Devices and Radiological Health
Document Control Center, WO66-G609
10903 New Hampshire Ave.
Silver Springs, MD 20993-0002

Re: **eCopy for Tyece OTC TENS Device, Model SEM44, RTA1**

We hereby state that **the eCopy is an exact duplicate of the paper copy provided**.

Thank you and with best regards,

Guenter Ginsberg
President MTC
Official Correspondent & US Agent
for Counter Scientific

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

002

FDA CDRH DMC
APR 08 2015
Received

MTC *Media Trade Corporation*

11820 Red Hibiscus Drive – Bonita Springs, FL 34135
Tel (239) 948-2001 – Fax (239) 948-2002
E-mail: info@mediatradecorp.net

To: Erin L. Keegan M.S.
FDA Branch: NSDB
Division: DNPMD
Center/Office: CDRH/ODE

Date: April 4, 2015

Re: **K150386 Response to RTA1**

Dear Ms. Keegan,
This is in response to your RTA1 on our K150386 TENS Device submission. We like to apologize for the delay but some of the answers required actual changes to the device.
We also want to thank you for answering our e-mail questions clarifying the points on "Page Numbering", "Electrodes" and the meaning of "Not a basis for RTA1 decision".

We like to respond to your Comments/Questions as follows:

(b)(4) Deficiencies

[redacted]

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

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

(b)(4) Deficiencies

(b)(4) Deficiencies

 Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

(b)(4) Deficiencies

[redacted]

Dear Ms. Keegan, we hope to have answered all your questions so that this submission can go ahead. Thank you very much.

With best regards,

Guenter Ginsberg

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

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Table of Contents for K150386 Response to RTA1

(b)(4) Deficiencies

[redacted]

.. Tab 1 ..... 1 page
.. Tab 2..... 4 pages
.. Tab 3 ..... 29 pages
... Tab 4 ..... 16 pages
... Tab 5 ..... 1 page
. Tab 6 ..... 7 pages
... Tab 7 ..... 1 page
. Tab 8 ..... 25 pages
... Tab 9 ..... 3 pages
... Tab 10 ..... 20 pages
.... Tab 11 ..... 29 pages

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

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002

MTC Media Trade Corporation

11820 Red Hibiscus Drive – Bonita Springs, FL 34135
Tel (239) 948-2001 – Fax (239) 948-2002
E-mail: info@mediatradecorp.net

To: Erin L. Keegan M.S.
FDA Branch: NSDB
Division: DNPMD
Center/Office: CDRH/ODE

Date: April 4, 2015

Re: **K150386 Response to RTA1**

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We also want to thank you for answering our e-mail questions clarifying the points on "Page Numbering", "Electrodes" and the meaning of "Not a basis for RTA1 decision".

We like to respond to your Comments/Questions as follows:

(b)(4) Deficiencies

[redacted]

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

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016
(b)(4) Deficiencies

[redacted]

Dear Ms. Keegan, we hope to have answered all your questions so that this submission can go ahead. Thank you very much.

With best regards,

Guenter Ginsberg

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

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Substantial Equivalence Discussion

Predicate Device Description:

The predicate device chosen is from Counter Scientific Development (GZ) Ltd.

Sponsor: Counter Scientific Development (GZ) Ltd.
2nd & 3rd Floor, Bld.6, DaPian Industrial Zone,
Tangxia Rd., Tianhe District,
Guangzhou 510665, China

Device: Counter TENS Device
See attached photo Program: PTS-IV
510(k) No: K132993

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle and joint pain relief, Model PTS-IV, The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle and Joint Pain. Outputs are almost the identical, each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500 Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both device are transiting pulses by the use of Electrode Pads. Both are portable devices.
More specific comparisons can be found in the following tables, graphs, photos, specifications etc.

Differences:

1. Device SEM44 has 15 preset programs, while the predicate device has 7. Having more programs offers more convenience to the patient and does not affect the safety of the device.
2. Intensity levels of SEM44 are selectable from 1 to 50, while the predicate device from level 1 to 16. Although the difference in the number of Intensity levels seems high, it merely means that the increments are smaller and do not affect the safety of the device.
3. All other parameters such as waveform, frequency, output current and voltage are somewhat similar. However, the output of the SEM44 has a pulse width of 360μS, and the predicate device has 200μS. This difference, again, does not affect the safety or effectiveness of the device.

Conclusion:

The comparison with the predicate device along with the non-clinical testing demonstrates that the Model SEM44 is safe, effective and performs as well as the predicate device PTS-IV and is therefore substantially equivalent to the predicate device.

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

Output Specifications:

Parameter		Your device	Predicate Device
Mode or Program Name		Tyece OTC TENS Device, Model SEM44	PAIN THERAPY DEVICE, PTS-IV
Waveform (e.g. positive-going, reverse, biphasic)		Positive-going, Reverse and Biphasic	Positive-going, Reverse and Biphasic
Shape(e.g., spike, rectangular, square ware)		Square ware	Square ware
Maximum Output Voltage (Volts)(+/-15%)		60vp p@500 Ω	69.2vp p@500 Ω
		105vp p@2K Ω	86.4vp p@2K Ω
		120vp p@10K Ω	88.8vp p@10K Ω
Maximum Output Current (+/-15%)		86mA@500 Ω	69.2mA@500 Ω
		23.3mA@2K Ω	21.6mA@2K Ω
		3.75mA@10K Ω	4.4mA@10K Ω
Duration of primary Program		50-360μS	200μS
Pulse Duration		50-360μS	200μS
Frequency		1-150Hz	1-136Hz
For multi-Program waveforms only:	Symmetrical Programs	N/A	N/A
	Pulse duration		
Net Charge (micro coulombs mC) (per pulse) (if zero, State method of achieving zero net charge)		0.001mC@500 Ω	0.0013mC@500 Ω
Maximum Program Charge(mC)		0.0454mC@500 Ω	0.0135mC@500 Ω
Maximum Current Density (mA/cm2, r.m.s)		3.60mA/cm2@500 Ω	3.308mA/cm2@500 Ω
Maximum Average Current(average absolute value), mA		4.0mA	2.218mA
Maximum Average Power Density, (W/cm2)(using smallest electrode conductive surface area)		0.195mW/cm2@500 Ω 1.0S	0.116mW/cm2@500 Ω 1.0S
Burst Mode(i.e. pulse trains)	(a) Pulses per burst	4	4/2
	(b) Bursts per second	4/83Hz	30/136Hz
	(c) Burst duration (seconds)	180μS	800μS/400μS

	(d) Duty Cycle	35ms/60ms	24ms/54.4ms
ON Time (seconds)		2s	0.5s
OFF Time (seconds)		2s	0.5s
Additional Features (specify, if applicable)		N/A	N/A
Electrode area:		20.25sqcm x 4(81sqcm)	21.2sqcm x 4(85sqcm)

Basic Unit Characteristics:

Parameter		**Your Device**	**Predicate Device**
510(k) Number		(to be assigned)	K132993
Device Name and See attached photo Program		Tyece OTC TENS Device, Model SEM44	PAIN THERAPY DEVICE PTS-IV
Manufacturer		SAVIA LTD.	COUNTER Scientific Development (GZ) Limited
Power Source		4.5V(batteries, 3x1.5V AAA)	3.7v Lithium (Power supply)
Method of Line Current Isolation		N/A	N/A
Patient Leakage Current		N/A	N/A
Normal Condition (μA)		N/A	N/A
Single Fault Condition (μA)		N/A	N/A
Average DC current through electrodes when device is on but no pulse are being applied (μA)		0μA	0μA
Numbers of Output Modes		15 Modes(01-15)	7 modes(A,B,C,D,E,F,ALL)
Number of Output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	PCB Insulation Boost Isolation	Boost Isolation
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage
Software/firmware/microprocessor control?		Yes	Yes
Automatic overload trip?		No	No
Automatic no-load trip?		Yes	Yes
Automatic shut off?		Yes	Yes
Users override control?		Yes	Yes
Indicator display	On/off status?	Yes	Yes
	Low battery?	Yes	Yes
	Voltage/current	Yes for voltage	Yes for voltage

level? Only voltage level display		
Timer range (minutes)	5-100min	20-40 min
Compliance with voluntary standards?	Yes	Yes
Compliance with 21CFR898-7?	Yes	Yes
Dimensions	L135xW65xT20mm	L120xW70xT18mm
Housing materials and construction	ABS	ABS

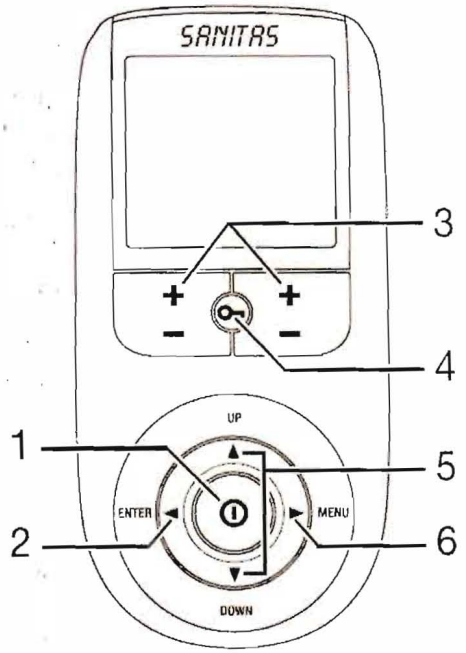
SEM44 Technical Specifications:

Output channel: Two
Output wave form: Biphasic rectangular pulse
Power supply: 3 x 1.5V AAA batteries

Buttons:

Buttons:

1 ON/OFF button ⏻
2 **ENTER** ◀ button
3 Intensity setting buttons (**Ch1** **+/-** left, **Ch2** **+/-** right)
4 Keylock
5 Selection button ▲ **UP** and ▼ **DOWN**
6 **MENU** ▶ button



Operation:

A. Before use, connect wires to the main unit and place electrodes on the treatment area
B. Using the UP/DOWN buttons, select the desired program and confirm your selection with the ENTER button.
C. If you wish to return to the previous selection menu, press the MENU button. By holding down the ENTER button, you can skip individual setting steps and start directly with the stimulation treatment.

D. At the start of the stimulation treatment, the impulse intensity is off for each channel and is set to 00 by default. No impulses are sent to the electrodes yet.
E. Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly. The impulse intensity of each channel can be set individually.
F. If the program is in a pause Program, the intensity cannot be increased.
G. If you wish to end the stimulation treatment early, press the ON/OFF button

Special Features:

1. Auto shut-off function:

If the unit is turned On for 2 minutes and the intensity is not increased on either channel beyond level 0, then the unit turns Off automatically. This is to save battery life.
When the Timer counts down to 0 min, the unit turns off automatically.

2. Auto increased/de-creased function:

The intensity can be increased/decreased by pressing the intensity button CH1 + /- and CH2+/- and keep it pressed. The intensity level changes at 2 steps per second. When the program is changed, the intensity level drops to level 0. It stays at level 0 for 2 seconds before increasing two levels per second back to the previous intensity level. If at any time during the increase of the levels the user wishes to stop the rise in intensity, he can simply do so by pressing the down button on the corresponding channel.

3. ON/OFF function:

To turn On the unit, press the On/Off button once and to turn Off the unit press the On/Off button and hold down for 2 seconds.

4. Pause function testing of the machine:

Any Program can be paused by pressing the On/Off button once. To restart the program, press the On/Off button again.
When a Program is Paused, the Pause sign comes on and it flashes at 2 flashes per second . To restart, press the Pause button again and the intensity starts to rise to the original intensity level.

5. Memory function:

The unit stores the last Program and the times it was used when it is shut off (This is only dependent on the internal ROM of the MCU and will be valid as long as the batteries are not removed from the unit)

6. Lock Function:

The buttons on the unit can be locked to prevent any accidental usage. This is done by holding the Keylock button down for 2 seconds . To cancel the keylock, press and hold down the Keylock button for 2 seconds.

7. Program timer function:

Each program has a preset time which is displayed in the timer box. When the timer counts down the program work time counts down to 0. If no other program is selected within this time the device automatically shuts off.

8. Open lead function testing:

The intensity will go to 0 when no-load is detected or if one of the electrodes should come off during use. This is a safety measure.

9. Low voltage check function testing:

When the battery voltage is low, a low battery sign will flash on the LCD at 2 flashes per second

10. Output pulses form the machine

When the intensity on either or both channels is increased to level 1 and up to level 50 the device delivers electrical pulses through the two output sockets located at the bottom of the unit.

Technical Specifications:

Channels:	Dual
Pulse Intensity:	Adjustable from 0-90mA peak into 500ohm per channel
Output Voltage:	60V(at 500 Ω) 105V(at 2K Ω) 120V(at 10K Ω)
Frequency:	1-150Hz
Pulse Width:	50-360 μs
Curve Shape:	Biphasic rectangular pulse
Programs:	15
Power Supply:	3 x 1.5V AAA batteries
Operating Conditions:	10°C-40°C(50°F-104°F) at a relative humidity of 30-85%
Storage Conditions:	-10°C-50°C(14°F-122°F) at a relative humidity of 10-95%
Key to symbols:	Warning! Read the safety information and all instructions to avoid serious injury.

Program	Pulse Intensity Max.	Pulse Width	Frequency	Mode
1	(b)(4) [redacted]			
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

13	(b)(4) [redacted]
14	
15	

SEM44:

Program	Description	Training Frequency (HZ)	Running Times(Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times(Min)	Waveform
1	Program 1	(b)(4) [redacted]							SEE ATTACHED PHOTO PROGRAM 1
2	Program1								SEE ATTACHED PHOTO PROGRAM 2
3	Program1								SEE ATTACHED PHOTO PROGRAM 3
4	Program1								SEE ATTACHED PHOTO PROGRAM 4
5	Program1								SEE ATTACHED PHOTO PROGRAM 5
6	Program-1 Program-2								SEE ATTACHED PHOTO PROGRAM 6
7	Program-1 Program-2								SEE ATTACHED PHOTO PROGRAM 7
8	Program-1 Program-2								SEE ATTACHED PHOTO PROGRAM 8
9	Program1								SEE

		(b)(4) [redacted]	ATTACHED PHOTO PROGRAM 9
10	Program1	[redacted]	SEE ATTACHED PHOTO PROGRAM 10
11	Program1	[redacted]	SEE ATTACHED PHOTO PROGRAM 11
12	Program1	[redacted]	SEE ATTACHED PHOTO PROGRAM 12
13	Program1	[redacted]	SEE ATTACHED PHOTO PROGRAM 13
14	Program1	[redacted]	SEE ATTACHED PHOTO PROGRAM 14
15	Program1	[redacted]	SEE ATTACHED PHOTO PROGRAM 15

(b)(4) Parameter and Waveform Photos

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Device Description

This Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated
with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

Product Group	stimulator, nerve, transcutaneous, for pain relief for OTC use
Regulation Number Product Code Medical Specialty	882.5890 NUH Neurology
Short Name of product:	N.A.
Product Name List of Sizes/Models/Article No. Product name	Transcutaneous Electrical Nerve Stimulation (TENS) Model: SEM44 Tyece OTC TENS Device
Classification Rule	Class II

The SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 1 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under [redacted]: K132588.

1. Technical details:

Checksum: A24A
Output channel: 2 Channel
Output wave form: Biphasic rectangular pulse
Pulse length: 50-450 us
Pulse frequency: 1-150 Hz
Output voltage: max. 100Vpp (500 ohm)
Output current: max. 200mApp (500 ohm)
Voltage supply: 3 x AAA batteries
Treatment time: Adjustable from 5 to 100 minutes
Intensity: Adjustable from 0 to 50

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

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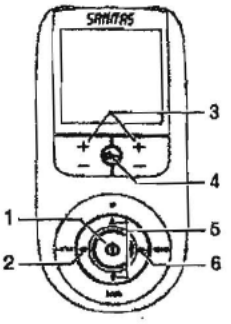
Program: Tens

2.

Buttons:
1 ON/OFF button ⏻
2 **ENTER** ◀ button
3 Intensity setting buttons (CH1 +/- left, CH2 +/- right)
4 Keylock
5 Selection button ▲ **UP** and ▼ **DOWN**
6 **MENU** ▶ button



2. Auto shut-off function:
If the unit is turned "On" for 2 minutes and the intensity is not increased on either channel beyond level O, then the unit turns off automatically. This is to save battery life.
When the Timer counts down to 0 min, the unit turns off automatically.

3. Auto increased/de-creased function:
The intensity can be increased/decreased by pressing the intensity button CH1 + /- and CH2+/-. The intensity level changes at 2 steps per second while the key is pressed. When the program is changed, the intensity level drops to level 0. It stays at level 0 for 2 seconds before increasing two levels per second back to the previous intensity level. If at any time during the increase of the levels the user wishes to stop the rise in intensity, he can simply do so by pressing the down button on the corresponding channel.

4. ON/OFF function:
To turn "On" the unit, press the On/Off button once and to turn "Off" the unit press the On/Off button and hold down for 2 seconds.

5. Pause function testing of the machine:
Any Program can be paused by pressing the On/Off button once. To restart the program, press the On/Off button again.
When a Program is paused, the pause sign comes on and it flashes at 2 flashes per second. To restart, the intensity starts to rise to the original intensity level.

6. Memory function:
The unit stores the last Program and the times that were used when it is shut off and will be memorized as long as the batteries are not removed from the unit.

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

127. Lock Function:
The buttons on the unit can be locked to prevent any accidental usage. This is done by holding the Program button down for 2 seconds. To cancel the key-lock, press and hold down the Program button for 2 seconds.

8. Program timer function:
Each program has a preset time which is displayed in the timer box. The timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

9. Open lead function testing:
Each program has a preset time which is displayed in the timer box. The timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

10. Low voltage check function testing:
When the battery voltage is low, a low battery sign will flash on the LCD at 2 flashes per second.

11. Output pulses from the device
When the intensity on either or both channels is increased to level 1 and up to level ~~20~~ 50 the device delivers electrical pulses through the two output sockets located at the bottom of the unit. The output parameters of these electrical pulses are referred to in the Table (next page).

