**CyMedica Orthopedics®**

**QB1™ USER'S MANUAL**

Read this manual carefully before operating the QB1 System

Customer Service 1-844-CYM-2014

**www.cymedicaortho.com**

**Please log onto www.cymedicaortho.com for instructional videos related to the proper use of QB1 system.**

QB-0090-001

Rev. M

Contents

# 1 INTRODUCTION

The CyMedica Orthopedics QB1™ system is an electrotherapy device with two treatment modes: neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). The QB1 system is a prescription device in the USA and is intended for use under the direction of a medical provider. The device may be used in a health care facility setting or by a patient at home.

The QB1 closed loop system provides strong yet comfortable muscle activation. In NMES mode, pulses stimulate motor points of target muscles causing a contraction. The QB1 has two different NMES treatment programs: Post-Operative treatment and Strength Building. Each program treats atrophy and re-educates muscles.

The QB1 TENS treatment is a safe and effective method of pain relief. In TENS mode, the system blocks the pain signal sent from nerves in the treated area. This is called the "Gate Theory" of pain control. Patients with chronic knee discomfort can use the QB1 TENS program for immediate and long-term pain relief.

In NMES mode, the QB1 system consists of a User Interface, wall charger, Conductive Garment, NMES electrodes, and electrode gel.

In TENS mode, the QB1 system consists of a User Interface, wall charger, TENS pod, and TENS electrodes, and electrode gel.

Read this User Manual carefully before using the device. Pay attention to the Safety Information and Warnings throughout the manual.

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

This product is covered by one or more U.S. Patents, see www.cymedicaortho.com for details.

## 2 INTENDED USE

The QB1 System is a multifunctional electrotherapy device with two treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).

The intended use of QB1 NMES device, including any indications for use, is limited to use in rehabilitation, including providing adjunctive therapy in rehabilitation for medical purposes.

Indications for Use:

*As an NMES device, indications are for the following conditions*:

- Relaxation of muscle spasms
- Retardation or prevention of disuse atrophy
- Increasing local blood circulation
- Re-educating muscles
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

The QB1 TENS device is intended for pain relief.

*As a TENS device, indications are for the following conditions*:

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain

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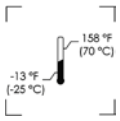
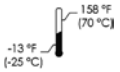
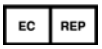
**Use environment**

The QB1 system is a prescription device in the USA and is intended for use in accordance with the directions of a health care provider. The device should be used indoors and may be used in a health care facility setting or by a patient or lay operator in a home environment.

## 3 EXPLANATION OF SYMBOLS

The following symbols are used in this user manual, and on the device packaging, or on the device or accessory labeling.

| Symbol | Description | Reference Number for Symbol |
|---|---|---|
|  | Reference number; part number | ISO 15223-1:2012(E) 5.1.6 |
|  | Lot number | ISO 15223-1:2012(E) 5.1.5 |
|  | Manufacturing date | ISO 15223-1:2012(E) 5.1.3 |
|  | Legal Manufacturer name and address | ISO 15223-1:2012(E) 5.1.1 |
|  | Follow instructions for use | ISO 7010:2011-M002 |
|  | Expiration date | ISO 15223-1:2012(E) 5.1.4 |
|  | The system is provided Non Sterile | ISO 15223-1:2012(E) 5.2.7 |
|  | Prescription only (USA) | FDA General Guidance Device Labeling – FDA 89-4203 |

