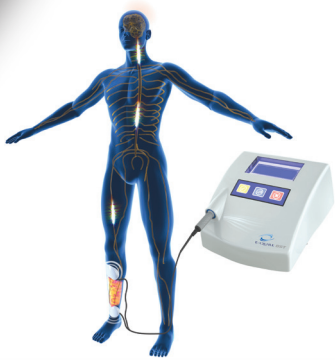
E-QURE BST

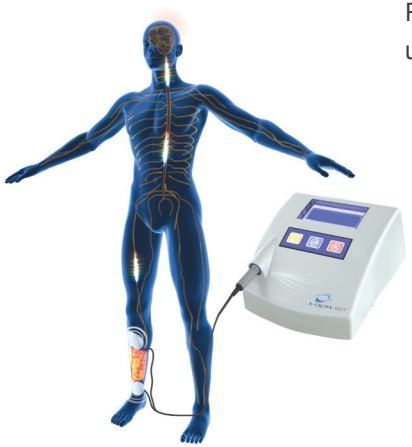
User Manual



www.e-qure.com

Table of Content:

Please read the user manual before using E-QURE's BST device



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Introduction

E-QURE BST Bioelectrical Signal Therapy is indicated for the treatment of chronic ulcers. The device emits a specific electrical signal across the wound to stimulate the natural wound healing process of the human body. This signal was identified on humans during the healing process of acute healing wounds and found to be associated with the nerves action during the healing process. The transmission of this signal to intractable chronic wound imitates and creates the electrical field found during "normal" (physiological) wound healing. The proprietary signal is delivered to the wound by a single channel stimulator to a pair of surface electrodes ("BST electrodes") that are attached to the skin around the wound. The usage of each pair of electrodes is according to the duration of use marked on the electrodes package. E-QURE BST is user-friendly and easy to operate.

Indications for Use

E-QURE BST is indicated for the treatment of chronic ulcers (i.e. hard-to-heal wounds).

General Device Description

The E-QURE BST model P-0001 (230v) and P-0002 (110v) consists of the following components:

1. **BST device (stimulator):** a computerized system based on specially designed software which generates the stimulation mode.
2. **E-QURE BST electrodes:** Pairs of disposable electrodes that deliver electrical stimulation to the skin surrounding the wound.

Contraindications

Do not use E-QURE BST if:

- You are below 18 years old
- You have an active pacemaker or defibrillator or any other implanted electrical device.
- You are pregnant or are nursing.
- You have wounds on the chest or epigastric region i.e. middle or upper abdomen.
- You are being treated with metal ion-containing wound-care products such as silver dressings.
- There is presence of a malignancy (cancer) in less than 10 cm distance from your wound.
- You have Epilepsy or suffer from other neuroexcitatory conditions (connected to the nervous system).
- There is presence of over-granulation (rough) tissue, discontinue treatment immediately.

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Side Effects

In addition to E-QURE's BST desired effect, some side effects may occur during treatment including: light itching, tingling, redness or discomfort in areas where the electrodes were placed. If these effects are bothersome to you and persist for more than a few days or even if the side effects cease spontaneously or with local treatment please contact your physician.
Some side effects requiring medical attention may include signs of allergic reaction, such as a skin rash, severe itching, skin blisters, swelling, or severe redness. If any of these reactions or side effects occur, please contact your physician immediately.

Warnings

- Avoid cellular phones or any communication equipment when operating the E-QURE BST.
- Do not operate E-QURE BST near shortwave or microwave therapy equipment.
- Do not simultaneously connect E-QURE BST and any other high-frequency equipment to yourself.
- Do not open the BST Device an electrical shock hazard exists.
- Do not use the E-QURE BST if there are any visible signs of damage to the connector cables, electrodes or the BST device.
- Do not expose E-QURE BST to water.
- Do not use another manufacturer's cables or electrodes.
- Do not apply E-QURE BST Electrodes directly on the wound itself or to its boundaries.

Warnings (continuance)

- Do not attach E-QURE BST Electrodes to each other.
- Do not fold or bend the E-QURE BST Electrodes.
- Carefully position all cables so you don't become entangled with them.
- Ensure that you do not lie down or sit on any E-QURE BST components during treatment.
- Operate E-QURE BST according to the conditions specified in the Environmental Conditions section of this manual.
- Do not sterilize any part of the E-QURE BST: Electrodes, E-QURE BST Connector Cable or BST device, damage or destruction may result.
- Refer all service calls to your physician or distributor.