12. Technical Documentation (attached below)

13. Photos (attached below)

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

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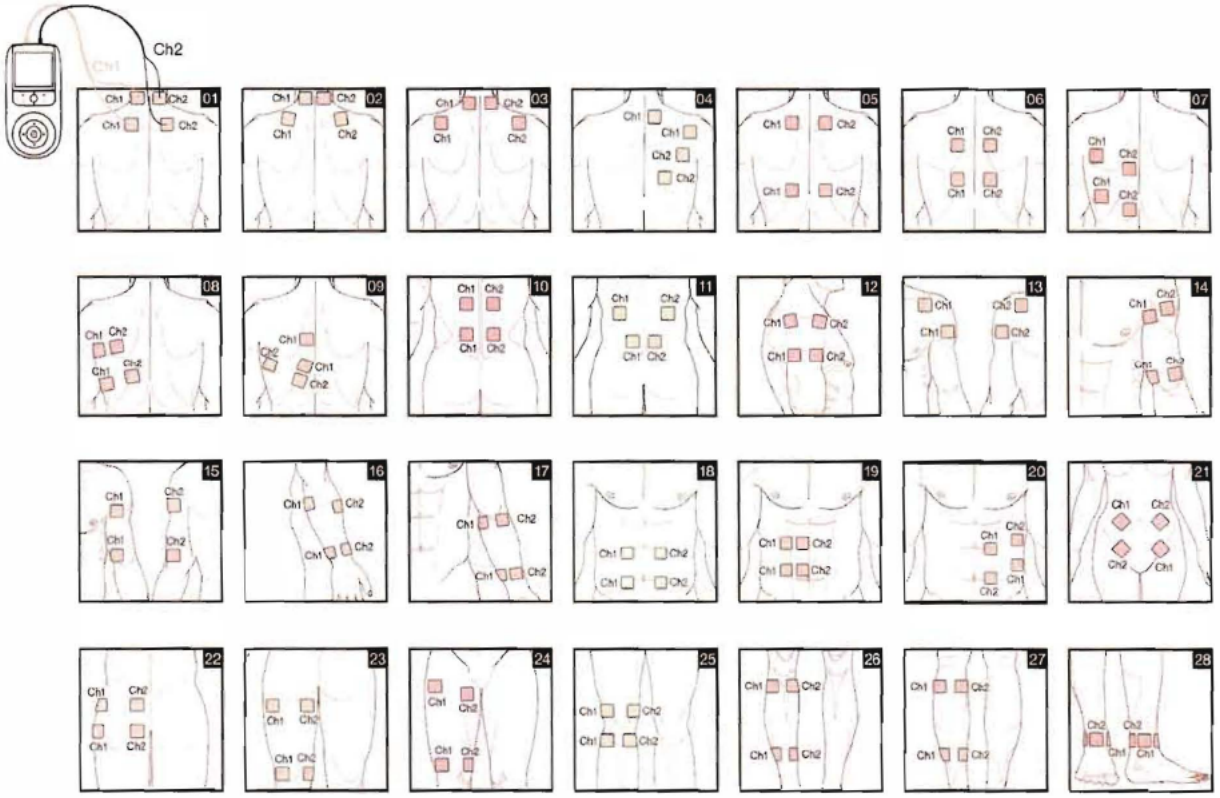
Electrode Placement Chart



TENS Programs and their suggested uses

1,2&3 Use for pain in the areas indicated in Electrode Placement Chart 01-17 & 23-28

4 &5 Use on pain in the areas indicated in the Chart 10 &11

6 Use on pain in the areas indicated in the Chart 12,13,25 &28

7 Use on pain in areas indicated in Chart 4-11

8 Use on pain in areas indicated in Chart 12,13,25,28

9 Use on pain in areas indicated in Chart 25

10 Use on pain in areas indicated in Chart 1-2

11&12 Use on pain in areas indicated in Chart 21

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

(b)(4) Third Party Technical Documentation

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TYECE

Unit 801, Block A
Po Lung Centre
11 Wang Chiu Road
Kowloon Bay, Hong Kong

13 March, 2015

Statement

The only patient contacting materials are the electrodes that are cleared under K132588 for OTC use.

The electrodes used with the Model SEM44 are identical in terms of materials, manufacturing and processing to the ones cleared under K132588.

For and behalf of Tyece Limited

Parshid Falahati
Managing Director

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

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Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132588

1. Date of Submission: Jul 20, 2013

2. Sponsor Identification

   Top-Rank Health Care Co., Ltd
   Chencun Village, Dongguan Street, Shangyu, Zhejiang, 312352, China

   Establishment Registration Number: 3006626283

   Contact Person: Liubo Shen
   Position: Management Representative
   Tel:+86-575-82576147
   Fax: +86-575-82563750
   Email: liubo.shen@etop-rank.com

3. Submission Correspondent

   Ms. Diana Hong& Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119
   Shanghai, 200120, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

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

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4. Proposed Device Identification

Proposed Device Name: Adhesive Electrodes
Proposed Device Common Name: Electrode

Regulatory Information:
Classification Name: Cutaneous Electrode;
Classification: II;
Product Code: GXY;
Regulation Number: 21 CFR 882.1320;
Review Panel: Neurology;

Intended Use Statement:
Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.

5. Predicate Device Identification

510(k) Number: K070612
Product Name: Top-Rank Adhesive Electrodes
Manufacturer: Top-Rank Health Care Co., Ltd.

6. Device Description

Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcuaneous Electrical Nerver Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.

The proposed device. Adhesive Electrode, is intended to be used with U.S. legally marketed Electrical Stimulator. i.e. TENS and EMS, as a conductive adhesive interface between the patient's skin and such stimulators. It is for single patient use only.

The proposed device mainly consists of substrate and wire. The substrate is available in rectangular shape and round shape.

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7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ANSI/AAMI HF18:2001 Electrosurgical devices

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, design feature and performance, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	PROPOSED DEVICE Adhesive Electrodes	PREDICATE DEVICE Top-Rank Adhesive Electrodes, K070612
Device Name	Adhesive Electrodes	Top-Rank Adhesive Electrodes
Regulation Number	882.1320	882.1320
Product Code	GXY	GXY
Classification Name	Cutaneous Electrode	Cutaneous Electrode
Device Class	CLASS II	CLASS II
Intended Use	Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcuaneous Electrical Nerver Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.	Top-Rank Adhesive Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).
Design Feature	Substrate / Wire / Hydro-Gel Scrim / Conductive Fiber Carbon Conductive Film / Liner	Same
Labeling	Conforms to 21 CFR 801	Same
OTC or Prescription	For OTC use	For prescription use
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993
Performance	Complies with ANSI/AAMI HF18:2001	Complies with ANSI/AAMI HF18:2001 E

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The proposed device, Adhesive Electrodes, is determined to be Substantially Equivalent (SE) to the predicate device, Top-Rank Adhesive Electrodes (K070612), in respect of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 22, 2013

Top Rank Health Care Equipment Co., Ltd
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai
China 200120

Re: K132588
Trade Name: Adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 8, 2013
Received: November 12, 2013

Dear Ms. Hong:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

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

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

Sincerely yours,

Joyce M. Whang -S

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

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Indications for Use

510(k) Number (if known): K132588

Device Name: Adhesive Electrodes

Indications For Use:

Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcuaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

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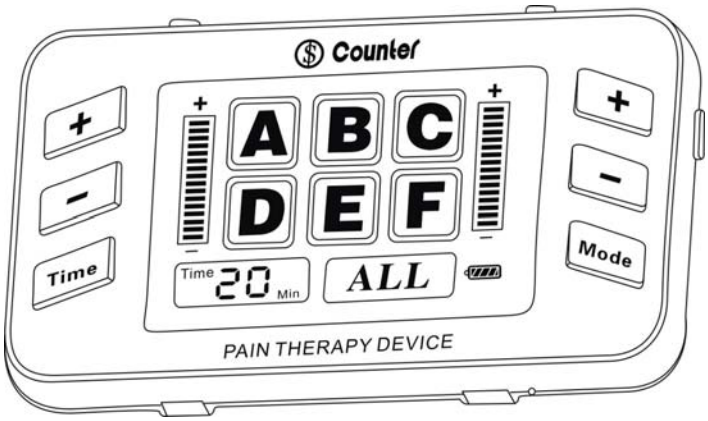
Counter

Pain Therapy Device

Model P.T.S - IV



Indications for Use:

This TENS device is to be used for temporary relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

Note:

Before operation, please read this user's manual carefully, and be clear about the instructions!

Warning:

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities
- Metals Implants or Electronic Auxiliary Devices
- Diabetes or Abnormal High Blood Pressure
- A tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

Rev. 28.02.2014

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User Instructions

Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Counter" brand "Pain Therapy Device".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
Danger	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
Warning	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol
Refers to prohibitive action in the proper use of the unit. The specific forbidden content is indicated inside the circle. The left picture means no dismantling.
Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. The left picture means general compulsion.
BF Isolated Applied Part

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

2. Precautions

1) Do not use the muscle stimulator during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:

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a. When there is a tendency to hemorrhage following acute trauma or fracture;
b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
c. Over areas of the skin which lack normal sensation.

5) Do not use the products near the heart; it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) The Pain Therapy Device must be kept out of the reach of children.
8) The Pain Therapy Device should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the Pain Therapy Device and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical short, do not connect two pads to each other.
12) Do not apply pads to the same spot for over 40 minutes at a time.
13) Do not use the Pain Therapy Device while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.
17) Never use this product near a microwave oven, or other high frequency equipment.
18) Never use this product while it is being charged.
19) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

3. Contraindication

1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions

1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application

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of electrical stimulation.
3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

5. Indications for Use

To be used for temporary relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your **pain, consult with your physician** before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for **more than five days**, stop using the device and **consult with your physician**. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, **consult your physician** in order to confirm that it is advisable for you to use this Pain Therapy Device.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to **normal, healthy, dry, clean skin** (of adult patients) because it may otherwise disrupt the healing process.
If you experience **any skin irritation or redness** after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, **put the pads only on the skin or on the plastic pad sheet provided**.
Place the pads **at least 1 inch apart** on your skin. The pads should never touch each other.
Always place clean pads **in accordance with illustrations** provided. Make sure the components are **connected well and the pads are fixed** on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

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Pads should not touch each other when placed onto your skin.
Do not place on your **spine or backbone**.
Pads **should not touch any metal object**, such as a belt buckle or necklace.
Pads should not be placed **simultaneously on the soles** of both feet.
Pads should not be placed **simultaneously on the calves** of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads **attached to the skin** after treatment.

CAUTION WHILE USING UNIT

If the unit **is not functioning properly** or you feel discomfort, immediately stop using the device.
Do not use for any other purpose except for what it is intended for.
Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
Do not pull on the electrode cord during treatment.
Do not use the device **while wearing electronic devices** such as watches as this may damage the device.
Do not use **near a cell phone** as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, **hold the plug and pull**.
Replace the cord when broken or damaged.
Do not throw the batteries **into a fire**. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads **may affect the safety and effectiveness** of electrical stimulation.
The electrical performance characteristics of pads **may affect the safety and effectiveness** of electrical stimulation.
Using pads that are **too small or incorrectly applied**, could result in discomfort or skin burns

General Precautions

• The long-term effects of electrical stimulation are unknown.
• Apply stimulation to only normal, intact, clean, dry, and healthy skin.
• TENS is not effective in treating the original source or cause of the pain, including headache.
• TENS is not a substitute for pain medications and other pain management therapies.
• TENS devices do not cure disease or injuries.
• TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.

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• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
Keep unit out of the reach of young children. The electrode cord can cause strangulation.

What is it?
The Counter Pain Therapy Device a 7-program, portable device designed for adults only. It is designed to reduce and relieve muscle and joint pain, stiffness and numbness in the arms, legs and foot by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.
How does it work?
Scientific theory suggests that electrical stimulation therapy may work in several ways:
1. The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.
2. The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
3. Furthermore, it is thought that the electrical stimulation improves blood circulation as well. Muscles contract and relax with the flow of the electrical stimulation. With repeated contracting and relaxing, the blood flows in and out and the blood circulation is improved.

Symbols

Symbol	Meaning
⚠	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⎓	Direct current
⧈	Class II equipment
	Re-back label

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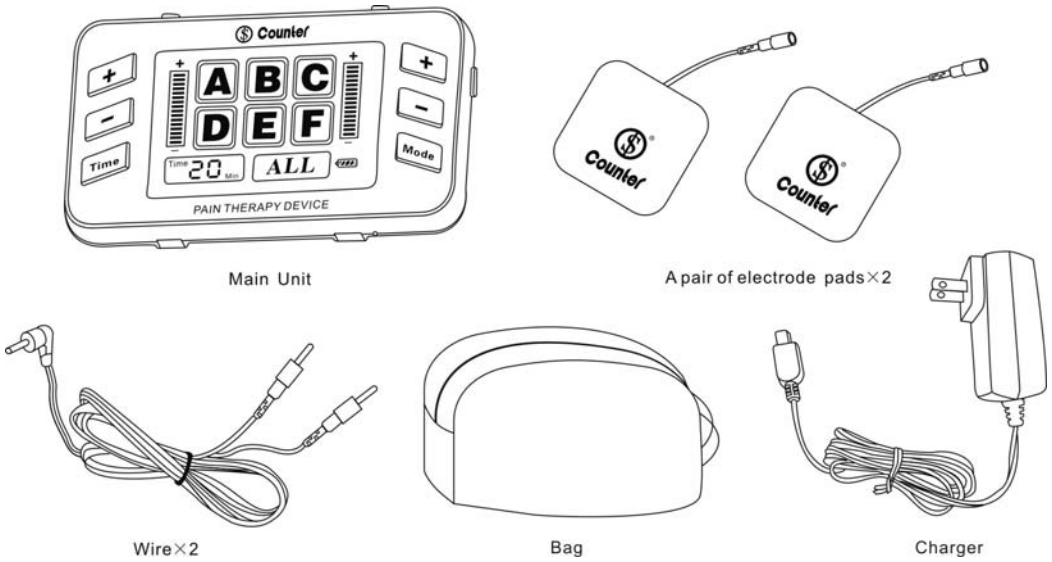
	Indoor use only

Indication for Use:

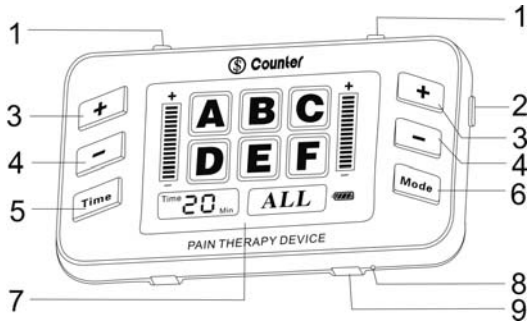
To be used for temporary relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

Name and function of Each Part

Components:



Features of the Main Unit



1. Output jack: to connect the electrode wire plug to output electric pulse signals;

2. ON/OFF Switch: to turn the device on and off.

3.Intensity increase button: Press the button once, the output of the pulse shall be intensified by one level correspondingly. The highest level is Level-16.

4. Intensity lessening button: Press the button once, the output of the pulse shall be lessened by one level correspondingly. The lowest level is Level-0 at which there is no output. The status of starting the device is Level-0.

5.Treatment time interval selection button: the treatment time intervals: there are three treatment time intervals available for setting, namely 20 min, 30 min and 40 min. The treatment time interval at starting the device is 20 minutes.

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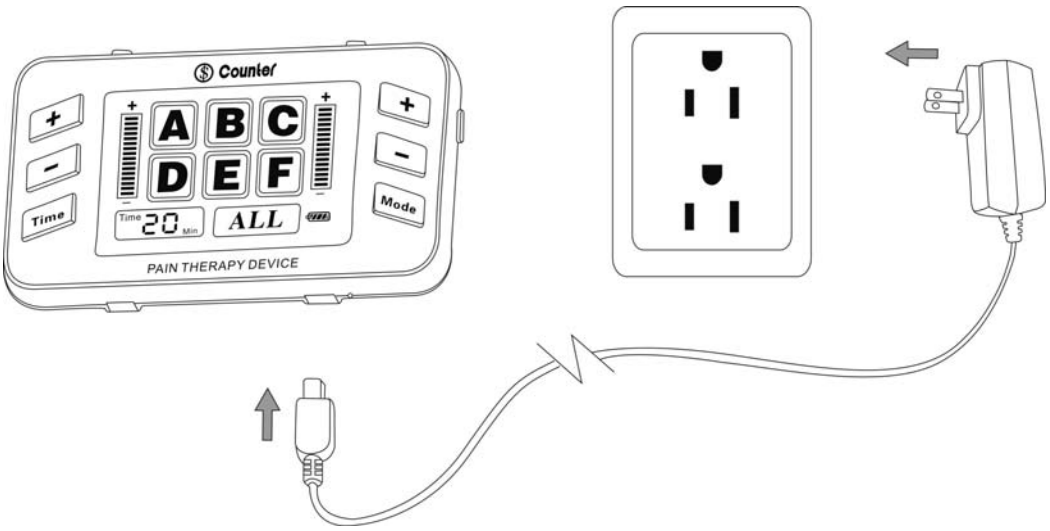
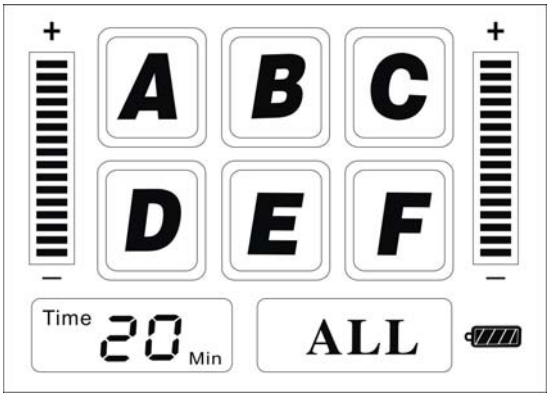
6. Mode selection button: Press the button once, a Mode is changed correspondingly and at the same time the Mode selected will blink on the LCD. There are seven Modes available in the device, namely Neck, Shoulder, Waist, Back, Legs, Feet and All.

7. LCD: It simultaneously displays the working status of the device.

8. The charging indicator light: the light is on when charging. When the unit gets full charge, the light will be off.

9. Charging Jack. It is used for charging the device. When the battery power of the device is low, plug in the special charger supplied with the device and connect it to a wall outlet (AC120V). The device will be charged.（please refer to the charging method in page 14-15 of the “Instructions for the Lithium Battery” of this manual.）





Reading the LCD Screen:

1. Mode display zone: There are seven Modes available with the device, namely A, B, C, D, E, F and All. When a certain Mode is blinking, it means the device is in the status of that Mode for output.

2. Intensity display zone: It simultaneously displays the intensity of both right and left output electronic pulse of the device. There are 16 levels of intensity. Intensity gradually increases from level-1 to level-16. There is no output intensity at Level-0.