| | | |
|---|---|---|
|  | Minimum and maximum operating range temperature range | **ISO 15223-1:2012(E)**<br>5.3.7 |
|  | Humidity Limitation | ISO 7000:2014-2620 |
|  | Temperature Limitation | ISO 7000:2014-0632 |
|  | Keep the device away from sunlight | ISO 15223-1:2012(E)<br>5.3.2 |
|  | Keep the device dry | ISO 15223-1:2012(E)<br>5.3.4 |
|  | Do not iron device | ISO 7000:2014-3113 |
|  | Do not machine wash device | ISO 7000:2014-3123 |
|  | Do not use bleach to clean device | ISO 7000:2014-3124 |
|  | Do not tumble dry device | ISO 7000:2014-3109 |
|  | CE Marking | Medical Device Directive 93/42/EEC |
|  | Authorized Representative | ISO 15223-1:2012(E)<br>5.1.2 |
|  | ETC Classified C US, 9900900, Electronic Testing Lab, indicates product meets US and Canadian product safety standards. This device conforms to AAMI Std. ES60601-1. Certified to CAN/CSA Std. C22.2#60601-1 | ISO 60601-1:2005(E) |
|  | Attention – consult instructions for use | ISO 15223-1:2012(E) |
|  | Caution | ISO 15223-1:2012(E)<br>5.4.4 |
| **IP20** | Protection against medium-sized foreign bodies with a diameter > 12 mm | IEC 60529 Edition 2.1 2001-02 |
| **IP02** | Protection against vertically falling water drops when enclosure tilted up to 15**°** | IEC 60529 Edition 2.1 2001-02 |
|  | Type BF applied parts | IEC 60417.1-2004-5333 |
|  | Dangerous voltage | IEC 60417.1-2004-5036 |
|  | Lead wires comply with the performance standard for electrode lead wires (21 CFR part 898) | IEC 60417.1-2004-5035 |
|  | Product contains electrical and electronic equipment. User should not discard this product along with other household waste; it must be collected and treated separately. | Directive 2016/19/EU |

| | | |
|---|---|---|
|  | Power ON | IEC 60417.1-2004-5007 |
|  | Power OFF | IEC 60417.1-2004-5008 |
|  | Battery charge port | CyMedica Symbol |
|  | Low battery; recharge battery | CyMedica Symbol |
|  | Charged battery | CyMedica Symbol |
|  | Electrical stimulation is being delivered | CyMedica Symbol |
|  | Electrical stimulation is OFF | CyMedica Symbol |
|  | Information | CyMedica Symbol |

**SAFETY INFORMATION**

## 3.1 CONTRAINDICATION

- Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

## 3.2 WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.
8. 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.
9. No modification of this device is allowed.
10. Use this device only with the leads, electrodes, electrode gel, and accessories recommended by CyMedica Orthopedics indicated in this User's Manual document.
11. Do not connect this device to equipment not supplied by CyMedica Orthopedics. Specifically do not charge this device from a USB adapter not provided by CyMedica Orthopedics.
12. Do not use this device while connected to high frequency surgical equipment. The simultaneous connection may result in burns at the site of the electrodes and possible damage to the device.
13. Do not use this device in close proximity (e.g. 1 m) of a shortwave or microwave equipment. The close proximity may produce instability in device performance.
14. Do not to use the User Interface device without the case other than while charging.