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Precautions

- E-QURE BST Electrodes are disposable and intended for a single wound. Each wound requires a new pair of electrodes.
- Inspect the wound frequently, following the procedures recommended by your physician. Contact your treating physician if deterioration occurs or if you suspect a worsening of the condition. If the wound seems to be worsening or changes colors including black, yellow or green, stop using the E-QURE BST and consult your physician
- If the wound is infected, treat the wound according to your physician's instructions in conjunction with using E-QURE BST.
- If you have hyperthrophic scars, a keloid scar or if you are prone to form keloid scars at the wound area, consult with your treating physician before using the device.
- If you have advanced cardiac disease, uncontrolled bleeding disorders or if you have a metallic implant, consult with your responsible physician before using the device.
- In case of a malignancy, any signs of deterioration occurring faster than expected should be followed up with your physician.
- Ensure that the BST device and connector cables underwent cleaning and disinfection process as described in cleaning and disinfection section before transferring them from one wound to another, if applicable.
- E-QURE BST requires special precautions regarding Electro Magnetic Compatibility (EMC), and needs to be operated according to the EMC parameters provided in the accompanying tables at the end of this manual.

Before You Begin

Use ONLY E-QURE BST Electrodes, Connector Cable and Power Cable.
E-QURE BST Electrodes are disposable and indicated for single-wound-use per-day only.

Note: The numbers correspond to the numbers in the photos.

1. Contents

Each E-QURE BST package contains the following:

1. BST device (Fig.1)
2. Power Cable (Fig.2)
3. Connector Cable (Fig.3)
4. E-QURE BST disposable Electrodes and their electrode lead (Fig.4)

- **Please check that you have all the components before starting treatment.**


Fig.1


Fig.2


Fig.3


Fig.4

2. Power Connection

1. Place the BST device on a clean flat surface and connect the power cable to the BST device.
2. Plug the device's power cable into a wall socket and press the power switch in order to turn on the device (Fig.5).
3. The E-QURE BST logo appears on-screen, indicating that the system is ready.

Note:

- To adjust the display contrast, turn the knob located on the right bottom side of the BST device (Fig.6).
- If the timer from a previous treatment is displayed, switch the BST device off and turn on again to reset.


Fig.5


Fig.6

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3. Electrode Connections

Clean and dry the skin around the wound according to your physician's instructions. Cleaning is necessary to ensure that the skin is free of any dirt or ointments and that it is dry enough to enable the attachment of the electrodes.

1. Connect the connector cable to the BST device (Fig.7).
2. Separate and remove the outer lining from the electrodes to expose the electrode's sticky surface (Fig.4).
3. Place the electrodes firmly on the healthy skin on opposite sides of the wound. Each electrode's concave edge should be 1.5 - 2 cm away from the edge of the wound.
4. Connect the electrode's connector to the connector cable (Fig.8).

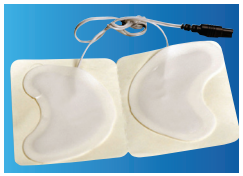


Fig.4


Fig.7

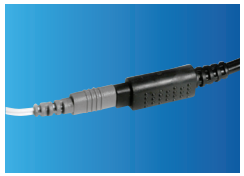


Fig.8

Treatment Session

1. Treatment Schedule

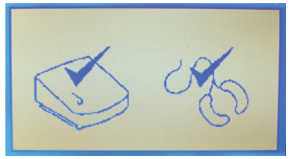
The duration of the programmed treatment session is 30 minutes. Three sessions per day per wound may be performed. Your physician may instruct you to perform additional sessions per wound. Each session should be no more than 30 minutes, with a minimum of 5 hours between sessions, on the same wound.

Important Note: For achieving best results it is important to adhere to the treatment regimen as instructed by your physician.

2. Start Treatment

Ensure that the electrodes are firmly attached to the surrounding skin throughout treatment.

1. Press the green start button (left button).
2. Two check marks (√√) will be displayed indicating that the E-QURE BST is properly connected and ready for use.



3. Press the green start button (left button) again. A 30-minute timer will appear and a countdown will begin.
4. After 30 minutes, the electronic signal is automatically cut off, and a signal is heard, indicating the end of the session.

- If an X mark is desplayed on the device symbol, please switch the BST device off and turn on again to reset. If the problem still occurs, please contact your physician or distributor.
- If an X mark is displayed on the electrodes symbol, please verify:

- Check that the electrodes are properly connected to your skin. If the problem still occurs, please contact your physician or distributor.
- Ensure that no metal containing wound care products is present at wound site. If the problem still occurs, please contact your physician or distributor.