3. Treatment time interval display. The remaining working time displays in a count-down way.

4. Built-in battery power display zone: Full space shows the highest power level and blank space

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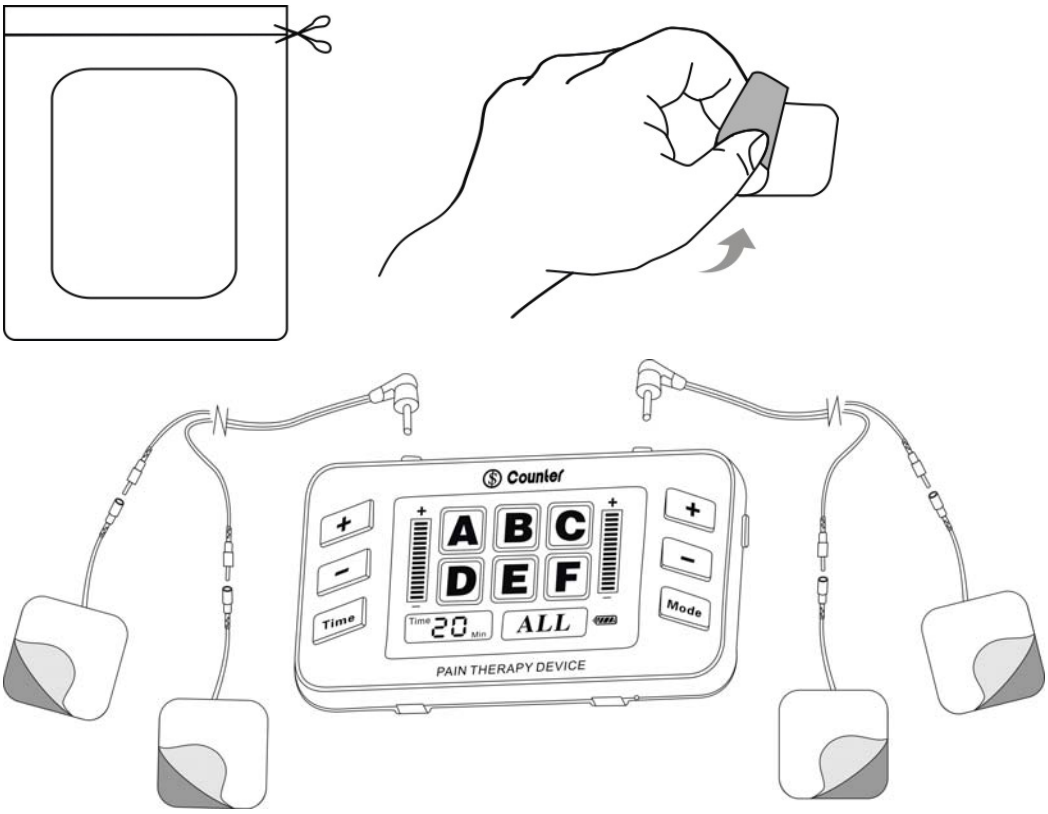
shows the lowest power level, which means the battery needs to be charged otherwise the device may be turn off.

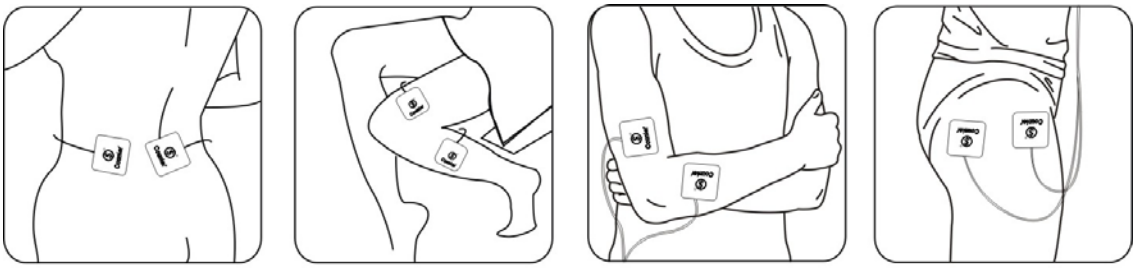
Preparation before use:

Correct Usage Method

As shown in the figure, connect the wire properly; take off the protective film on the electrode pad.



Put the electrode pad on the area to be treated.



Waist Leg Elbow hip&Thigh

Note:

If you like to use both channels (4 electrodes) simultaneously for enhanced stimulation, always place the second pair of electrodes near the first pair making sure that they don't touch each other (see below). The intensity for the second channel can be controlled by the separately by using the other (right) side of the controls (+/-).

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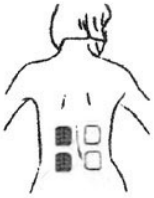
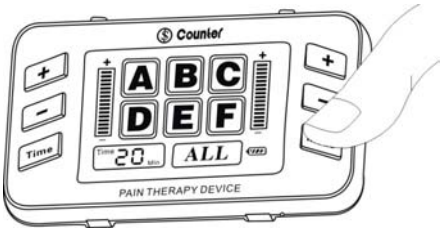


Proper use

1. Turn on the power: Push the ON/OFF switch to “ON” and the power is on as shown in the figure. The device now is in the state of START: intensity: 0, Mode: “A”; treatment time interval: 20 min.

2. Selection of treatment Modes: Press the mode button; you may select seven Modes repeatedly in the order of A, B, C, D, E, F and All. When a Mode is chosen, the letter corresponding to the Mode starts blinking on the screen.



3. Intensity adjustment: Press the intensity increase/decrease button until the intensity is adjusted to a proper level.

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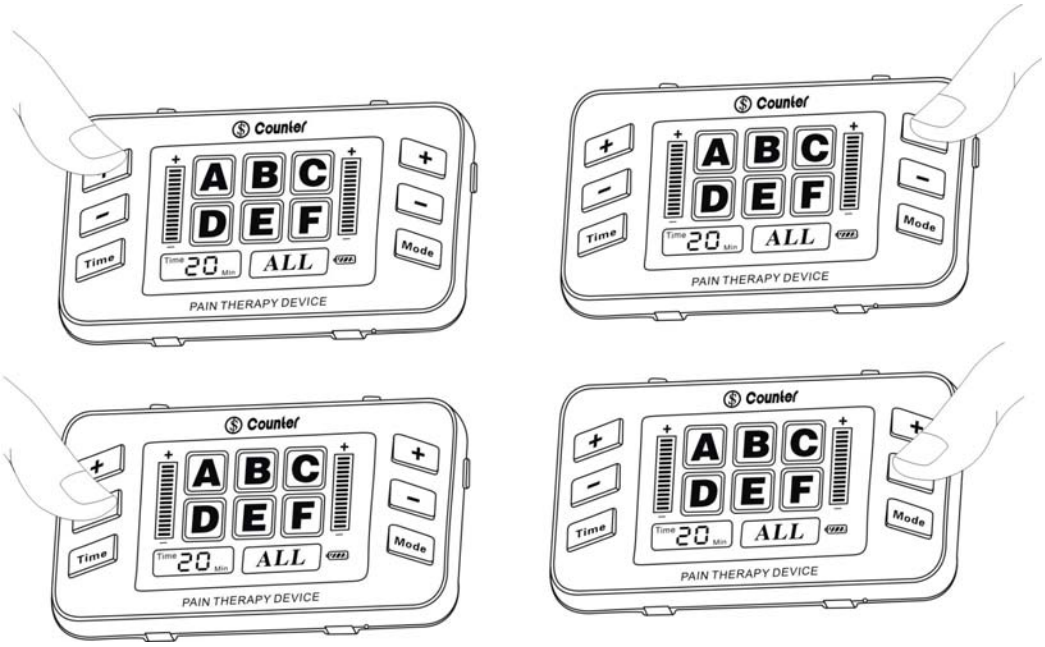
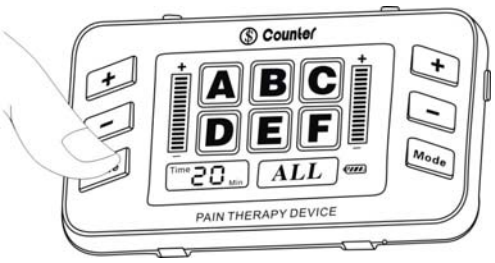
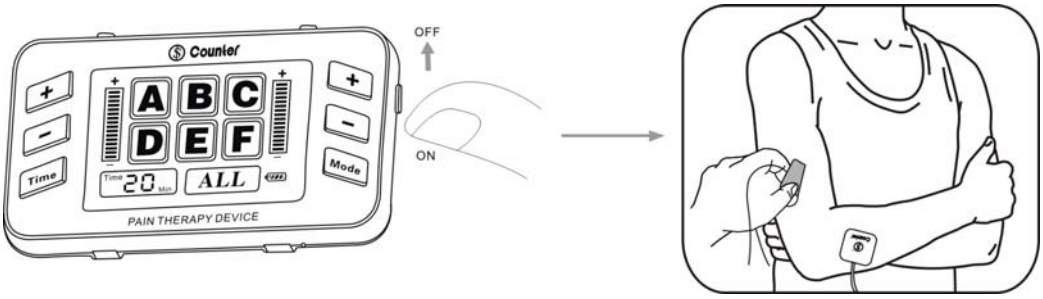


4. Selection of treatment time: Press the timing button, there are three treatment time intervals available for selection, namely 20 min, 30 min and 40 min. 20 minutes treatment interval for one area, once or twice per day is recommended. However, the treatment time interval and treatment frequencies may also be prolonged or shortened depending on the patient's specific conditions. The device will automatically turn off when the treatment time is up. If you want to continue the operation, you should not restart the device until the power is off for at least 3 seconds.



5. If you want to change the treatment position in the process of treatment, namely change the location of the electrode pad, you must turn the power button to "OFF" before changing the treatment position and restart the device so as to avoid the irritation arising from abrupt change.



6. If you want to stop during the treatment, please don't take off the electrode pads until the device is switched off.

7. Please turn off the power after the use: Set the power switch to OFF to turn off the device.

8. After the device is turned off, hold the plug of the electrode wire and pull out of the socket. Never try to pull out the plug by holding the wire.

9. Insufficient battery power may affect the device's normal operation. Please charge the battery timely.
Note: You must use the special charger supplied to charge the device.
Note: Only charge the device when battery is completely drained the first 2 times. Unplug charger from charging jack when charging is complete. When massage strength decreases, it indicates that the device needs charging. Recharge it and then continue to use the device. Do not use the controller when charging.

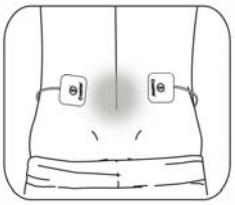
10. Pads can be used for approximately 150 times at home, but it depends on different situations. When the pads are dirty or the stickiness is not enough, you should consider washing or changing them. For detailed washing and cleaning criteria and methods, please refer to t the "Product Cleaning, Maintenance and Storage" section in the page 13-14 of this manual. Replacement electrodes can be purchased from your supplier of the device or by calling Customer Service **1-239-498-2001** or go to www.counter-csd.com.

Attention: Do not use other unauthorized electrodes, the output current density may exceed 2 mA r.m.s./cm², which could be dangerous.

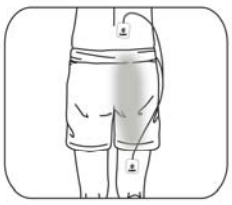
Recommended Electrode Placements

STEP 1 – PAD PLACEMENT
Place pads on clean, dry and healthy skin near the area with pain at least 1" apart, and do not let them touch. OK to place near or surrounding the pain. Make sure there is a linear path between the two pads. (See Pad Placement Guide insert or the following illustrations).

Before starting your therapy, rate your pain from 1 low to 10 high. This mental check gives you a basis you can compare to once the session is complete.



LOWER BACK
Attach both pads on the lower back with the backbone in the center. Do not place on the backbone or spine.



SCIATIC
Attach one pad below and above the region in pain, both on same side (NOT on spine).

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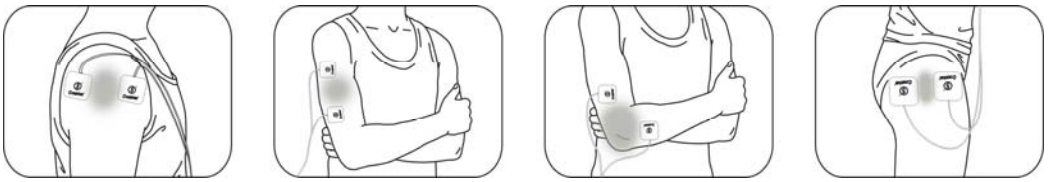
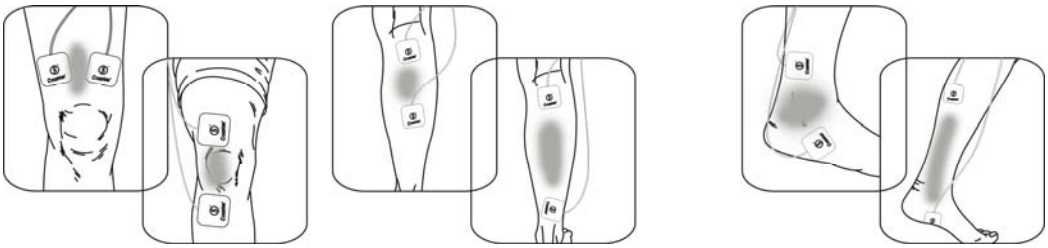


DELTOID
Attach one pad in front and one in back of the muscle.

UPPER ARM
Attach both pads on either side of the region where you feel pain.

ELBOW
Attach both pads on either side of the joint with the pain.

HIP & THIGH
Attach both pads on either side of the area with pain.



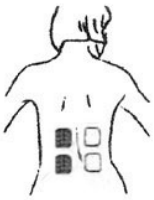
KNEE
Attach both pads above the knee or above and below the joint with pain.

CALF
Attach both pads on the calf/leg where you feel pain. (Do not place electrode pads simultaneously to the calves of both legs.)

ANKLE/FOOT
Attach pads per the illustration, on the left for pain on the outside of your ankle/foot. Attach the pads per the illustration on the right for pain on the inside of your ankle/foot.

Note: (again)

If you like to use both channels (4 electrodes) simultaneously for enhanced stimulation, always place the second pair of electrodes near the first pair making sure that they don't touch each other (see below).



Product Cleaning, Maintenance and Storage

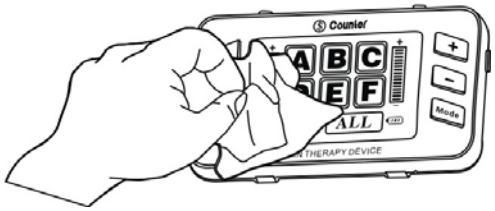
The unit is designed for repeated use over time. The pads will last up to 150 uses, or 5 months (based on use 1/day). Here are important cleaning and storage instructions:

Cleaning the main unit

1. Turn unit off and disconnect the electrode wires from the pads.
2. Clean with a lightly moistened cloth (or a cloth moistened with a neutral cleaning solution) and wipe

- Do not use chemicals (like thinner, benzene).
- Do not let water get into the internal area.

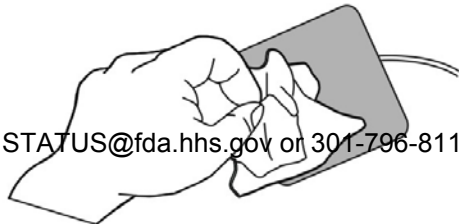
Cleaning the main unit



Cleaning the electrode pads

1. Turn the power off and remove the electrode cord from the pads.

Cleaning the electrode pads



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2. Wash the pads when the adhesive surface becomes dirty and/or the pads are difficult to attach.
   • Wash the pad softly with your fingertips under slow running cold water for several seconds（do not use a sponge or sharp object like a nail on adhesive side, do not use detergents, chemicals or soap.）
3. Pads can be washed after 15 uses; approximately ten times for up to 150 uses (do not wash the pads too long or too frequently).
4. Let the adhesive surface air-dry completely.
5. Pads are replaceable and can be purchased when needed by calling 1-800-634-4350 or go to www.counter-csd.com.

The life of pads may vary by the frequency of washing, skin, condition, and storage state.

When should you replace your pads?

If the pad no longer sticks to your skin or if more than 25% of the pad's surface is not in contact with your skin.

Storage

Store the device in a place where it is out of reach of children. Do not disassemble the unit without authorization.

After the unit has not been used for a long time, charge the battery before use.

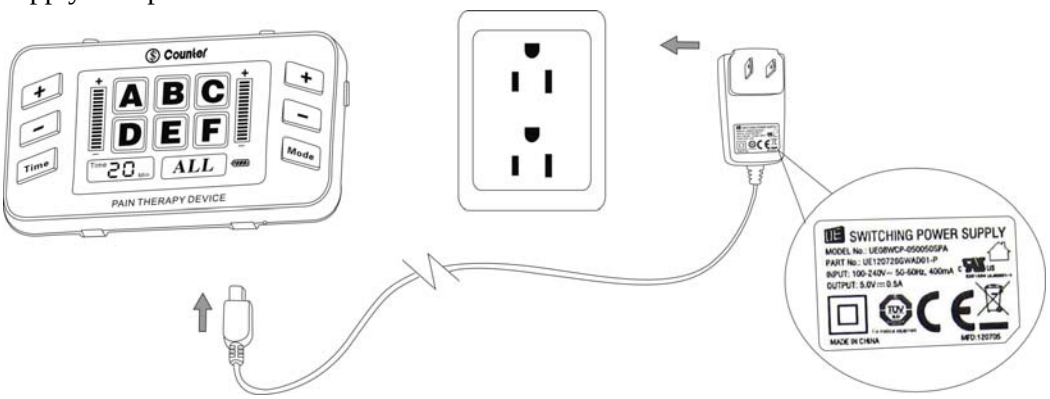
Do not disassemble for repair without prior notification or you may void your warranty.

Instructions for the Lithium Battery

P.T.S—IV is equipped with one "built-in" rechargeable lithium battery and need not to be exchanged; only recharged. Only charge the battery with the equipped charger supplied. Use of other chargers may lessen the working life of the device or result in damage of device and could be dangerous.

Charging Method:

1. Please insert the plug of charger to the main unit, and connect the charger to power supply. See picture below.



2. The charging indicator light is on or the LCD battery icon blinks when charging. When the indicator light is off or the battery icon stops blinking, it means the unit is fully charged. Charge OK.
3. When charging the unit for the first time, please make sure the unit is fully charged.
4. Do not continue charging after the battery icon has stopped blinking. Continuous charging will affect the life of the device.