## 3.3 PRECAUTIONS

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used 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 the menstruating or pregnant uterus; and
    d- Over areas of the skin which lack normal sensation.
5. 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, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
9. Portable powered muscle stimulators such as QB1 device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
10. Inspect electrodes before each use. Replace electrodes when they begin to deteriorate or lose adhesion. Poor contact between the electrodes and the patient's skin increases the risk of skin irritation or burns. Electrodes will last longer if used and stored according to instructions on electrode packaging. Attach the electrodes in such a way that their entire surface is in contact with the skin.
11. Use of electrodes with an active area less than 16 $cm^2$ will risk suffering a burn injury. Caution should always be exercised with current densities more than 2 $mA/cm^2$.
12. Do not wrap electrode lead wires around your neck and keep them out of the reach of children. Strangulation may result from entanglement in the electrode lead wires.
13. Keep this device out of the reach of children.
14. Do not allow any foreign bodies (soil, water, metal, etc.) to penetrate the QB1 device and the battery compartment.
15. Do not use the QB1 Conductive Garment in proximity of fire or excessive heat sources due to the risk of fire. Make sure that the electrodes cover the connectors on the garment before use to avoid shocking, skin irritation, and burns.
16. Care should be used to avoid tripping on lead wires.
17. Do not operate this device while charging.
18. Do not disconnect any stimulation cables during a session while the stimulator is switched on. Switch the stimulator off first. Always turn off the stimulator before moving or removing any electrodes during a session.
19. Do not apply stimulation in the vicinity of metal. Remove jewelry, body piercings, buckles or any other removable metallic product or device in the area of stimulation.
20. Never use the electrodes contra-laterally; i.e., do not use two pins connected to the same channel on opposite segments of the body.
21. For an effective stimulation and maximum comfort, follow your clinician instructions or the following guideline for placing the electrodes on the Conductive Garment (NMES) and Knee Joint (TENS).
22. Hair may be trimmed in vicinity of electrodes for additional comfort.
23. Apply electrode gel on the treatment area of the skin for additional comfort.
24. The following equipment or environments could generate enough electromagnetic interference to potentially create unwanted activation of your QB1 system. Avoid them if possible.
    a. Antennas of citizen band (CB) or ham radios.
    b. Electric arc welding equipment.
    c. Electric induction heaters.
    d. Electric steel furnaces.
    e. High-voltage areas (safe if outside the fenced area).
    f. Large stereo speakers.
    g. Magnets or other equipment that generate strong magnetic fields.
    h. Microwave communication transmitters (safe if outside the fenced area).
    i. Power lines or power generators.
    j. Television and radio transmitting towers (safe if outside the fenced area).
25. If you suspect that equipment is interfering with the QB1 system, do the following:
    a. Move away from the equipment or object.
    b. If possible, turn off the equipment or object,

26. The presence of lint, dust, pets, pests, and children in the operating environment can impact the performance of the QB1 system. Prior to use, the system should be inspected for the following:
    a. Dust, dirt, lint, or pet hair on the face of the electrode(s). Should the electrodes pick up small amounts of debris you may use a drop of water or the electrode gel on your finger to gently rub the debris off the electrode. Electrodes are reusable as long as they are clean without any sign of visible damage and still tacky. Replace the electrodes if they no longer adhere to the skin properly.
    b. Damage to User Interface, User Interface cable, or electrode wires by pests, pets, or children. If there is evidence of damage, the system should be returned to CyMedica Orthopedics for repair.

### 3.4 ADDITIONAL PRECAUTIONS FOR TENS

- 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 of TENS is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

### 3.5 ADVERSE REACTIONS

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

## 4 QB1 SYSTEM COMPONENTS

The QB1 system provides NMES and TENS treatments to prevent or reduce quadriceps atrophy and to provide pain relief.

The QB1 NMES system consists of user interface, wall charger, conductive garment, extra NMES electrodes set, and electrode gel.

The QB1 TENS system consists of user interface, wall charger, TENS pod, TENS electrodes set, and electrode gel.

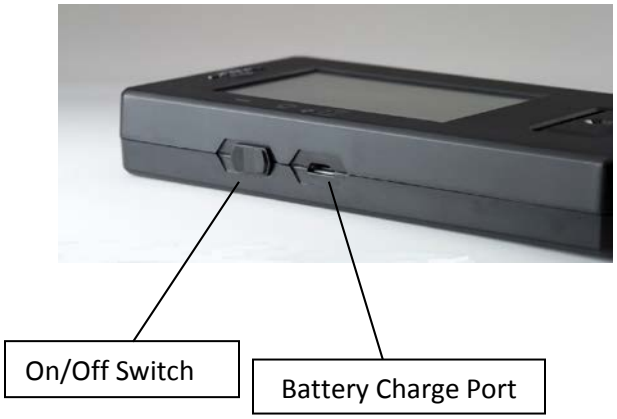
### 4.1 User Interface (UI)

The QB1 UI is the stimulation generator and the control device for the QB1 system. It sends the selected therapeutic program to the electrodes on the body. The UI utilizes a touchscreen and tactile buttons for user control.

In the ON position (**I**), the Touchscreen will turn on and allow you to interact with it. In the OFF position (**O**), the UI will be off and will not deliver treatment.