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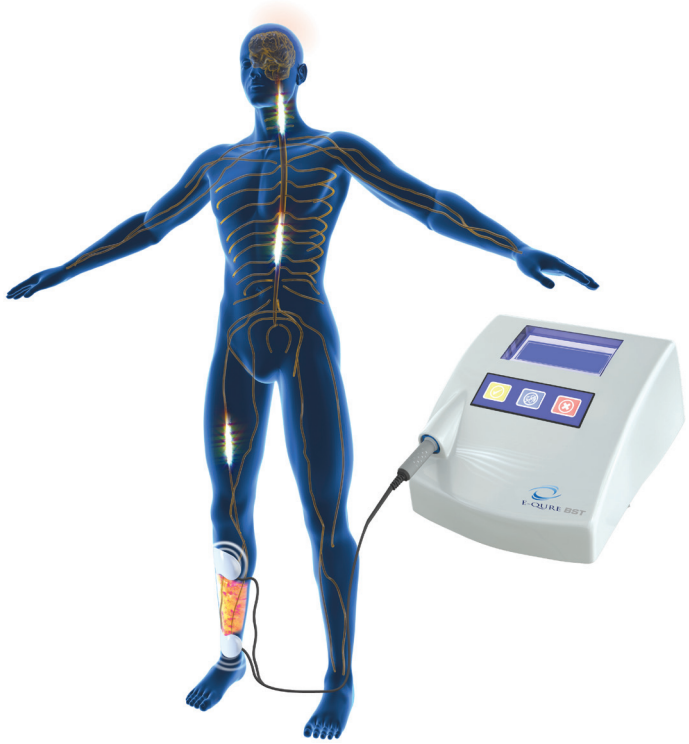
Treatment Session - Notes

Note!

- If audio button (mid blue button) is switched on, a beep will be heard every 10 seconds during treatment, indicating that the E-QURE BST is operating properly.
- If the device identifies a problem, a beep will be heard every 2 seconds. In such an event, recheck whether all cables are connected properly.
- To disable the alarm signal with the session's completion, press the blue audio button to switch it off. When the sound is disabled, you will receive only visual notification when the treatment has been completed.
- To pause a session at any time, press the red stop button (right button) once. Press the green start button to continue the session from the point it was paused.
- To stop the session at any time, press the red stop button twice.

End Treatment Session

1. Once the session has been completed, turn off the BST device's power switch.
2. Disconnect the electrodes' lead from the connector cable. Leave the electrodes on your skin.
3. If this is the last daily session, remove the electrodes by holding their edge and peeling them away from the skin towards the wound. Do not pull the electrode lead to remove the electrodes.



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Cleaning and Disinfecting

Clean and disinfect the BST device and cables before use or at the completion of treatment.

If you have more than one wound that needs to be treated, clean and disinfect the device between sessions with separate wounds.

Use the following procedure to clean and disinfect the BST device and cables:

1. Disconnect the power cable from the wall socket and from the BST device.
2. Disconnect the electrode's lead from the connector cable, and discard the electrodes with their lead.
3. Use a damp, soft, fiber-free fabric moistened with clean water to remove dirt and debris from the surface of the BST device and cables. Do not use plastic solvents or abrasive cleaners. Use with care in order to prevent water from entering the BST device's internal components.
4. Dry with a separate soft cloth.
5. Wipe down all surfaces of the BST device and cables with a fiber free fabric damped with 70% alcohol or commercially available disinfectant wipe.
   Moisten another fiber-free fabric with clean water. Wipe down all surfaces and cables.
7. Dry with a separate dry fiber free fabric.

Storage and Environmental

Store E-QURE BST at room temperature and in a dry place.

Environmental Allowed Conditions	
Operating temperature range	5°C to 40°C (41°F to 104°F)
Storage temperature range	-10°C to 50°C (14°F to 122°F)
Operating humidity	5% to max. 95% RH relative humidity (non-condesing)
Storage humidity	30% max. 85% RH (non-condensing)
Atmospheric operating pressure	70 KPa to 110 KPa

Maintenance and Replacement Parts

If you need to replace any part, please contact your physician or distributor.
Expected service life: 5 years.

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Troubleshooting

The following table summarizes possible malfunctions and actions to be taken in response.

You noticed	Possible Cause	Actions to be taken
Screen shows nothing after turning on the E-QURE BST.	1. No power to E-QURE BST 2. The contrast knob is either in the MIN or MAX position.	1. Check the power cable connections (wall socket, BST device). Make sure that the power switch is switched on. 2. Turn the display contrast knob and look for a change in display contrast.
Timer stopped in the middle of a session (the √√ icon appears).	The red Stop button was inadvertently pressed.	Press the green start button again and note that the counter continues from the time it was stopped.
Timer stopped in the middle of a session (the √√ icon appears).	The circuit BST Device-Electrodes - Body is broken.	1. Make sure that the electrodes are firmly attached to your skin. 2. Make sure the connector cable is firmly connected to the electrode's lead and the BST device. 3. Contact the physician or distributor if 1 or 2 does not solve the problem.