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Product Problem Solving

Problem	Have you checked	Solutions
The LCD is working but there is no massage sensations	That the electrodes are connected to the main unit	Insert the output jack to the machine
	The electrode wire is connected to the electrode	Connect properly the electrode wire to the electrode
The stimulation becomes weak or the user feels a slight tingle on the nerves	That the electrode are fully touching the skin	Place the electrodes tightly to the skin
	That the surface of the electrode has not been contaminated	Clean or replace the electrode
	That the body surface is not lubricated in any way	Clean and dry the body surface and electrode then retry the unit
During the treatment, the unit stops output before the end time	Make sure the battery is fully charged and/or the output jack has not been loosened	Charge the battery or reconnect the jack to the main unit
The skin under where I place the electrode has turned red and/or itches or prickles	Check to see whether you are allergic to the electrode	Stop using the machine until you ascertain the cause of the skin irritation. Consult with your Doctor.
The stimulation is too weak even with the strength turned up	Skin or electrode are dirty attaching position is correct or battery needs to be charged	Clean the skin with a wet towel change the electrode positioning recharge the battery

Technical Manual

Specification

Power	DC 3.7V
Normal working ambient temperature	5~40℃ (40-105°F)
Normal working ambient humidity	≤80%RH
Store and transport ambient temperature	-20~55℃ (-4-130°F)
Store and transport ambient humidity	10-95%RH
Weight	About 80g (2.8 oz.)
Outline dimension	L120mm × W70mm × H18mm (L4.7in. × W2.8in.×H 0.63in)
Safety classifications	Internal powered equipment, Type BF applied part, not suitable for use in the presence of a flammable anesthetic mixture with air or with

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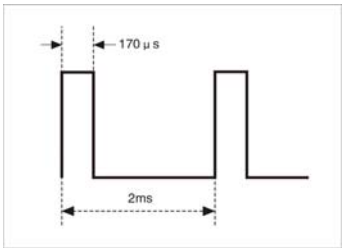
	oxygen or nitrous oxide, continuous operation
Product Life	5 Years
Battery Life (30 min./CYCLE)	20 CYCLES before recharging
maximum amplitude of output voltage	35 V

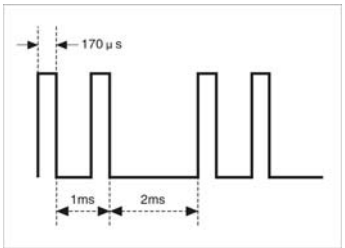
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Waveforms of the various Modes/Programs

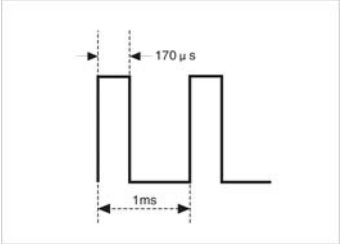
"A" (recommended for use on Deltoid)	
Pulse durations	170μs
pulse repetition frequencies	10-100Hz



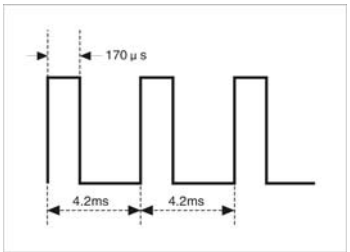
1



2



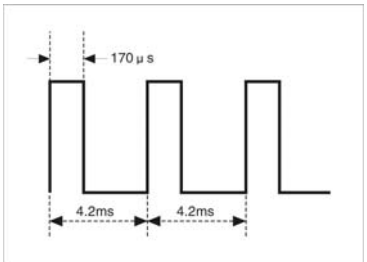
3



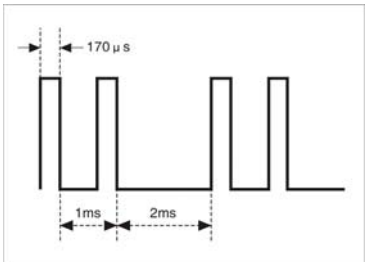
4

Waveform is the pulse group as a unit, pulse group frequency 10-100Hz,

"B" (recommended for use on Sciatica, Calf)	
Pulse durations	170μs
pulse repetition frequencies	1-20Hz



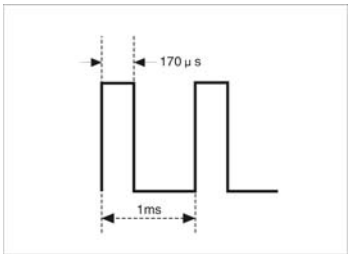
1

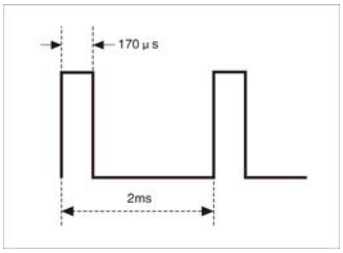


2

Waveform is the single pulse as a unit, pulse group frequency 1-20Hz

“C” (recommended for use on Elbow, Upper Arm)	
Pulse durations	170μs
pulse repetition frequencies	48-136Hz

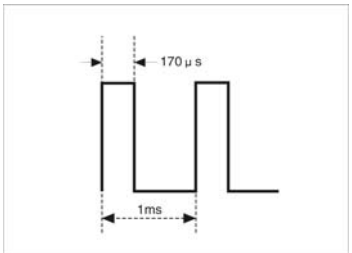


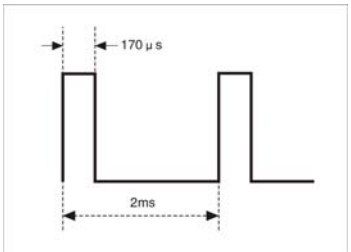


1 2

Waveform is the single pulse as a unit, pulse group frequency 48-136Hz

“D” (recommended for use on Lower Back)	
Pulse durations	170μs
pulse repetition frequencies	20-100Hz

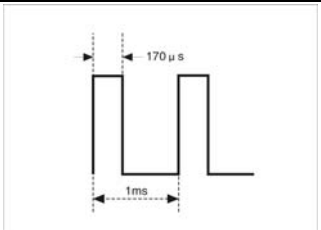


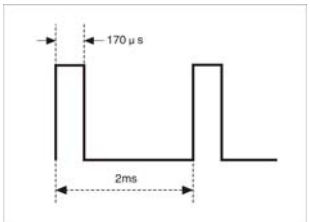


1 2

Waveform is the single pulse as a unit, pulse group frequency 20-100Hz,

“E”(recommended for use on Knee)	
Pulse durations	170μs
pulse repetition frequencies	10-120Hz





1 2

Waveform is the single pulse as a unit, pulse group frequency 10-120Hz

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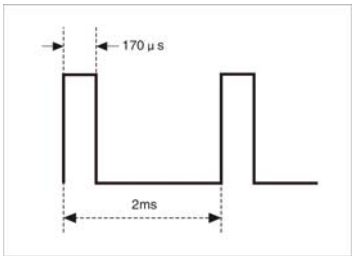
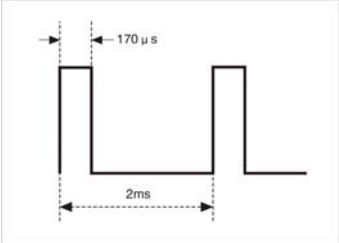
“F” (recommended for use on Hip & Thigh, Ankle/Foot)	
Pulse durations	170μs
pulse repetition frequencies	100-120Hz

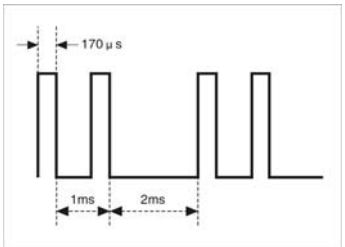


Waveform is the single pulse as a unit, pulse group frequency 10-120Hz

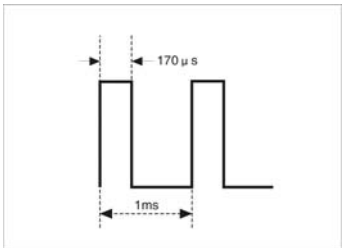
“All” (recommended for use on ALL the positions “A” to “F”)	
Pulse durations	170μs
pulse repetition frequencies	10-100Hz



1



2



3

The pulses of the “All” mode are without any “bursts” and therefore feel smoother.
Waveform is the pulse group as a unit, pulse group frequency 10-100Hz,

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ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4) Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

5) Warning:

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the P.T.S-IV PAIN THERAPY DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The P.T.S-IV PAIN THERAPY DEVICE *is* intended for use in the electromagnetic environment specified below. The customer of the user of the P.T.S-IV PAIN THERAPY DEVICE should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The P.T.S-IV PAIN THERAPY DEVICE use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

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RF emission CISPR 11	Class B	The P.T.S-IV PAIN THERAPY DEVICE is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The P.T.S-IV PAIN THERAPY DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of P.T.S-IV PAIN THERAPY DEVICE should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level IEC60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air ±2 kV contact ±4kV air	±6 kV contact ±8 kV air ±2 kV contact ±4kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1KV for power supply lines	±2kV for power supply lines ±1KV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the P.T.S-IV PAIN THERAPY DEVICE requires continued

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input lines IEC 61000-4-11	40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	operation during power mains interruptions, it is recommended that the P.T.S-IV PAIN THERAPY DEVICE be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacture's declaration – electromagnetic immunity			
The P.T.S-IV PAIN THERAPY DEVICE *is* intended for use in the electromagnetic environment specified below. The customer or the user of P.T.S-IV PAIN THERAPY DEVICE should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the P.T.S-IV PAIN THERAPY DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			

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NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the P.T.S-IV PAIN THERAPY DEVICE is used exceeds the applicable RF compliance level above, the P.T.S-IV PAIN THERAPY DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the P.T.S-IV PAIN THERAPY DEVICE.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the P.T.S-IV PAIN THERAPY DEVICE .

The P.T.S-IV PAIN THERAPY DEVICE *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the P.T.S-IV PAIN THERAPY DEVICE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the P.T.S-IV PAIN THERAPY DEVICE as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

LIMITED WARRANTY

Your Pain Therapy Device and electrode cords are warranted for 1 year and the electrode pads are warranted for 30 days. They are guaranteed to be free from defects in materials and workmanship if used in accordance with the instructions provided. The above warranties extend only to the original retail purchaser. We will, at our option, repair or replace without charge any device covered by the above warranties. Repair or replacement is our only responsibility and your only remedy under the above warranties. To obtain warranty service, contact Customer Service by calling 1-800-xxx-xxxx for the address of the repair location and the return shipping and handling fee. Enclose the Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY COUNTER SCIENTIFIC IN CONNECTION WITH THIS PRODUCT, AND COUNTER SCIENTIFIC HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY. COUNTER SCIENTIFIC SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS, EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction. Because of special local requirements, some of the above limitations and exclusions may not apply to you.

FOR CUSTOMER SERVICE

Call: 1-239-948-2001

Manufacturer: Counter Scientific development (GZ) Limited

Address: 2nd& 3nd Floor, Building 6, DaPian Industrial Zone, Tangxia Road, Tianhe District, Guangzhou 510665, China

www.counter-csd.com

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

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K122744, 510(K) SUMMARY, TABLE A: Comparisons of PL009/PL009A/PL029 Basic Unit Characteristics with Predicate Devices:

Parameter		Your Device			Predicate	Predicate	Predicate
510(k) Number		K122744	K122744	K122744	K102598	K112392	K060846
Device Name and Model		PL009	PL009	PL029	JQ-5C	PP907	T1040
Manufacturer		Prospera	Prospera	Prospera	Hi-Dow international Inc	HIVOX BIOTEK INC	Endurance Therapeutics
Power Source(s)		6V Battery	6V Battery	3V Battery	3.7V Lithium	3V Battery	4.5V Battery
- Method of Line Current Isolation		Battery Supply N/A	Battery Supply N/A	Battery Supply N/A	Battery Supply N/A	Battery Supply	Battery Supply
- Patient Leakage Current							
- Normal Condition (μA)		1.8μA	1.8μA	2.0μA	2.0μA	NA	NA
- Single Fault Condition (μA)		3.3μA	3.3μA	3.0μA	4.2μA	NA	NA
Average DC current through electrodes when device is on but no pulses are being applied		0μA	0μA	0μA	0μA	0μA	0μA
Number of Output Modes		3	3	8	6	1	10
Number of Output Channels:	Synchronous/Alternating?	Synchronous	Synchronous	Alternating	Synchronous	Synchronous	Synchronous
	Method of Channel Isolation	ON/OFF switch	ON/OFF switch	By software	ON/OFF switch	ON/OFF switch	ON/OFF switch
Regulated Current or Regulated Voltage?		Voltage control	Voltage control	Voltage control	Voltage control	Voltage control	Voltage control
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	Yes	Yes	Yes
Automatic Overload Trip?		No	No	No	No	No	No
Automatic No-Load Trip?		No	No	No	No	No	No
Automatic Shut Off?		Yes	Yes	Yes	Yes	Yes	No
User Override Control?		Yes	Yes	Yes	Yes	Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes	Yes	Yes	No	Yes
	Low Battery?	No	No	No	No	No	No
	Voltage/Current	No	No	No	No	No	No
Timer Range (minutes)		15 min	15 min	5 min, 10min,		20min	
Compliance with Voluntary Standards?		Yes	yes	Yes.	Yes	Yes	Yes
Compliance with 21 CFR 898?		Yes	yes	Yes	Yes	Yes	Yes
Weight (lbs., oz.)		0 lb., 8.21 oz.	0 lb., 8.21 oz.	0 lb., 6.40 oz		0 lb.,0.53 oz.	0lbs, 14.4 oz
Dimensions (in.) [W x H x D]		2.24 x 7.80 x 0.91	2.24 x 7.80 x 0.91	2.32 x 7.87 x 0.83	4.45 x 2.76 x 0..38	3.55 x	6 x 1 x 2.8
Housing Materials and Construction		Enclosure: ABS	Enclosure: ABS	Enclosure: ABS	ABS	silicone	ABS

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K122744, 510(K) SUMMARY, TABLE B: PL009 & PL 009A'S COMPARISON WITH PREDICATE DEVICES

Parameter		PL009 K122744	PL009A K122744	JQ-5C K102598	PP909 K112392	PP907 K112392	PP904 K112392	T1040 K060846
Waveform		Monophasic	Monophasic	Monophasic	Symmetrical biphasic	Symmetrical biphasic	Symmetrical biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum output voltage (Volts +/- 20%) at 500Ω		12.8	12.8	62.4	40.0	68.8	57.6	40.7
Maximum output voltage (Volts +/- 20%) at 2KΩ		51	51	79.2	84.0	88.0	89.6	105.1
Maximum output voltage (Volts +/- 20%) at 10kΩ		368	368	84	92.0	95.2	96.0	154.1
Maximum output current (mA +/- 20%) at 500Ω		15 mA	15 mA	124.8	80.0	137.6mA	115.2	81.4
Maximum output current (mA +/- 20%) at 2KΩ		3.2 mA	3.2 mA	39.6	42.0	44.0mA	44.8	47.8
Maximum output current (mA +/- 20%) at 10KΩ		0.6 mA	0.6 mA	8.4	9.2	9.52mA	9.6	15.4
Duration of primary (depolarizing phase (μSec)		40 nsec	40 nsec	N/A	N/A	N/A	N/A	N/A
Pulse Duration (μSec)		120-6800 μSec	120-6800 μSec	16.3-781mS	200 μSec (fixed)	200 μSec (fixed)	200 μSec (fixed)	4.1~500mS
Frequency (Hz)		1-100	1-100	61.3	35	2 and 40	2, 5, and 40	245Hz
Net Charge per pulse (μC) at 500Ω		18000 μC	18000 μC		0.3200	1.1008	0.2304	4.07
Maximum charge (μC) at 500Ω		23 μC	23 μC	17.92	16.0	27.52	23.04	16.9
Maximum current density (mA/cm^2) at 500Ω		1.4 mA/cm^2	1.4 mA/cm^2	9.92	1.964	3.378	2.828	2.71
Maximum average power density (W/cm^2) at 500Ω		0.23 W/cm^2	0.23 W/cm^2	2.72	0.078	0.232	0.163	5.35 (mW/cm^2)
Burst Mode	(a) Pulse per burst	1	1	N/A	1	N/A	N/A	N/A
	(b) Burst per second	0-25	0-25	N/A	4	N/A	N/A	N/A
	(c) Burst-duration (sec)	1	1	N/A	2	N/A	N/A	N/A
	(d) Duty Cycle	5	5	N/A	8	N/A	N/A	N/A
ON time (sec)		Potentiometer switch	Potentiometer switch	N/A	120	120	120	N/A
OFF time (sec)		Potentiometer switch	Potentiometer switch	N/A	0	0	0	N/A
Additional features		N/A	N/A	N/A	N/A	N/A	N/A	N/A

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K122744, 510(K) SUMMARY, TABLE C: PL029'S COMPARISON WITH PREDICATE DEVICES

Parameters		PL029 K122744	JQ-5C K102598	PP909 K112392	PP907 K112392	PP904 K112392	T1040 K060846
Waveform		Monophasic	Monophasic	Symmetrical biphasic	Symmetrical biphasic	Symmetrical biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum output voltage (Volts +/- 20%) at 500Ω		49.6	62.4	40.0	68.8	57.6	40.7
Maximum output voltage (Volts +/- 20%) at 2KΩ		99.2	79.2	84.0	88.0	89.6	105.1
Maximum output voltage (Volts +/- 20%) at 10kΩ		114	84	92.0	95.2	96.0	154.1
Maximum output current (mA +/- 20%) at 500Ω		18 mA	124.8	80.0	137.6mA	115.2	81.4
Maximum output current (mA +/- 20%) at 2KΩ		3.2 mA	39.6	42.0	44.0mA	44.8	47.8
Maximum output current (mA +/- 20%) at 10KΩ		0.6 mA	8.4	9.2	9.52mA	9.6	15.4
Duration of primary (depolarizing phase (μSec)		40 msec	N/A	N/A	N/A	N/A	N/A
Pulse Duration (μSec)		100-200 μSec	16.3-781mS	200 μSec (fixed)	200 μSec (fixed)	200 μSec (fixed)	4.1~500mS
Frequency (Hz)		0.5-86Hz	61.3	35	2 and 40	2, 5, and 40	245Hz
Net Charge per pulse (μC) at 500Ω		18000 μC		0.3200	1.1008	0.2304	4.07
Maximum charge (μC) at 500Ω		23	17.92	16.0	27.52	23.04	16.9
Maximum current density (mA/cm^2) at 500Ω		1.4 mA/cm^2	9.92	1.964	3.378	2.828	2.71
Maximum average power density (W/cm^2) at 500Ω		0.23 W/cm^2	2.72	0.078	0.232	0.163	5.35 (mW/cm^2)
Burst Mode	A. Pulse per burst	1	N/A	1	N/A	N/A	N/A
	B.Burst per second	0-7	N/A	4	N/A	N/A	N/A
	C.Burst-duration (sec)	1	N/A	2	N/A	N/A	N/A
	D.Duty Cycle	7	N/A	8	N/A	N/A	N/A
ON time (sec)		40 ms	N/A	120	120	120	N/A
OFF time (sec)		18 ms	N/A	0	0	0	N/A
Additional features		N/A	N/A	N/A	N/A	N/A	N/A

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

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Tyece OTC TENS Device
Model SEM 44

Instructions for Use

Please read these instructions carefully before use

Indication for Use:

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household activities.

Rev: 03.22.15

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

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Warning:

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities
- Metals Implants or Electronic Auxiliary Devices
- Diabetes or Abnormal High Blood Pressure
- A tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

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User Instructions

Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Tyece OTC TENS Device, Model SEM44".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
Danger	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
Warning	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol
Refers to prohibitive action in the proper use of the unit. The specific forbidden

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content is indicated inside the circle. The left picture means no dismantling.	
	Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. The left picture means general compulsion.
	BF Isolated Applied Part

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

2. Precautions

1) Do not use Device during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over areas of the skin which lack normal sensation.
5) Do not use the products near the heart; it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) The Device must be kept out of the reach of children.
8) The Device should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the Device and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical shock, do not connect two pads to each other
12) Do not apply pads to the same spot for over 40 minutes at a time.
13) Do not use the Device while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.
17) Never use this product near a microwave oven, or other high frequency equipment.
18) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

3. Contraindication

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1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions

1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application of electrical 3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your pain, consult with your physician before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this Device.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The upper neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic pad sheet provided.
Place the pads at least 5 cm (1 inch) apart on your skin. The pads should never touch each other.
Always place clean pads in accordance with illustrations provided. Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin.
Do not place on your spine or backbone.
Pads should not touch any metal object, such as a belt buckle or necklace.
Pads should not be placed simultaneously on the soles of both feet.
Pads should not be placed simultaneously on the calves of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads attached to the skin after treatment.