**Battery Charge Port**

The Wall Charger plugs into the UI Battery Charge Port to recharge the UI.



**UI Carrying Case**

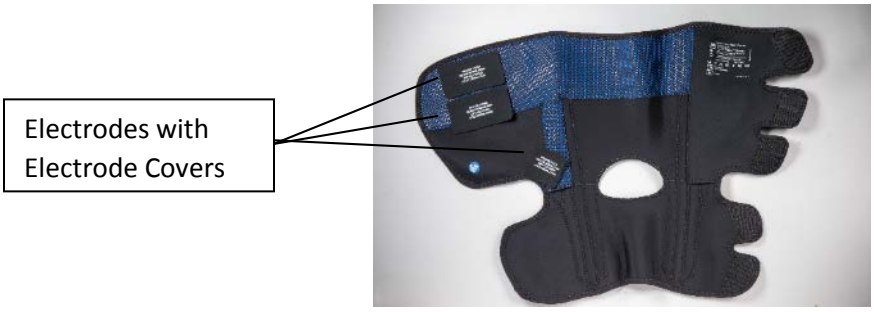
The UI Carrying Case is used to protect the UI and attach it to the Conductive Garment during use.

**Wall Charger**

The Wall Charger is used to charge the UI.

## 4.2 Conductive Garment (NMES mode only)

The QB1 Conductive Garment is used to secure the electrodes against your leg during NMES treatment.




## 4.3 Electrodes and Covers

The QB1 uses hydrogel electrodes to deliver the stimulation program to your leg. The NMES Conductive Garment employs three electrodes: two 2" x 4" (5.1 cm x 10.2 cm) electrodes and one 2" x 2" (5.1 cm x 5.1 cm) electrode. The QB1 TENS employs two 2” x 2” (5.1 cm x 5.1 cm) electrodes.

These electrodes are reusable as long as they are clean and without any sign of visible damage, and still tacky.

The electrode covers protect the electrodes from debris and damage. Before treatment, remove covers so the electrodes can contact the skin. After treatment, place the plastic side of the cover over the electrode.


### 4.4 Electrode Gel (Both NMES & TENS modes)

Electrode gel can be used for additional treatment comfort for patients with dry skin.


### 4.5 TENS Pod (TENS mode only)

The QB1 TENS Pod is used for delivery of TENS pain management therapy.

### 4.6 QB1 System Replacement Part Numbers

The table below shows a list of replacement electrode sets. Please contact CyMedica Orthopedics (1-844-CYM-2014) to order these items.

| Part | Part Number |
|---|---|
| NMES Electrodes Set | QB-1000-005 |
| TENS Electrodes Set | QB-1000-004 |

### 4.7 NMES Garment Electrodes Replacement Instructions

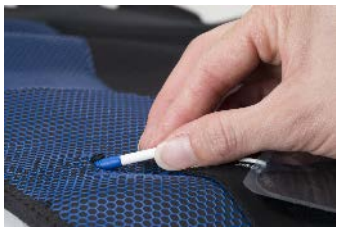
Your garment is provided with pre-installed electrodes. Follow these instructions when you need to change your electrodes with a new set. Acquire replacement electrode set. Peel electrode off of garment.



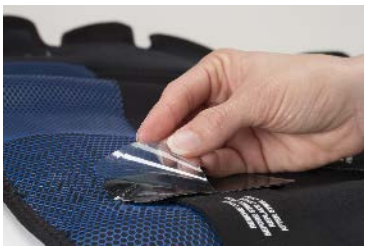
Pull white wire connected to electrode out of garment until second wire (blue, black, red) is exposed. Unplug electrode wire. Plug in a new electrode of the same size (2" x 2" or 2" x 4") all of the way so that the metal pin is completely covered.



Push electrode wire back into garment as far as possible. Remove clear plastic liner off of tan side of electrode. Rotate electrode so the black side of electrode is facing up and firmly place within the electrodes outlines on the garment.