Technical Specifications & Data

1. E-QURE BST

Physical Characteristics	
Height	130mm (5.11”)
Length	256mm (10.07”)
Width	220mm (8.66”)
Weight	1850 g

Physical Characteristics	
Maximum Output Current: Maximum Output Voltage:	6.5 mA r.m.s. (on 500 Ω) The complete output provides net zero DC. 13.2 V
Power Source:	120V, 60Hz, 0.2A or 230V, 50Hz, 0.1A, model dependent.
Output Waveform:	- The BST device generates bi-phase, symmetrical electrical pulses of 2Hz and pulse width of 4ms. The maximum pulse amplitude is ±12V ±1.2 merges with a stochastic pulse with a random AC frequency of up to 3 kHz.
Rated Load:	500 Ohm (∓50 Ohm) - 5000 Ohm (∓200 Ohm)

Classification	Safety
Class II Type BF	EN60601-1 IEC 60601-1:90+A1(93)+A2(95) CSA C22.2 No. 60 1.1

* BST output does not contains DC components.

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Technical Specifications

2. Electrodes

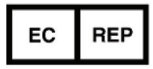
Physical Characteristics	
L x W, cm(in)	7.5cm x 4.5cm (2.96” x 1.72”)
Cable Length, cm(in)	66cm (26”)

Please use manufacturer electrodes only! Please be advised that any electrodes that have current densities exceeding 2 mA/cm2 may require special attention of the operator.

Definition of Symbols and Labels

Symbol	Description
	Class II equipment
	Caution, consult accompanying documents
	Type BF applied equipment (according to EN/IEC 60601-1)
	Date of manufacture
	Caution, avoid injury. Read and understand owner’s manual before operating this product
CE 0482	CE mark, in accordance with the Medical Device Directive 93/42/EEC

Definition of Symbols and Labels

Symbol	Description
	Manufacturer
	Serial Number
	Authorized Representative in the European Union
	Wast Electrical and Electronic Equipment (WEEE) compliance symbol
	Do not reuse
	Catalog number
	Temperature limits
	Batch code
	Use by date
	Keep dry

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Warranty

E-QURE Corp. (E-QURE), the manufacturer of the E-QURE BST, guarantees E-QURE BST Wound Treatment Device (E-QURE BST, or “device”) throughout its local distribution against defects in materials and workmanship under normal use for a period of one year from the date of purchase/start of use. In case of any complaint, please contact your local distributor whose details are attached on the opposite page.

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EMC Parameter

Guidance and manufacturer’s declaration for electromagnetic compatibility (EMC)
For the E-QURE BST according to EN 60601-1-2:2007 (Tables 1, 2, 4 and 6).

EMC Parameter

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Table 1

Guidance and manufacturer's declaration – electromagnetic emissions – E-QURE BST

The **E-QURE BST** is intended for use in the electromagnetic environment specified below; The customer or the user of the **E-QURE BST** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The **E-QURE BST** 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.
RF emissions CISPR 11	Class B	The **E-QURE BST** 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	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity – E-QURE BST

The **E-QURE BST** is intended for use in the electromagnetic environment specified below; The customer or the user of the **E-QURE BST** 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Main power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment.

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EMC Parameter

Table 3

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	<5 %UT (>95 %dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles <5 %UT 70 %UT (30 %dip in UT) for 25 cycles <5 %UT <5 %UT (>95 %dip in UT) for 5 s	Main power quality should be that of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment. If the user of the **E-QURE BST** requires continued operation during main power interruptions it is recommended that **E-QURE BST** be powered from an uninterruptible power supply or battery.
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 public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity – E-QURE BST

The **E-QURE BST** is intended for use in the electromagnetic environment specified below; The customer or the user of the **E-QURE BST** 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 Vrms 150 k Hz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **E-QURE BST**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter . **Recommended separation distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 M Hz t o 800 MHz $d = 2.34\sqrt{P}$ 800 MHz t o 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

EMC Parameter

Table 4 (Cont.)

			Distance in meters (m). Field strengths from fixed R F transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [d]. 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 **E-QURE BST** is used exceeds the applicable RF compliance level above, the **E-QURE BST** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **E-QURE BST.**

b

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the E-QURE BST

The **E-QURE BST** is intended f or use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of t **E-QURE BST** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters)and the **E-QURE BST** as recommended below, according to t he maximum output power of the communications equipment .

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter Meters [m]		
Watts [W]	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.34\sqrt{P}$

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EMC Parameter

Table 6 (Cont.)

Recommended separation distances between portable and mobile RF communications equipment and the E-QURE BST

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Rated maximum output power of transmitter	Separation distance according to frequency of transmitter Meters [m]		
Watts [W]	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.34\sqrt{P}$

E-QURE
ELECTRIC QUICK ULCER REMEDY

CE 0482

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