CAUTION WHILE USING UNIT

If the unit is not functioning properly or you feel discomfort, immediately stop using the device.
Do not use for any other purpose except for what it is intended for.

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

Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
Do not pull on the electrode cord during treatment.
Do not use the device while wearing electronic devices such as watches as this may damage the device.
Do not use near a cell phone as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, hold the plug and pull.
Replace the cord when broken or damaged.
Do not throw the batteries into a fire. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
Using pads that are too small or incorrectly applied, could result in discomfort or skin burns

General Precautions

• The long-term effects of electrical stimulation are unknown.
• Apply stimulation to only normal, intact, clean, dry, and healthy skin.
• TENS is not effective in treating the original source or cause of the pain, including headache.
• TENS is not a substitute for pain medications and other pain management therapies.
• TENS devices do not cure disease or injuries.
• TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your phycician
• Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Use caution if stimulation is applied over areas of skin that lack normal sensation.
Keep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
• Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
Keep unit out of the reach of young children. The electrode cord can cause strangulation.
• Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

What is it?

The Tyece OTC TENS Device, Model SEM44 is a multi-program, portable device designed for adults only. It is designed to reduce and relieve muscle pain in the upper and lower back, legs and arms by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.

How does it work?

The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

Symbols

Symbol	Meaning
	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Direct current
	Class II equipment
	Re-back label
	Indoor use only

Included in the delivery

– 1 x digital TENS unit (including belt clip)
– 2 x connection cables
– 4 x adhesive electrodes (50x 50 mm)
– 3 x AAA batteries
– These instructions for use

Replacement items

8 x adhesive electrodes (50 x 50 mm), item no.: 661.22
4 x adhesive electrodes (50 x 100 mm), item no.: 661.21

Damage

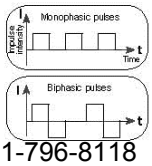
• If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
• Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
• Switch the device off immediately if it is faulty or not working properly.
• Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
• The manufacturer is not liable for damage resulting from improper or careless use.

Current parameters

Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

Impulse form

This describes the time function of the electrical impulse.



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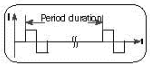
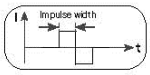
It distinguishes between monophasic and biphasic pulse currents. In monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.

Impulse frequency



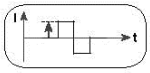
The frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards.

Impulse width



This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.

Impulse intensity

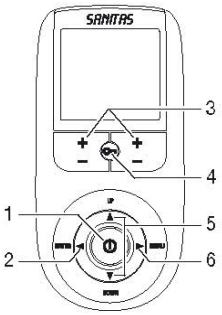


Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided. During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.

Cycled impulse parameter variation

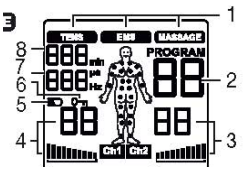
In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the Tyece OTC TENS Device, Model SEM44, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This also prevents individual muscle groups at the site of application being affected by fatigue.
The Tyece OTC TENS Device, Model SEM44 unit provides sensible default current parameter settings. With this, you can change the impulse intensity at any time during use. For 6 programs you can also set various parameters for stimulation yourself.

Unit description



Buttons:

1 ON/OFF button
2 ENTER button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button UP and DOWN
6 MENU button



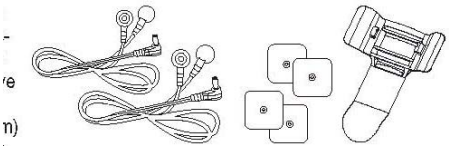
Display (full screen):

1 TENS
2 Program number
3 Impulse intensity channel 2 (CH2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (µs) or pause time
8 Timer function (remaining time display) or working time

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

Accessories:

- 2 x connection cables
- 4 x adhesive electrodes (45 x 45 mm)
- 1 x belt clip



Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP and DOWN

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU

(1) Navigation between the , and MENUs.
(2) Return to program selection screen or MENU selection.

ENTER

(1) MENU selection
(2) Confirmation of a selection made using UP / DOWn , except channel intensity

Intensity setting buttons (+/- left, +/- right) Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.
1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

Initial use

1. Remove the belt clip from the unit (if attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5 V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).
   The electrodes feature clip closures to make connection particularly easy.
7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).
   Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

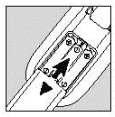


Fig. 1

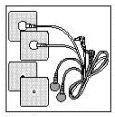
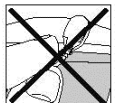


Fig. 2

Fig. 3



Program overview

Fundamentals

The Tyece OTC TENS Device, Model SEM44 features a total of 15 programs.

In all programs you can set the impulse intensity of both channels individually.
You can also set various parameters in the TENS programs 13 – 15 to adjust the stimulating effect to the application area.

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

Information regarding the positioning of electrodes

It is fundamental to the intended success of electrostimulation applications that electrodes are positioned sensibly. We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

The figures displayed are intended as an initial aid to help you position the electrodes.

The following applies to the selection of electrode positions:

Electrode distance

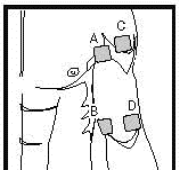
The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:

- Sensible distance: approx. 2-6 inches
- At distances below 2 in, the unit primarily stimulates surface structures intensively
- At distances in excess of 6 in, large areas and deep structures are stimulated very weakly

Relation between electrodes and muscle fibre structures

Adapt the current flow direction to the fibre structure of the muscle according to the muscle layer you would like to treat. If you are targeting superficial muscles, position the electrodes in parallel to the fibre structure (A – B / C – D) and if you are targeting deeper layers of tissue, position the electrodes across the fibre structure. You can do this by positioning electrodes as crosses (i.e. diagonally), such as A – D / B – C.



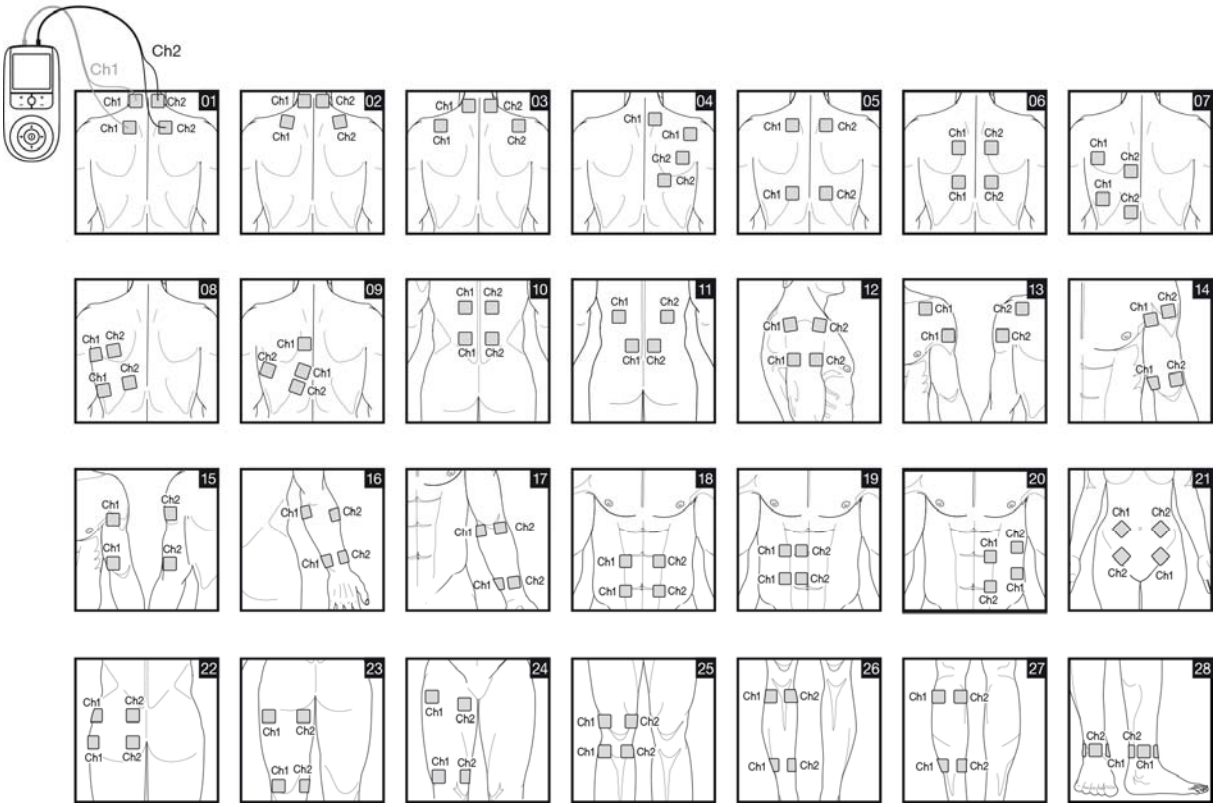
As part of pain relief treatment using the digital Tyece OTC TENS Device, Model SEM44 and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2 in.
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses.

Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

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

Electrode Placement Chart



TENS Programs and their suggested uses

1,2&3 Use for pain in the areas indicated in Electrode Placement Chart 01-17 & 23-28

4 &5 Use on pain in the areas indicated in the Chart 10 &11

6 Use on pain in the areas indicated in the Chart 12,13,25 &28

7 Use on pain in areas indicated in Chart 4-11

8 Use on pain in areas indicated in Chart 12,13,25,28

9 Use on pain in areas indicated in Chart 25

10 Use on pain in areas indicated in Chart 1-2

11&12 Use on pain in areas indicated in Chart 21

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ⓘ TENS programs 13 – 15 can be set individually, see pages 12-13

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve pain, surround the area with electrodes at the front and back as well as on the left and right of the area, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Please note Figures 25 and 28, which apply to areas above and below the knee and lower leg areas.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

Position the electrodes so that they surround the affected muscular segments. For optimum effect, do not exceed an electrode distance of approximately 6 in.

Do not apply the electrodes to the front wall of the chest, i.e. do not apply to the large left and right pectoral muscles.

Use
Information regarding application

• The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the MENU selection and the most recently used MENU flashes.
• A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
• You can pause the stimulation at any time by briefly pressing the ON/OFF button . To continue the stimulation, briefly press the ON/OFF button again and set the desired impulse intensity again.

Procedure for TENS programs 1 – 12,

• Select a suitable program from the program tables (page 11).
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions (page 10) and connect them to the device.
• The figure on the display is intended as an additional aid to help you position the electrodes.

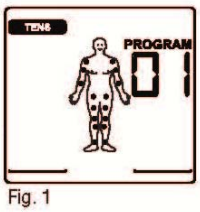
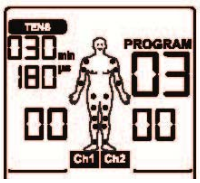


Fig. 1

Selecting a program

• Press the ON/OFF button to switch on the device.
• Press the **MENU** button to activate the TENS program (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.
• Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).



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General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

• Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.
• If the program is in a pause phase, the intensity cannot be increased.
• If you wish to end the stimulation treatment early, press the ON/OFF button.

Fig. 3

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

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Setting your own parameters for individual programs
Setting the treatment duration

(TENS programs 13 – 15 only).
Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treat-ment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

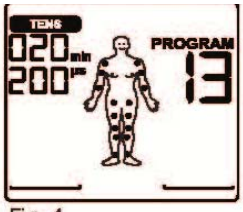
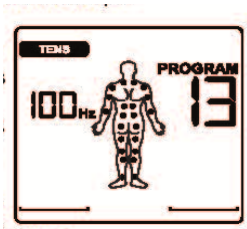


Fig. 4

Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, page 10) and connect them to the device. Select the TENS 13 program, as described in section "Selecting a program" (p. 12).



• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 2, example shows an impulse width of 200 µs).
• Select the desired treatment time, as described in "Setting the treatment time" (p. 12).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 12).

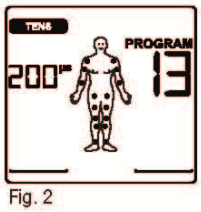
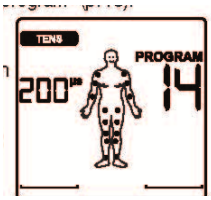


Fig. 2

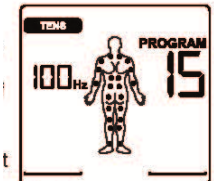
Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 14 program, as described in section"Selecting a program" (p. 11).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
• Select the desired treatment time, as described in "Setting the treatment time" (p. 12).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 12).



Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.
• Place the electrodes on the desired area for treatment (for positioning suggestions see electrode positions, p. 10) and connect them to the device. Select the TENS 15 program, as described in section "Selecting a program" (p. 11).
• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired treatment time, as described in"Setting the treatment time" (p. 12).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 12).



Changing the settings

Changing the intensity (during treatment)

• Ch1 +/- and Ch2 +/-: changes the intensity of each channel

Interrupting stimulation.

Press the ON/OFF button.

Changing application (completely or individual parameters)

• ON/OFF : interrupt stimulation
• Setting the programs, see page 12; setting your own parameters, see page 12.

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

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Doctor's function

The Doctor's function is a special setting to allow you to access your personal program even more easily and directly. Your individual program settings are instantly recalled and activated when the device is switched on.
You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor's function

• Select your program and the corresponding settings as described on page 12.
• At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the Ch2 - button for 5 seconds. Storage in the Doctor's function is confirmed with a long acoustic signal.
If you switch on the device again, the program you saved using the Doctor's function is automatically opened directly.

Deleting the Doctor's function

To clear the device again and to re-allow access to other programs, press and hold the Ch2 - button again for approx. 5 seconds. To do this, the impulse intensity of Ch1 and Ch2 must be set to 00. Deletion of the Doctor's function is confirmed with a long acoustic signal.

Cleaning and storage

Adhesive electrodes

• To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
ⓘ Before cleaning with water, remove the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

• Remove the batteries from the device before cleaning.
• Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
• Do not use any chemical or abrasive cleaning agents.
⚠ Ensure that no water ENTERs the device.

Storage

• Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.
• Do not make sharp bends in the connection cables and electrodes.
• Disconnect the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil after use.
• Store the device and accessories in a cool, well-ventilated space.
• Never place any heavy objects on the device.

Disposal

Warning!

Danger of explosion if wrong type of battery is used as replacement! Replace only with the same or equivalent type recommended by the manufacturer.
DO NOT dispose of batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e.g. to the collecting points for disposal of batteries).

Problems/solutions

The device does not switch when the On/OFF button is pressed. how to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.
(2) Replace batteries, if applicable.
(3) Contact Customer Services.

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

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lintfree cloth. Replace the electrodes if they still do not adhere securely.
(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.
(2) Ensure the connection plug is firmly connected to the device.
(3) Press the ON/OFF button to restart the program.
(4) Check electrode positions and ensure that adhesive electrodes do not overlap.
(5) Gradually increase the impulse intensity.
(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow. However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

Technical specifications

Name and model	Tyece OTC TENS Device, Model SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries (3 x 1.5 V)
Treatment time	Adjustable from 5 to 100 minutes
Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (5.2 x 2.5 x1.2 inches, including belt clip)
Weight	101 g (3.5 oz, including belt clip, without batteries), 127 g (4.5 oz, including belt clip and batteries)
Product Life	5 years
Electrode Pads, Size	50 x 50 mm (2 x 2 in)

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!
We reserve the right to make technical changes to improve and develop the product.
This device complies with US and European standards and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

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

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ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5) Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the Device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The Tyece OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer of the user of the Device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Tyece OTC TENS Device SEM44 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

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

RF emission CISPR 11	Class B	The Tyece OTC TENS Device SEM44 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The Tyece OTC TENS Device SEM44 is intended for use in the electromagnetic environment specified below. The customer or the user of Device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level IEC60601**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and	<5% U_T (>95% dip in U_T)	<5% U_T (>95% dip in U_T)	Mains power quality should be that of a typical commercial or hospital

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voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	environment. If the user of the Device requires continued operation during power mains interruptions, it is recommended that the Device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The OTC TENS Device SEM44 *is* intended for use in the electromagnetic environment specified below. The customer or the user of Device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

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

Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Tyece OTC TENS Device SEM44 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the Tyece OTC TENS Device SEM44.

The Tyece OTC TENS Device SEM44 *is* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Tyece OTC TENS Device SEM44 as recommended below, according to the maximum output power of the

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communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Limited Lifetime Warranty for Original Purchaser

Your TYECE OTC TENS Device SEM44, excluding all enclosed accessories as these require routine maintenance, is warranted to be free from defects in materials and workmanship for the life of the product under normal conditions of intended use and service. This warranty extends only to the original retail purchaser and does not extend to retailers or subsequent owners.

We will, at our option, repair or replace the Tyece OTC TENS Device SEM44, without charge, for any part or parts covered by these written warranties. No refunds will be given. Repair or replacement is our only responsibility and your only remedy under this written warranty. If replacement parts for defective materials are not available, the manufacturer/distributor reserves the right to make product substitutions in lieu of repair or replacement.

For warranty service contact our customer service department at **1-800-740-0287** to provide a description of the problem. If the problem is deemed to be within the scope of the limited lifetime warranty, you will be asked to mail the product at your costs in its original package with proof of purchase, your name, address and phone number. If the problem is not deemed to be within the scope of the limited lifetime warranty, we will provide quotation for repair, respectively, replacement and return shipping fee.

This warranty does not cover damage caused by misuse or abuse; accident; failures of the atomizer, tubing, or accessories; parts or cleaning solutions; the attachment of unauthorized accessories; alteration to the product; improper installation; misapplication; lack of reasonable care with respect to the product; unauthorized repairs or modifications; improper use of electrical/power supply; normal wear; loss of power; dropped product; malfunction or damage of an operating part as a result of failure to comply with instructions for use or to provide

manufacturer's recommended maintenance; transit damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of the manufacturer/distributor. This warranty is void if the product is ever used in a commercial or business environment. The maximum liability of Tyece under this warranty is limited to the purchase price actually paid by the customer for the product covered by the warranty, as confirmed by proof of purchase, regardless of the amount of any other direct or indirect damage suffered by the customer.

This warranty is effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adaptation to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THE WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. ANY IMPLIED WARRANTIES, OBLIGATIONS, OR LIABILITES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS APPLICABLE WRITTEN WARRANTY. Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL TYECE BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES FOR BREACH OF THIS OR ANY OTHER WARRANTY, EXPRESS, IMPLIED OR ANY OTHER THEORY OF LIABILITY, WHATSOEVER. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

Tyece does not authorize anyone, including, but not limited to, retailers, the subsequent consumer purchaser of the product from a retailer or remote purchaser, to obligate the manufacturer/distributor in any way beyond the terms set forth herein.