Remove clear plastic liner from top of electrode. Remove reusable black electrode cover from old electrode and place on new electrode. Repeat the above steps for the other two electrodes.




## 5 QB1 OPERATING INSTRUCTIONS

### 5.1 Charging the User Interface (UI)

When fully charged, the UI can deliver at least three 20-minute treatments.

**Caution**: Do not operate this device while charging.

When not in use, disconnect the UI from the Conductive Garment and TENS Pod.

To charge the UI, **slide the ON / OFF Switch to the OFF position** ( ). The UI will not charge if the switch is not turned to the OFF position.

Connect the micro USB plug of the Wall Charger to the UI Battery Charge Port ( ).

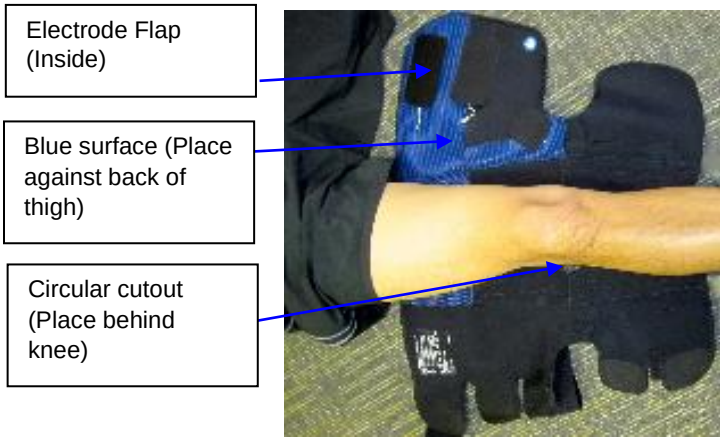
Connect the AC plug of the Wall Charger to a wall outlet. The battery indicator light will be Blue while battery is charging. The UI and Wall Charger should be positioned so that the AC plug of the Wall Charger is accessible.

The UI requires about five hours to fully recharge. Once the charge cycle is complete, the battery indicator light will turn off. The Wall Charger should be only be disconnected from its power source by removing the AC plug from the wall outlet.

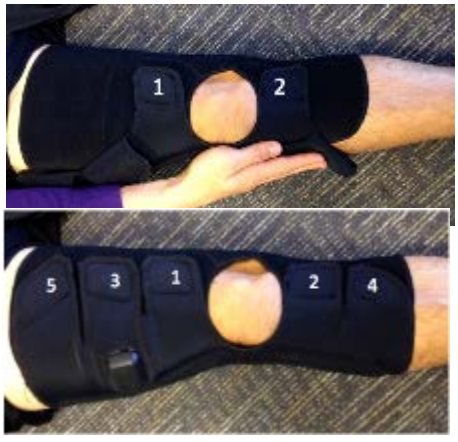
## 5.2 Wearing the Conductive Garment- NMES Treatment

**Note: Remove the electrode covers to expose the VMO, RF, and Common electrodes.**

For best results: Wash and dry skin. Apply electrode gel to electrode area of skin.
Sit down with the leg extended. Place the Conductive Garment under the leg. The blue surface should be against the back of the thigh and the round cut out behind the knee.
(Note- The pictures shown here are the right leg garment).
Wrap the Electrode Flap over top of thigh as shown.




Pull Garment Strap 1 over the electrode flap and attach to the garment as shown.
Wrap the calf side inside flap over the top of the leg.
Pull Garment Strap 2 over the calf flap and attach as shown.
Verify the knee opening fits comfortably around the knee.
Attach Garment Straps 3, 4, and 5 in order around leg ensuring a snug but comfortable fit as shown.
Refer to CyMedica Orthopedics website, www.cymedicaortho.com for instructions related to the use of QB1 knee brace.



## 5.3 Operating the QB1 Device- NMES Treatment

All electrodes should be in direct contact with the patient skin. Turn on power to the UI by sliding the ON / OFF Switch to the ON position (**I**). The initial UI screen should appear briefly.