This warranty does not extend to the purchase of opened, used, repaired, repackaged and/or resealed products, including but not limited to sale of such products on Internet auction sites and/or products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate in connection with any products or parts thereof which are repaired, replaced, altered, or modified, without the prior explicitly written consent of the manufacturer/distributor.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state.

Manufacturer: Savia Electronics, Ltd.
4th Industrial District, Feng Huang Village,
Fu Yong County, Bao an District
Shenzhen, China
Tel: 0755-27306741, Fax: 0755-27306744, Email: info@savia.com

Distributed By: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
www.cvs.com Service: 1-800-shop-cvs (1-800-740-0287)

(b)(4) Third Party Software Analysis Report

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K150386 / S002 40

FDA/CDRH/DCC
SEP 30 2015
RECEIVED

MTC *Media Trade Corporation*

11820 Red Hibiscus Drive – Bonita Springs, FL 34135
Tel (239) 948-2001 – Fax (239) 948-2002
e-mail: mediatradecorp@gmx.net

eCopy Cover Letter

Date: Sep.28, 2015

To: US Food and Drug Administration
Att: Ashlee Jones
Center for Devices and Radiological Health
Document Control Center, WO66-G609
10903 New Hampshire Ave.
Silver Springs, MD 20993-0002

Re: **eCopy for Tyece OTC TENS Device, K150386**

Dear Ms/Mr,

We hereby state that **the eCopy is an exact duplicate of the documents** submitted.

Thank you and with best regards,

Guenter Ginsberg
President MTC
Official Correspondent & US Agent
for Tyece Co., Ltd

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

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

ADDITIONAL INFORMATION REQUESTED FOR K150386-S001

Date: Sept. 27, 2015

To: Erin Keegan, M.S.
Biomedical Engineer, DNPMD/NSDB

From: Guenter Ginsberg - on behalf of Tyece Ltd.
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135

Subject: Additional Information requested for K150386-S001
Tyece OTC TENS Device, Model SEM44

Dear Ms. Keegan:
We like to answer your request for additional information as follows:

(b)(4) Deficiencies

[redacted]

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

(b)(4) Deficiencies

[redacted]

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[redacted]

Ms. Keegan, we hope that we have answered all your questions satisfactory. Please do not hesitate to contact us for further clarification.

Best regards,

Guenter Ginsberg

Records processed under FOIA Request # 2016-301; Released by CDRH on 03-15-2016

510(k) SUMMARY (revised 6.30.2015)

Date of Summary Prepared: 02/05/2015

1. Submitter's Name: Tyece Ltd.

Address: Unit 801, Block A, Po Lung Centre, 11 Wang Chiu Rd., Kowloon Bay, Kowloon, Hong Kong, SAR

Contact person: Parshid Falahati

Tel: 852- 2 - 3497456

Fax: 852 -2 - 3499166

E-mail sales@tyece.com

2. Proposed New Device:

Trade Name: Tyece OTC TENS Device, Model SEM44
Classification Name: TENS
Regulation Number: 882.5890
Product Code: NUH
Device Class: II

3. Predicate (cleared) Device:

Counter TENS Device, Model PTS-IV

510(k) Number: K132993

Manufacturer: Counter Scientific Development Ltd.

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

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4. Description of Proposed Device:

The Tyece OTC TENS Device, Model SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 0 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under K132588.
The device has been tested to and meets the requirements of the following recognized consensus standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

5. Indication for Use:

This Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the lower back, arms, or legs due to strain from exercise or normal household work activities.

6. Environment of Use:

Clinics, Hospitals and home environments

7. Contraindications:

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

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

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Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

8. Technological Characteristics Compared to the Predicate Device

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle pain relief, Model PTS-IV, The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle areas. Outputs are almost the identical, each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500 Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both devices are transiting pulses by the use of Electrode Pads. Both are portable devices. Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicate device. The differences that exist between the devices are insignificant in terms of safety or effectiveness.

Differences:
1. Device SEM44 has 15 preset programs, while the predicate device has 7.
2. Intensity levels of SEM44 are selectable from 0 to 50, while the predicate device is from 0 to 16, however, the maximum intensity settings of both units produce very similar outputs to the electrode pads. The SEM44 model can be adjusted in finer increments.
3. All other parameters such as waveform, frequency, pulse width, output current and voltage, although not exactly similar to this particular predicate, they do not raise any new questions of safety or effectiveness.

Note: It is very difficult, if not impossible, to find predicate devices that completely match the specifications of the subject device.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Savia did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the SEM44 vs. the predicate. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

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

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IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

a. **EMC and electrical safety**

IEC 60601-1:2005+Corr.1(2006)+Corr.2(2007) + AM1 (2012), EN 60601-1:2006/A1:2013 general requirements for basic safety and essential performance

IEC 60601-2-10 Edition 2.0 2012-08 basic safety and essential performance of nerve and muscle stimulators. (Neurology)

IEC 60601-1-2 Edition 2007-03 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC)

IEC 60601-1-11 First Edition: 2010 medical electrical equipment – part 1-11: general requirement for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

b. **Biocompatibility**

The electrode pads are the only body contacting parts. They have been FDA cleared for OTC under K132588. The patient contacting electrodes comply with ISO 10993 and are considered Class A $\leq$ 24 hrs contact.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. The software of this device carries a MODERATE level of concern. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

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

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d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Tyece OTC TENS Device, Model SEM44 can be cleaned by the use of the methods described in the Instruction Manual.

10. Conclusions:

The Tyece OTC TENS Device, Model SEM44 has the same intended use and similar technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the predicate device.

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

Output Specifications:

Parameter		Your device	Predicate Device
Mode or Program Name		PAIN THERAPY DEVICE, SEM44	PAIN THERAPY DEVICE, PTS-IV
Waveform (e.g. positive-going, reverse, biphasic)		Biphasic	Positive-going, Reverse and Biphasic
Shape(e.g., spike, rectangular, square ware)		Square ware	Square ware
Maximum Output Voltage (Volts) (+/-15%)		70vp p@500 Ω	69.2vp p@500 Ω
		110vp p@2K Ω	86.4vp p@2K Ω
		190vp p@10K Ω	88.8vp p@10K Ω
Maximum Output Current (+/-15%)		86mA@500 Ω	69.2mA@500 Ω
		23.3mA@2K Ω	21.6mA@2K Ω
		3.75mA@10K Ω	4.4mA@10K Ω
Duration of primary Phase		0	0
Pulse Duration		50-360μS	200μS
Frequency		1-150Hz	1-136Hz
For multi Program waveforms only:	Symmetrical Programs	N/A	N/A
	Pulse duration		
Net Charge (micro coulombs μC) (per pulse) (if zero, State method of achieving zero net charge)		0.001μC@500 Ω	0.0013μC@500 Ω
Maximum Phase Charge (mC)		0.0454mC@500 Ω	0.0135mC@500 Ω
Maximum Current Density (mA/cm2, r.m.s)		0.790mA/cm2@500 Ω	3.270mA/cm2@500 Ω
Maximum Average Current (average absolute value), mA		16.0mA	2.218mA
Maximum Average Power Density, (W/cm2)(using smallest electrode conductive surface area)		0.00632W/cm2@500 Ω 1.0S	0.00116W/cm2@500 Ω 1.0S
Burst Mode(i.e. pulse trains)	(a) Pulses per burst	4	4/2
	(b) Bursts per second	4/83Hz	30/136Hz
	(c) Burst duration (seconds)	180μS	800μS/400μS
	(d) Duty Cycle	35ms/60ms	24ms/54.4ms
ON Time (seconds)		2s	0.5s
OFF Time (seconds)		2s	0.5s
Additional Features (specify, if applicable)		N/A	N/A
Electrode area:		20.25sqcm x 4 (81sqcm)	21.16sqcm x 4(84.64sqcm)

Basic Unit Characteristics:

Parameter		Your Device	Predicate Device
510(k) Number		K150386	K132993
Device Name and See attached photo Program		PAIN THERAPY DEVICE SEM44	PAIN THERAPY DEVICE PTS-IV
Manufacturer		SAVIA LTD.	COUNTER Scientific Development (GZ) Limited
Power Source		4.5V(batteries, 3x1.5V AAA)	3.7v Lithium (Power supply)
Method of Line Current Isolation		N/A	N/A
Patient Leakage Current		N/A	N/A
Normal Condition (μA)		N/A	N/A
Single Fault Condition (μA)		N/A	N/A
Average DC current through electrodes when device is on but no pulse are being applied (μA)		0μA	0μA
Numbers of Output Modes		15 Modes(01-15)	7 modes(A,B,C,D,E,F,ALL)
Number of Output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	PCB Insulation Boost Isolation	Boost Isolation
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage
Software/firmware/microprocessor control?		Yes	Yes
Automatic overload trip?		No	No
Automatic no-load trip?		Yes	Yes
Automatic shut off?		Yes	Yes
Users override control?		Yes	Yes
Indicator display	On/off status?	Yes	Yes
	Low battery?	Yes	Yes
	Voltage/current level? Only voltage level display	Yes for voltage	Yes for voltage
Timer range (minutes)		5-100min	20-40 min
Compliance with voluntary standards?		Yes	Yes
Compliance with 21CFR898-7?		Yes	Yes
Dimensions		L135xW65xT20mm	L120xW70xT18mm
Housing materials and construction		ABS	ABS

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Substantial Equivalence Discussion

Predicate Device Description：

The predicate device chosen is from Counter Scientific Development (GZ) Ltd.

Sponsor: Counter Scientific Development (GZ) Ltd.
2nd & 3rd Floor, Bld.6, DaPian Industrial Zone,
Tangxia Rd., Tianhe District,
Guangzhou 510665, China

Device：Counter TENS Device
See attached photo Program: PTS-IV
510(k) No: K132993

The Tyece OTC TENS Device, Model SEM44 is substantially equivalent to the Counter healthcare product OTC TENS for muscle pain relief, Model PTS-IV. The function, performance, and intended use of the two devices are very similar. Both systems are designed to relief pain in the muscle areas. Outputs are almost the identical. Each can produce square electronic pulses and positive-going, reverse and bidirectional waveform output. Each can produce an asymmetrical biphasic pulse with peak voltages up to 60/70 volts on 500Ohms load. Both devices have selection modes to allow users to select preset programs and adjust intensity level by pressing the keypad on the main unit. Both devices are transmitting pulses by the use of Electrode Pads. Both are portable devices. Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicate device. The differences that exist between the devices are insignificant in terms of safety or effectiveness.
More specific comparisons can be found in the following tables, graphs, photos, specifications etc.

Differences:

1. Device SEM44 has 15 preset programs, while the predicate device has 7.
2. Intensity levels of SEM44 are selectable from 0 to 50, while the predicate device from level 1 to 16, However, the maximum intensity setting of both units produce very similar output current and voltage outputs to the electrode pas. The SEM44 model can be adjusted in finer increments.
3. All other parameters such as waveform, frequency, output current and voltage, although not exactly similar to this particular predicate, they do not raise any new questions of safety or effectiveness.
4. Note: it is very difficult, if not impossible, to find predicate devices that completely match the specifications of the subject device.

Conclusion:

The comparison with the predicate device along with the non-clinical testing demonstrates that the Model SEM44 is safe, effective and performs as well as the predicate device PTS-IV and is therefore substantially equivalent to the predicate device.

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

Output Specifications:

Parameter		Your device	Predicate Device
Mode or Program Name		PAIN THERAPY DEVICE, SEM44	PAIN THERAPY DEVICE, PTS-IV
Waveform (e.g. positive-going, reverse, biphasic)		Biphasic	Positive-going, Reverse and Biphasic
Shape(e.g., sp ke, rectangular, square ware)		Square ware	Square ware
Maximum Output Voltage (Volts) (+/-15%)		70vp p@500 Ω	69.2vp p@500 Ω
		110vp p@2K Ω	86.4vp p@2K Ω
		190vp p@10K Ω	88.8vp p@10K Ω
Maximum Output Current (+/-15%)		86mA@500 Ω	69.2mA@500 Ω
		23.3mA@2K Ω	21.6mA@2K Ω
		3.75mA@10K Ω	4.4mA@10K Ω
Duration of primary Phase		0	0
Pulse Duration		50-360μS	200μS
Frequency		1-150Hz	1-136Hz
For multi Program waveforms only:	Symmetrical Programs	N/A	N/A
	Pulse duration		
Net Charge (micro coulombs μC) (per pulse) (if zero, State method of achieving zero net charge)		0.001μC@500 Ω	0.0013μC@500 Ω
Maximum Phase Charge (mC)		0.0454mC@500 Ω	0.0135mC@500 Ω
Maximum Current Density (mA/cm2, r.m.s)		0.790mA/cm2@500 Ω	3.270mA/cm2@500 Ω
Maximum Average Current (average absolute value), mA		16.0mA	2.218mA
Maximum Average Power Density, (W/cm2)(using smallest electrode conductive surface area)		0.00632W/cm2@500 Ω 1.0S	0.00116W/cm2@500 Ω 1.0S
Burst Mode(i.e. pulse trains)	(a) Pulses per burst	4	4/2
	(b) Bursts per second	4/83Hz	30/136Hz
	(c) Burst duration (seconds)	180μS	800μS/400μS
	(d) Duty Cycle	35ms/60ms	24ms/54.4ms
ON Time (seconds)		2s	0.5s
OFF Time (seconds)		2s	0.5s
Additional Features (specify, if applicable)		N/A	N/A
Electrode area:		20.25sqcm x 4 (81sqcm)	21.16sqcm x 4(84.64sqcm)

Basic Unit Characteristics:

Parameter		Your Device	Predicate Device
510(k) Number		K150386	K132993
Device Name and See attached photo Program		PAIN THERAPY DEVICE SEM44	PAIN THERAPY DEVICE PTS-IV
Manufacturer		SAVIA LTD.	COUNTER Scientific Development (GZ) Limited
Power Source		4.5V(batteries, 3x1.5V AAA)	3.7v Lithium (Power supply)
Method of Line Current Isolation		N/A	N/A
Patient Leakage Current		N/A	N/A
Normal Condition (μA)		N/A	N/A
Single Fault Condition (μA)		N/A	N/A
Average DC current through electrodes when device is on but no pulse are being applied (μA)		0μA	0μA
Numbers of Output Modes		15 Modes(01-15)	7 modes(A,B,C,D,E,F,ALL)
Number of Output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	PCB Insulation Boost Isolation	Boost Isolation
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage
Software/firmware/microprocessor control?		Yes	Yes
Automatic overload trip?		No	No
Automatic no-load trip?		Yes	Yes
Automatic shut off?		Yes	Yes
Users override control?		Yes	Yes
Indicator display	On/off status?	Yes	Yes
	Low battery?	Yes	Yes
	Voltage/current level? Only voltage level display	Yes for voltage	Yes for voltage
Timer range (minutes)		5-100min	20-40 min
Compliance with voluntary standards?		Yes	Yes
Compliance with 21CFR898-7?		Yes	Yes
Dimensions		L135xW65xT20mm	L120xW70xT18mm
Housing materials and construction		ABS	ABS

SEM44 Technical Specifications:

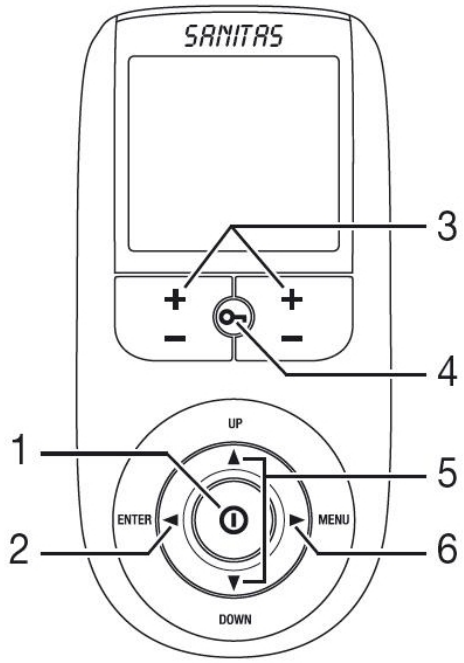
Output channel: Two
Output wave form: Biphasic rectangular pulse
Power supply: 3 x 1.5V AAA batteries

Buttons:

-

Buttons:

1 ON/OFF button
2 **ENTER** ◀ button
3 Intensity setting buttons (**Ch1** **+/-** left, **Ch2** **+/-** right)
4 Keylock
5 Selection button ▲ **UP** and ▼ **DOWN**
6 **MENU** ▶ button



Operation:

A. Before use, connect wires to the main unit and place electrodes on the treatment area
B. Using the UP/DOWN buttons, select the desired program and confirm your selection with the ENTER button.
C. If you wish to return to the previous selection menu, press the MENU button. By holding down the ENTER button, you can skip individual setting steps and start directly with the stimulation treatment.
D. At the start of the stimulation treatment, the impulse intensity is off for each channel and is set to 00 by default. No impulses are sent to the electrodes yet.
E. Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly. The impulse intensity of each channel can be set individually.
F. If the program is in a pause Program, the intensity cannot be increased.
G. If you wish to end the stimulation treatment early, press the ON/OFF button

Special Features:

1. Auto shut-off function:

If the unit is turned On for 2 minutes and the intensity is not increased on either channel beyond level 0,

then the unit turns Off automatically. This is to save battery life.
When the Timer counts down to 0 min, the unit turns off automatically.

2. Auto increase/de-crease function:

The intensity can be increased/decreased by pressing the intensity button CH1 + /- and CH2+/- and keep it pressed. The intensity level changes at 2 steps per second. When the program is changed, the intensity level drops to level 0. It stays at level 0 for 2 seconds before increasing two levels per second back to the previous intensity level. If at any time during the increase of the levels the user wishes to stop the rise in intensity, he can simply do so by pressing the down button on the corresponding channel.
Note: When changing the intensity, the voltage is changing between 1-3 Volts per level (step).

3. ON/OFF function:

To turn On the unit, press the On/Off button once and to turn Off the unit press the On/Off button and hold down for 2 seconds.

4. Pause function testing of the machine:

Any Program can be paused by pressing the On/Off button once. To restart the program, press the On/Off button again.
When a Program is paused, the Pause sign comes on and it flashes at 2 flashes per second. To restart, press the Pause button again and the intensity starts to rise to the original intensity level.

5. Memory function:

The unit stores the last Program and the times it was used when it is shut off (This is only dependent on the internal ROM of the MCU and will be valid as long as the batteries are not removed from the unit)

6. Lock Function:

The buttons on the unit can be locked to prevent any accidental usage. This is done by holding the Keylock button down for 2 seconds. To cancel the keylock, press and hold down the Keylock button for 2 seconds.

7. Program timer function:

Each program has a preset time which is displayed in the timer box. When the timer counts down the program work time counts down to 0. If no other program is selected within this time the device automatically shuts off.

8. Open lead function testing:

The intensity will go to 0 when no-load is detected or if one of the electrodes should come off during use. This is a safety measure.

9. Low voltage check function testing:

When the battery voltage is low, a low battery sign will flash on the LCD at 2 flashes per second

10. Output pulses form the machine

When the intensity on either or both channels is increased to level 1 and up to level 50 the device delivers

electrical pulses through the two output sockets located at the bottom of the unit.

Technical Specifications:

Channels:	Dual
Pulse Intensity:	Adjustable from 0-90mA peak into 500ohm per channel
Output Voltage:	70V(at 500 Ω) 110V(at 2K Ω) 190V(at 10K Ω)
Frequency:	1-150Hz
Pulse Width:	50-360 us
Curve Shape:	Biphasic rectangular pulse
Programs:	15
Power Supply:	3 x 1.5V AAA batteries
Operating Conditions:	10°C-40°C(50°F-104°F) at a relative humidity of 30-85%
Storage Conditions:	-10°C-50°C(14°F-122°F) at a relative humidity of 10-95%
Key to symbols:	Warning！Read the safety information and all instructions to avoid serious injury.

Program	Phase	Pulse Intensity Max.	Pulse Width	Frequency
1	1	(b)(4) [redacted]		
2	1			
3	1			
4	1			
5	1			
6	1			
	2			
7	1			
	2			
8	1			
	2			
9	1			
10	1			
11	1			
12	1			
13	1			
14	1			
15	1			

SEM44: Program Description

Program	Description	Frequency (HZ)	Running Times (Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times (Min)	Waveform
1	PHASE 1	(b)(4) [redacted]							SEE ATTACHED PHOTO PROGRAM 1
2	PHASE 1								SEE ATTACHED PHOTO PROGRAM 2
3	PHASE 1								SEE ATTACHED PHOTO PROGRAM 3
4	PHASE 1								SEE ATTACHED PHOTO PROGRAM 4
5	PHASE 1								SEE ATTACHED PHOTO PROGRAM 5
6	PHASE 1 PHASE 2								SEE ATTACHED PHOTO PROGRAM 6
7	PHASE 1 PHASE 2								SEE ATTACHED PHOTO PROGRAM 7
8	PHASE 1 PHASE 2								SEE ATTACHED PHOTO PROGRAM 8
9	PHASE 1								SEE ATTACHED PHOTO PROGRAM 9

10	PHASE 1	(b)(4) [redacted] (b)(4)	SEE ATTACHED PHOTO PROGRAM 10
11	PHASE 1	[redacted]	SEE ATTACHED PHOTO PROGRAM 11
12	PHASE 1	[redacted]	SEE ATTACHED PHOTO PROGRAM 12
13	PHASE 1	[redacted]	SEE ATTACHED PHOTO PROGRAM 13
14	PHASE 1	[redacted]	SEE ATTACHED PHOTO PROGRAM 14
15	PHASE 1	[redacted]	SEE ATTACHED PHOTO PROGRAM 15

(b)(4) Parameter and Waveform Photos

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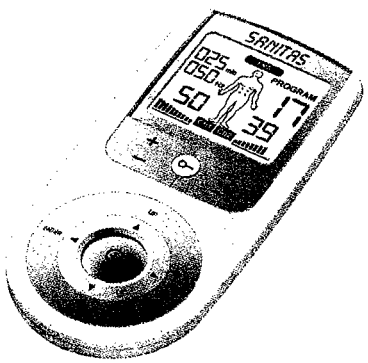
Tyece OTC TENS Device
Model SEM 44

Instructions for Use



Please read these instructions carefully before use

Indication for Use:

The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the lower back, arms, or legs due to strain from exercise or normal household activities.

Rev: 09.26.15

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

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User Instructions

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Safety Precautions

• The graphic warning symbols indicated below are for the purpose of ensuring the safe and correct use of the "Tyece OTC TENS Device, SEM44".

• Please take time to read them as they will prevent harm to yourself and other parties through improper use of this product and its accessories.

Warning Symbol	Meaning
⚠ **Danger**	This device must not be used in combination with the following other devices: pacemakers, respirators, electrocardiographs and other electronic equipment.
⚠ **Warning**	Indicates a potential hazardous situation which, if not avoided, could result in death or serious injury.
⚠ **Caution**	Indicates a potential hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient.

Graphic Symbol
⊘ Refers to prohibitive action in the proper use of the unit. The specific forbidden content is indicated inside the circle. ⊘ The left picture means no dismantling.
❗ Refers to required action in the proper use of the unit. The specific enforced content is indicated inside the circle. ❗ The left picture means general compulsion.
BF Isolated Applied Part

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

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1. Contraindication

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

PAIN MANAGEMENT WARNINGS

If you have had medical or physical treatment for your pain, consult with your physician before using this device.
If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician. The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Device.

2. Warnings

- If you are in the care of a physician! consult with your physician before using this device;
- If you have had medical or physical treatment for your pain, consult with your physician before using this device;
- If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult with your physician;
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- Do not apply stimulation over, or in proximity to, cancerous lesions;
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
- Do not apply stimulation when in the bath or shower;
- Do not apply stimulation while sleeping;
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury; and
- Do not use the device on children, if it has not been evaluated for pediatric use.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals; and
- Apply stimulation only to normal, intact, clean, healthy skin.

3. Precautions

- TENS is not effective for pain of central origin, including headache;
- TENS is not a substitute for pain medications and other pain management therapies;
- TENS devices have no curative value;
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients
- The long-term effects of electrical stimulation are unknown;
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head
- The safety of electrical stimulation during pregnancy has not been established;
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);

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

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- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician; and
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;
- Use caution if stimulation is applied over the menstruating or pregnant uterus; and use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children; and
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer (also see Note on page 5).

4. Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
- You may experience headache and other painful sensations during or following the application of electric stimulation near your eyes and to your head and face; and
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process. If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

NEVER APPLY THE PADS TO:

- The upper neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- The head or any area of the face.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

Do not bend or fold because the pad may not function properly. Store on the plastic pad sheet when not in use.
Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
The pads are already pre-gelled and will adhere to your skin.
To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic pad sheet provided.
Place the pads at least 5 cm (1 inch) apart on your skin. The pads should never touch each other.
Always place clean pads in accordance with illustrations provided. Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin.
Do not place on your spine or backbone.
Pads should not touch any metal object, such as a belt buckle or necklace.
Pads should not be placed simultaneously on the soles of both feet.
Pads should not be placed simultaneously on the calves of both legs.
Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
Do not place or relocate the pads while the device is on.
Always turn the power off before removing or changing the pad location.
Do not leave pads attached to the skin after treatment.

⚠ **CAUTION WHILE USING UNIT**

If the unit is not functioning properly or you feel discomfort, immediately stop using the device.
Do not use for any other purpose except for what it is intended for.
Do not insert the electrode plug into any place other than the jack on the main unit.
Do not mix Alkaline and Manganese batteries as this will shorten the battery life.

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

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Do not pull on the electrode cord during treatment.
Do not use the device while wearing electronic devices such as watches as this may damage the device.
Do not use near a cell phone as this may cause the stimulator to malfunction.
Do not bend or pull the end of the cord.
When pulling out the cord from the device, hold the plug and pull.
Replace the cord when broken or damaged.
Do not throw the batteries into a fire. The batteries may explode.
Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
Using pads that are too small or incorrectly applied, could result in discomfort or skin burns.

Note: Use only electrodes of the type supplied and recommended by the manufacturer, namely: Top Rank Health Care Corp. Adhesive Electrodes, #661.22

What is it?

The Tyece OTC TENS Device, Model SEM44 is a multi-program, portable device designed for adults only. It is designed to reduce and relieve muscle pain in the lower back, legs and arms by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It can be successfully used in conjunction with any other pain treatment or medication.
This type of therapy, called Transcutaneous Electrical Nerve Stimulator (TENS), has been used for over 30 years by medical professionals such as physical therapists and chiropractors.

Symbols

Symbol	Meaning
	Attention, consult accompanying documents
	BF Isolated Applied Part
CE0120	CE Mark
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Direct current
	Class II equipment
	Re-back label
	Indoor use only

Included in the delivery

- 1 x digital TENS unit (including belt clip)
- 2 x connection cables
- 4 x adhesive electrodes (45x 45 mm) (Top Rank Health Care Corp. Adhesive Electrodes #661.22)
- 3 x AAA batteries
- These instructions for use

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

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Damage

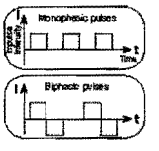
• If the device is damaged, do not use it and contact your retailer or the specified Customer Services address.
• Check the device for signs of wear and tear or damage. If there are such signs of wear and tear or damage or if the device was used improperly, it must be returned to the manufacturer or retailer before further use.
• Switch the device off immediately if it is faulty or not working properly.
• Do not attempt to open and/or repair the device yourself. Repairs may only be carried out by Customer Services or authorised retailers. Failure to comply will result in voiding of the warranty.
• The manufacturer is not liable for damage resulting from improper or careless use.

Current parameters

Electrostimulation units operate with the following current settings, which may affect stimulation effects differently, depending on the setting:

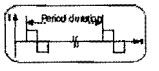
Impulse form

This describes the time function of the electrical impulse.
As monophasic pulse currents, the current flows in one direction and in biphasic pulse currents the electrical impulse alternates its direction.



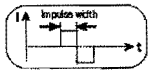
Impulse frequency

The frequency indicates the number of individual impulses each second and is given in Hz (Hertz). It can be calculated by determining the cyclic value for the time period. The relevant frequency determines which types of muscle fibres react favourably. Slow-reacting fibres react more easily to lower impulse frequencies up to 15 Hz, whereas fast-reacting fibres only respond from approximately 35 Hz onwards.



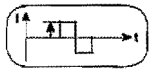
Impulse width

This indicates the duration of an individual impulse in microseconds. The impulse width therefore determines, among other things, the penetration of the electricity, where usually: larger muscle masses require larger impulse widths.



Impulse intensity

Setting the intensity levels depends on the individual sensitivity of each user and is determined by a variety of variables, such as site of application, blood circulation to the skin, skin thickness and the quality of the electrode contact. The setting used should be effective but should never cause an unpleasant sensation, such as pain, at the site of application. While a gentle tingling indicates sufficient stimulation energy levels, any setting that causes pain should be avoided. During longer applications it may be necessary to make readjustments due to the adjustment processes over time at the site of application.



Cycled impulse parameter variation

In many cases it is necessary to cover the overall tissue structure at the site of application by applying several impulse parameters. In the TENS Device SEM44, this is achieved by the provided programs, which automatically make a cyclical impulse parameter change. This also prevents individual muscle groups at the site of application being affected by fatigue.
The TENS Device SEM44 unit provides 12 sensible default current parameter settings. With this, you can change the impulse intensity at any time during use.
For 3 programs (13,14,15) you can also set various parameters for stimulation yourself.

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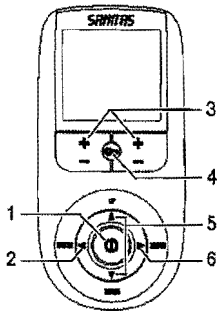
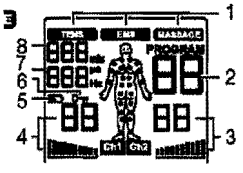
Unit description



Buttons:

1 ON/OFF button
2 ENTER button
3 Intensity setting buttons (Ch1 +/- left, Ch2 +/- right)
4 Keylock
5 Selection button UP and DOWN
6 MENU button

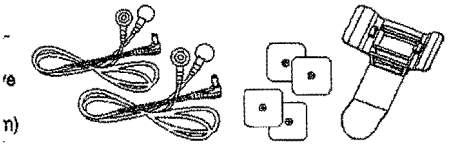


Display (full screen):

1 TENS
2 Program number
3 Impulse intensity channel 2 (CH2)
4 Impulse intensity channel 1 (Ch1)
5 Low battery
6 Keylock
7 Frequency display (Hz), pulse width (µs) or pause time
8 Timer function (remaining time display) or working time

Accessories:

- 2 x connection cables
- 4 x adhesive electrodes (45 x 45 mm)
- 1 x belt clip



Button functions

Each time you press a button, the unit emits an acoustic signal to notify you in case you are pressing any buttons unintentionally. This acoustic signal cannot be switched off.

ON/OFF

(1) Press briefly to switch the device on.
(2) Press once to interrupt stimulation treatment.
(3) Press and hold to switch off the device (approx. 2 seconds).

UP and DOWN

Choice of treatment program, treatment time, frequency, pulse width, working time and pause time.

MENU

(1) Navigation between the , and MENUs.
(2) Return to program selection screen or MENU selection.

ENTER

(1) MENU selection
(2) Confirmation of a selection made using UP / DOWn , except channel intensity

Intensity setting buttons (+/- left, +/- right) Adjusting the impulse intensity

Keylock

Locks the buttons to avoid them being pressed unintentionally.
1) To activate the keylock, hold down the button until the symbol is visible in the display (approx. 3 seconds).
(2) To deactivate the keylock, hold down the button until the symbol disappears from the display (approx. 3 seconds).

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Initial use

1. Remove the belt clip from the unit (if attached).
2. Press the battery compartment cover on the rear of the device and slide it downwards.
3. Insert the three alkaline AAA 1.5 V batteries. Make sure that the batteries are inserted the correct way round.
4. Close the battery compartment lid again carefully (Fig. 1).
5. Reattach the belt clip, if required.
6. Connect the connection cables with the electrodes (Fig. 2).
   The electrodes feature clip closures to make connection particularly easy.
7. Guide the connection cable plugs into the socket on the top of the device (Fig. 3).
8. Do not pull, twist or make sharp bends in the cables (Fig. 4).
   Please note that when the battery is replaced or removed, all settings are restored to the factory default settings.

Fig. 1

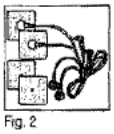
Fig. 2

Fig. 3

Program overview
Fundamentals

The TENS Device SEM44 features a total of 15 programs.

In all programs you can set the impulse intensity of both channels individually.
You can also set various parameters in the TENS programs 13 – 15 to adjust the stimulating effect to the application area.

Information regarding the positioning of electrodes

It is fundamental to the intended success of electrostimulation applications that electrodes are positioned sensibly. We recommend that you consult your doctor to establish the ideal electrode positions for your intended application area.

The figures displayed are intended as an initial aid to help you position the electrodes.

The following applies to the selection of electrode positions:

Electrode distance
The larger the distance between electrodes, the larger the stimulated tissue volume. This applies to the area and depth of the tissue volume. At the same time, however, the stimulation intensity of the tissue falls the further the electrodes are apart. As a result, greater distances between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity to boost stimulation.

The following guideline applies to selection of the electrode distance:
- Sensible distance: approx. 2-6 inches
- At distances below 2 in, the unit primarily stimulates surface structures intensively
- At distances in excess of 6 in, large areas and deep structures are stimulated very weakly

As part of pain relief treatment using the digital Tyece OTC TENS Device and its two separately adjustable channels and two adhesive electrodes each, it is advisable either to position the electrodes of a channel so that the area affected by the pain is between the electrodes or to position one electrode directly on the area affected by the pain and the other electrode at a minimum distance of 2 in.
You may use the electrodes of the second channel to simultaneously treat additional areas affected by pain or use them in conjunction with the electrodes of the first channel to restrict the area affected by pain (position electrodes opposite). In this case, we once again recommend positioning electrodes as crosses (diagonal).

Use the electrodes on skin that is clean and preferably free from hair and grease, in order to extend the lifecycle of the electrodes. If required, clean the skin with water and remove hair prior to treatment.

If an electrode should come loose during use, the impulse intensity of both channels is reduced to the lowest level. Apply the electrode again and reset the desired impulse intensity.

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TENS Programs and their suggested uses

- For lower Back pain: use Programs 1 through 12
- For pain in the arms: use Programs 6 & 8
- For pain in the legs: use Programs 6 through 9

ⓘ TENS programs 13 – 15 can be set individually and can be used on all indicated areas.

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve pain, surround the area with electrodes at the front and back as well as on the left and right of the area, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).

Note:
Do not apply the electrodes to the front wall of the chest, i.e. do not apply to the large left and right pectoral muscles.

SEM44 Program Description:

Program	Description	Frequency(HZ)	Running Times (Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times (Min)
1	PHASE 1	83.17	30	Level1-3.92 Level50-71.2	122	Continuous output	1-50	30
2	PHASE 1	99.8	30	Level1-3.76-4.04 Level50-69.6-83.2	80-140	Intermittent output	1-50	30
3	PHASE 1	83.17	30	Level1-3.76 Level50-62.4	180	Continuous output	1-50	30
4	PHASE 1	99.8	30	Level1-3.76 Level50-71.2	128	Continuous output	1-50	30
5	PHASE 1	99.8	30	Level1-3.72 Level50-52	252	Continuous output	1-50	30
6	PHASE 1 PHASE 2	5.01 1-40	20 15	Level1-3.76 Level50-45 Level1-3.88 Level50-45.6	368 368	Program 1 5min and Program 2 15min circulation	1-50 1-50	5 15
7	PHASE 1 PHASE 2	83.17 99.8	30 20	Level1-3.76 Level50-57.2 Level1-3.72 Level50-5.24	204 252	Program1 and Program 2 20 minutes for each in turn	1-50 1-50	20 20
8	PHASE 1 PHASE 2	124.3 99.8	20 10	Level1-4.24 Level50-90.4 Level1-4.56 Level50-52.4	70 252	Program 1 15min and Program 2 20min circulation	1-50 1-50	15 10
9	PHASE 1	71.4	30	Level1-3.92 Level50-76.8	102	Continuous output	1-50	30
10	PHASE 1	83.1	30	Level1-3.92 Level50-76.8	70-110	Intermittent output	1-50	30
11	PHASE 1	110.5	30	Level1-3.76 Level50-72	122	Continuous output	1-50	30

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12	PHASE 1	142.8	30	Level1-4.6 Level50-72.4	52	Continuous out put	1-50	30
13	PHASE 1	1-124.2	20	Level1-4.6 Level50-72.4	50-250	Continuous out put	1-50	5-100
14	PHASE 1	55.6	20	Level1-3.88 Level50-59.2	50-250	Intermittent output	1-50	5-100
15	PHASE 1	1-124.2	20	Level1-3.76-3.84 Level50-52.4-69.6	100-250	Continuous out put	1-50	5-100

Use
Information regarding application

• The device switches itself off automatically if you do not use it for two minutes (automatic switch-off). When the unit is switched on again, the LCD screen displays the MENU selection and the most recently used MENU flashes.
• A brief acoustic signal is output when a valid button is pressed. Two brief acoustic signals are output when an invalid button is pressed.
• You can pause the stimulation at any time by briefly pressing the ON/OFF button . To continue the stimulation, briefly press the ON/OFF button again and set the desired impulse intensity again.

Procedure for TENS programs 1 – 12,

• Select a suitable program from the program tables (above).
• Place the electrodes on the desired area for treatment and connect them to the device.
• The figure on the display is intended as an additional aid to help you position the electrodes.

Selecting a program

• Press the ON/OFF button to switch on the device.
• Press the **MENU** button to activate the TENS program (Fig. 1, example of a TENS display) and press the **ENTER** button to confirm your selection.
• Using the **UP/DOWN** buttons, select the desired program and confirm your selection with the **ENTER** button (Fig. 2, example of TENS program 03).

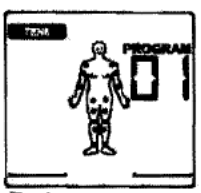
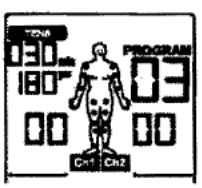


Fig. 1



General information

If you wish to return to the previous selection menu, press the **MENU** button. By holding down

Setting the impulse intensity

At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet.

• Using the INTENSITY SETTING buttons, select the desired impulse intensity. The impulse intensity display is adjusted accordingly (Fig. 3). The impulse intensity of Ch1 and Ch2 can be set individually.
• If the program is in a pause phase, the intensity cannot be increased.
• If you wish to end the stimulation treatment early, press the ON/OFF button.

Fig. 3

Setting your own parameters for individual programs
Setting the treatment duration

(TENS programs 13 – 15 only).
Using the **UP/DOWN** buttons, select the desired treatment time. You can set a treat-ment time of between 5 minutes and 100 minutes (Fig. 4, example shows a treatment duration of 20 min). Confirm your selection with the **ENTER** button.

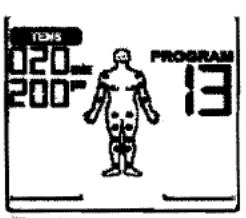


Fig. 4

NOTE: Allthough the timer can be adjusted up to 100 minutes, it is recommended that 3 treatment sessions per day for 30 minutes each are sufficient. Prolonged stimulation can contribute to **uncomfortable feeling, burning, tingling, redness or irritation of the skin**. Stop the stimulation if you experience these adverse events.

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Setting individual TENS programs

Procedure for TENS 13 program

TENS 13 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz and the impulse width to between 50 and 250 µs.

• Place the electrodes on the desired area for treatment and connect them to the device. Select the TENS 13 program, as described in section "Selecting a program" (p. 10).

• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 2, example shows an impulse width of 200 µs).
• Select the desired treatment time, as described in "Setting the treatment time" (p. 10).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 10).

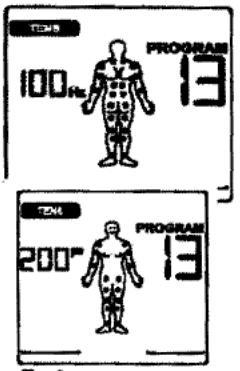
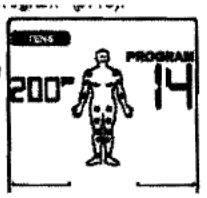


Fig. 2

Procedure for TENS 14 program

TENS 14 is a preset **burst** program that you can also personalise. In this program you can set an impulse width of between 50 and 250 µs.

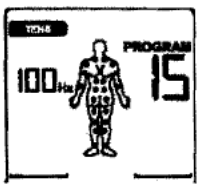
• Place the electrodes on the desired area for treatment and connect them to the device. Select the TENS 14 program, as described in section"Selecting a program" (p. 10).
• Select the desired impulse width using the **UP/DOWN** buttons and press the **ENTER** button (Fig. 1, example shows an impulse width of 200 µs) to confirm.
• Select the desired treatment time, as described in "Setting the treatment time" (p. 10).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 10).



Procedure for TENS 15 program

TENS 15 is a preset program that you can also personalise. In this program, you can set the impulse frequency to between 1 and 120 Hz. The impulse width changes automatically during the stimulation treatment.

• Place the electrodes on the desired area for treatment and connect them to the device. Select the TENS 15 program, as described in section "Selecting a program" (p. 10).
• Select the desired impulse frequency using the **UP/DOWN** buttons and press the **ENTER** button to confirm (Fig. 1, example shows an impulse frequency of 100 Hz).
• Select the desired treatment time, as described in"Setting the treatment time" (p. 10).
• Select the desired impulse intensity, as described in "Setting the impulse intensity" (p. 10).



Changing the settings

Changing the intensity (during treatment)

• Ch1 +/- and Ch2 +/-: changes the intensity of each channel

Interrupting stimulation.

Press the ON/OFF button.

Changing application (completely or individual parameters)

• ON/OFF : interrupt stimulation
• Setting the programs, see page 10; setting your own parameters, see page 10.

Doctor's function (your personal default function)

The Doctor's function is a special setting to allow you to access your personal program even more easily and directly. Your individual program settings are instantly recalled and activated when the device is switched on. You may wish to adjust this individual program following advice from your doctor.

Setting the Doctor's function

• Select your program and the corresponding settings as described on page 10.

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• At the start of the stimulation treatment, the impulse intensity of Ch1 and Ch2 is set to 00 by default. No impulses are sent to the electrodes yet. Before setting the desired impulse intensity using the intensity setting buttons, press and hold the Ch2 - button for 5 seconds. Storage in the Doctor's function is confirmed with a long acoustic signal.
If you switch on the device again, the program you saved using the Doctor's function is automatically opened directly.

Deleting the Doctor's function

To clear the device again and to re-allow access to other programs, press and hold the Ch2 - button again for approx. 5 seconds. To do this, the impulse intensity of Ch1 and Ch2 must be set to 00. Deletion of the Doctor's function is confirmed with a long acoustic signal.

Cleaning and storage

Adhesive electrodes

• To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
Before cleaning with water, remove the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil following treatment.

Cleaning the unit

• Remove the batteries from the device before cleaning.
• Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
• Do not use any chemical or abrasive cleaning agents.
Ensure that no water ENTERs the device.

Storage

• Remove the batteries from the device if you will not be using it for a prolonged period of time. Leaking batteries may damage the device.
• Do not make sharp bends in the connection cables and electrodes.
• Disconnect the connection cables from the electrodes.
• Reapply the electrodes to the carrier foil after use.
• Store the device and accessories in a cool, well-ventilated space.
• Never place any heavy objects on the device.

Disposal

Warning!

Danger of explosion if wrong type of battery is used as replacement! Replace only with the same or equivalent type recommended by the manufacturer.
DO NOT dispose of batteries in domestic waste. Dispose of the batteries according to the local regulations dealing with the disposal of these special materials (e.g. to the collecting points for disposal of batteries).

Problems/solutions

The device does not switch when the On/OFF button is pressed. how to proceed

(1) Ensure batteries have been inserted correctly and are in contact with the terminals.
(2) Replace batteries, if applicable.
(3) Contact Customer Services.

Electrodes do not adhere to the body. How to proceed:

(1) Clean the adhesive surface of the electrodes using a damp, lintfree cloth. Replace the electrodes if they still do not adhere securely.
(2) Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment. Shaving may increase the life of electrodes.

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There is no noticeable stimulation. How to proceed:

(1) Press the ON/OFF button to interrupt the program. Check the connection cables are correctly connected to the electrodes. Ensure the electrodes are in firm contact with the treatment area.
(2) Ensure the connection plug is firmly connected to the device.
(3) Press the ON/OFF button to restart the program.
(4) Check electrode positions and ensure that adhesive electrodes do not overlap.
(5) Gradually increase the impulse intensity.
(6) The batteries are almost empty. Replace the batteries.

The battery symbol is shown. How to proceed:

Replace all batteries.

You have an unpleasant sensation at the electrodes. How to proceed:

(1) The electrodes are not positioned correctly. Check their positions and re-position, if necessary.
(2) The electrodes are worn. This may cause irritated skin as even distribution of the current across the entire area is no longer guaranteed. For this reason, replace the electrodes.

Skin in the treatment area turns red. How to proceed:

Immediately stop treatment and wait until your skin has returned to its normal condition. If the redness is under the electrode and disappears quickly, there is no risk – this is caused by the locally stimulated, increased blood flow. However, consult your doctor before you continue treatment if the skin irritation persists and this is accompanied by an itchy sensation or inflammation. This may be caused by an allergic reaction to the adhesive surface.

Technical specifications

Name and model	Tyece OTC TENS Device, Model SEM 44
Output wave form	Biphasic rectangular pulse
Pulse length	50 – 450 µs
Pulse frequency	1 – 150 Hz
Output voltage	max. 100 Vpp (500 ohm)
Output current	max. 200 mApp (500 ohm)
Voltage supply	3 x AAA batteries (3 x 1.5 V)
Treatment time	Adjustable from 5 to 100 minutes
Intensity	Adjustable from 0 to 50
Operating conditions	10°C – 40°C (50°F – 104°F) at a relative humidity of 30 – 85%
Storage conditions	-10°C – 50°C (14°F – 122°F) at a relative humidity of 10 – 95%
Dimensions	132 x 63 x 29.5 mm (5.2 x 2.5 x1.2 inches, including belt clip)
Weight	101 g (3.5 oz, including belt clip, without batteries), 127 g (4.5 oz, including belt clip and batteries)
Product Life	5 years
Electrode Pads, Size	50 x 50 mm (2 x 2 in)

Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!
We reserve the right to make technical changes to improve and develop the product.
This device complies with US and European standards and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit.

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ELECTROMAGNETIC IMMUNITY

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4)* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.
5) Warning:
The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the OTC TENS Device SEM44 as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacturer's declaration - electromagnetic emissions		
The models SEM44, EM49 are intended for use in the electromagnetic environment specified below. The customer or the user of the models SEM44, EM49 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The models SEM44, EM49 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The models SEM44, EM49 are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

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Guidance & Declaration — electromagnetic immunity			
The models SEM44, EM49 are intended for use in the electromagnetic environment specified below. The customer or the user of the models SEM44, EM49 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T.) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The models SEM44, EM49 are intended for use in.the electromagnetic environment specified below. The customer or the user of the models SEM44, EM49 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	*3V* *3 V/m*	Portable and mobile RF communications equipment should be used no closer to any part of the models SEM44, EM49, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[3,5/V_1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and *d* Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol:
NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models SEM44, EM49 is used exceeds the applicable RF compliance level above, the models SEM44, EM49 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models SEM44, EM49. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and the models SEM44, EM49

The models SEM44, EM49 are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models SEM44, EM49 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models SEM44, EM49 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Limited Lifetime Warranty for Original Purchaser

Your TYECE OTC TENS Device SEM44, excluding all enclosed accessories as these require routine maintenance, is warranted to be free from defects in materials and workmanship for the life of the product under normal conditions of intended use and service. This warranty extends only to the original retail purchaser and does not extend to retailers or subsequent owners.

We will, at our option, repair or replace the OTC TENS Device SEM44, without charge, for any part or parts covered by these written warranties. No refunds will be given. Repair or replacement is our only responsibility and your only remedy under this written warranty. If replacement parts for defective materials are not available, Tyece reserves the right to make product substitutions in lieu of repair or replacement.

For warranty service contact our customer service department at **1-800-740-0287** to provide a description of the problem. If the problem is deemed to be within the scope of the limited lifetime warranty, you will be asked to mail the product at your costs in its original package with proof of purchase, your name, address and phone number. If the problem is not deemed to be within the scope of the limited lifetime warranty, we will provide quotation for repair, respectively, replacement and return shipping fee.

This warranty does not cover damage caused by misuse or abuse; accident; failures of the atomizer, tubing, or accessories; parts or cleaning solutions; the attachment of unauthorized accessories; alteration to the product; improper installation; misapplication; lack of reasonable care with respect to the product; unauthorized repairs or modifications; improper use of electrical/power supply; normal wear; loss of power; dropped product; malfunction or damage of an operating part as a result of failure to comply with instructions for use or to provide

manufacturer's recommended maintenance; transit damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of Tyece. This warranty is void if the product is ever used in a commercial or business environment. The maximum liability of Tyece under this warranty is limited to the purchase price actually paid by the customer for the product covered by the warranty, as confirmed by proof of purchase, regardless of the amount of any other direct or indirect damage suffered by the customer.

This warranty is effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adaptation to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THE WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. ANY IMPLIED WARRANTIES, OBLIGATIONS, OR LIABILITES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS APPLICABLE WRITTEN WARRANTY. Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL TYECE BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES FOR BREACH OF THIS OR ANY OTHER WARRANTY, EXPRESS, IMPLIED OR ANY OTHER THEORY OF LIABILITY, WHATSOEVER. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

Tyece does not authorize anyone, including, but not limited to, retailers, the subsequent consumer purchaser of the product from a retailer or remote purchaser, to obligate Tyece in any way beyond the terms set forth herein.

This warranty does not extend to the purchase of opened, used, repaired, repackaged and/or resealed products, including but not limited to sale of such products on Internet auction sites and/or products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate in connection with any products or parts thereof which are repaired, replaced, altered, or modified, without the prior explicitly written consent of Tyece.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state.

Manufacturer: Savia Electronics, Ltd.
4th Industrial District, Feng Huang Village,
Fu Yong County, Bao an District
Shenzhen, China
Tel: 0755-27306741, Fax: 0755-27306744, Email: info@savia.com

Distributed By: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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Device Description

This Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated
with sore and aching muscles in the upper and lower back, arms, or legs due to strain from exercise or normal household work activities.

Product Group	stimulator, nerve, transcutaneous, for pain relief for OTC use
Regulation Number Product Code Medical Specialty	882.5890 NUH Neurology
Short Name of product:	N.A.
Product Name List of Sizes/Models/Article No. Product name	Transcutaneous Electrical Nerve Stimulation (TENS) Model: SEM44 Tyece OTC TENS Device
Classification Rule	Class II

The SEM44 is a dual channel TENS device operated by DC 4.5V (3 AAA batteries). It is made up of one main unit, two electrode cables, and two pairs of electrode pads. There are 12 selectable, pre-programmed output waveforms (modes) to choose from, plus 3 programmable modes. The two channels can be individually adjusted for intensity from 0 to 50. Running time can be selected from 5 to 100 minutes.
All parameters (Menu, Program Number, Impulse intensity for channels, low battery, key-lock, frequency, pulse width and timer) are displayed on a full screen display.
The only patient contacting components are the Electrode Pads. The patient contacting materials are FDA cleared under [redacted]: K132588.

1. Technical details:

Checksum: A24A
Output channel: 2 Channel
Output wave form: Biphasic rectangular pulse
Pulse length: 50-450 us
Pulse frequency: 1-150 Hz
Output voltage: max. 100Vpp (500 ohm)
Output current: max. 200mApp (500 ohm)
Voltage supply: 3 x AAA batteries
Treatment time: Adjustable from 5 to 100 minutes
Intensity: Adjustable from 0 to 50

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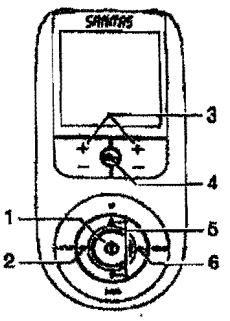
Program: Tens

2.

Buttons:
1 ON/OFF button ⏻
2 ENTER ◀ button
3 Intensity setting buttons (CH1 +/- left, CH2 +/- right)
4 Keylock O-1
5 Selection button ▲ UP and ▼ DOWN
6 MENU ▶ button



2. Auto shut-off function:
If the unit is turned "On" for 2 minutes and the intensity is not increased on either channel beyond level O, then the unit turns off automatically. This is to save battery life.
When the Timer counts down to 0 min, the unit turns off automatically.

3. Auto increased/de-creased function:
The intensity can be increased/decreased by pressing the intensity button CH1 + /- and CH2+/-. The intensity level changes at 2 steps per second while the key is pressed. When the program is changed, the intensity level drops to level 0. It stays at level 0 for 2 seconds before increasing two levels per second back to the previous intensity level. If at any time during the increase of the levels the user wishes to stop the rise in intensity, he can simply do so by pressing the down button on the corresponding channel.

4. ON/OFF function:
To turn "On" the unit, press the On/Off button once and to turn "Off" the unit press the On/Off button and hold down for 2 seconds.

5. Pause function testing of the machine:
Any Program can be paused by pressing the On/Off button once. To restart the program, press the On/Off button again.
When a Program is paused, the pause sign comes on and it flashes at 2 flashes per second. To restart, the intensity starts to rise to the original intensity level.

6. Memory function:
The unit stores the last Program and the times that were used when it is shut off and will be memorized as long as the batteries are not removed from the unit.

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7. Lock Function:

The buttons on the unit can be locked to prevent any accidental usage. This is done by holding the Program button down for 2 seconds. To cancel the key-lock, press and hold down the Program button for 2 seconds.

8. Program timer function:

Each program has a preset time which is displayed in the timer box. The timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

9. Open lead function testing:

Each program has a preset time which is displayed in the timer box. The timer counts down the program work time to 0. If no other program is selected within this time the device automatically shuts off.

10. Low voltage check function testing:

When the battery voltage is low, a low battery sign will flash on the LCD at 2 flashes per second.

11. Output pulses from the device

When the intensity on either or both channels is increased to level 1 and up to level ~~20~~ 50 the device delivers electrical pulses through the two output sockets located at the bottom of the unit. The output parameters of these electrical pulses are referred to in the Table (next page).

Note: When changing the intensity, the voltage is changing between 1-3 Volts per level (step).

12. Technical Documentation (attached below)

13. Photos (attached below)

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TENS Programs and their suggested uses

For lower Back pain: use Programs 1 through 12
For pain in the arms: use Programs 6 & 8
For pain in the legs: use Programs 6 through 9
TENS programs 13 – 15 can be set individually and can be used on all indicated areas.

Note: The electrode positions should surround the area affected by pain. In the event that groups of muscles cause pain, group the electrodes around the affected muscles.
To relieve pain, surround the area with electrodes at the front and back as well as on the left and right of the area, providing this is feasible with regard to the electrode distances. The minimum electrode distance must not fall below 2 in or exceed 6 in.
Burst programs are suitable for all areas of application to be treated with changing signal patterns (to minimise the level of accustoming to the treatment).
Note:
Do not apply the electrodes to the front wall of the chest, i.e. do not apply to the large left and right pectoral muscles.

SEM44 Program Description:

Program	Description	Frequency(HZ)	Running Times (Min)	Voltage(V)	Pulse Duration (us)	Output Method	Intensity Levels	Total Running Times (Min)
1	PHASE 1	(b)(4) [redacted]						
2	PHASE 1							
3	PHASE 1							
4	PHASE 1							
5	PHASE 1							
6	PHASE 1 PHASE 2							
7	PHASE 1 PHASE 2							
8	PHASE 1 PHASE 2							
9	PHASE 1							
10	PHASE 1							
11	PHASE 1							
12	PHASE 1							
13	PHASE 1							
14	PHASE 1							
15	PHASE 1							

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(b)(4) Third Party Technical Documentation

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Risk Management Report

(b)(4) Risk Managment Report

(b)(4) Third Party Risk Management Report

[redacted]

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(b)(4) Third Party Risk Management Report

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RISK ANALYSIS:

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(b)(4) Risk Analysis

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Answers to Additional Information Request for K150386-S001

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