The Information Button (i) may be pressed to display the UI hardware and software versions and patient device usage time and number of completed treatments.


The UI screen will notify you to connect the UI to the Conductive Garment by plugging it into the socket.


Connecting the UI to the Conductive Garment for NMES

The UI will display the available treatments: NMES POST-OP and STRENGTH.

Select the treatment prescribed by your medical professional.


On the Stimulation Level screen, you set the intensity levels. Each level begins with a setting of 0 and has a maximum setting of 100.
Press "+" to increase knee treatment intensity
Press "-" to decrease knee treatment intensity
**NOTE:** It is common to have different desired intensity levels for the KNEE AREA and THIGH AREA.


Once the intensity levels are set, select the "START" button. If you don't start the program, the treatment will start automatically after 5 minutes. NMES treatment programs are 20 minutes long.
**NOTE:** To pause treatment, press the Pause button on the UI. To resume treatment, press the RESUME button the touchscreen.

**Treatment Completion**

Once treatment is complete, this screen will be displayed:

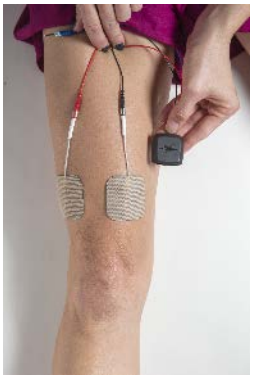

If the UI battery requires charging, the following screen will be displayed.

After treatment is complete, **squeeze both sides of UI cable connector to disconnect from the NMES socket**.

### 5.4 Operating the QB1 Device- TENS Treatment

The QB1 TENS treatment is a safe and effective method of pain relief. In TENS mode, the system blocks the pain signal sent from nerves in the treated area. TENS treatment program is 30 minutes long.

#### 5.4.1 Wearing the TENS Electrodes



Attach the two TENS electrodes to the skin in the locations prescribed by your health care professional.
For best results: Wash and dry skin. Apply electrode gel to electrode area of skin**.**
Plug each pin from the TENS Pod into one of the electrodes.

#### 5.4.2 Operating QB1 Device for TENS Treatment


Connect the User Interface to the TENS Pod by connecting the UI cable to the socket on the TENS Pod.

The UI will display the TENS treatment program. Select the TENS program. Change the intensity level by pressing "+" or "-" buttons. Once the intensity level is set, select the "START" button. If you don't start the program, the treatment will start automatically after 5 minutes.

Once the treatment is completed, squeeze both sides of UI cable connector to disconnect from the TENS socket.

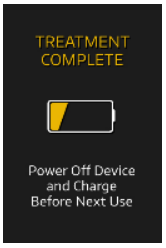
## 6 QB1 SYSTEM TROUBLESHOOTING

**User Interface (UI) Error Messages:**


**The UI is not connected to an accessory.**

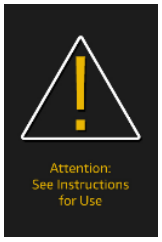
If the UI is powered ON but not communicating with a Conductive Garment or a TENS Pod, this screen will appear. Verify that the UI cable is properly connected to the device you wish to use.

**UI battery discharged**




Should the UI internal battery become discharged, this screen will be displayed on the UI once treatment is complete. The UI needs to be recharged before the next treatment. Refer to Section 5.1, "Charging the UI" for battery charging instructions.

**Attention: See Instructions for Use.**




The UI will display this screen when an error within the QB1 System exists. Should this screen appear, all stimulation will halt immediately.

To receive additional treatment, the error must be addressed and the UI power switch must be turned off and on. Below are examples of failure modes that would result in the display of this screen:

- The UI is unable to communicate properly with the Conductive Garment or TENS Pod
- The UI has an internal problem

**Troubleshooting Table**

| Problem | Possible cause | Solution |
|---|---|---|
| The User Interface (UI) is not responding | Loose connection | Check the UI Cable connection to NMES or TENS receptacle |
| | Battery discharged | Recharge UI |
| | Bad connection | Verify the connection of lead wires to electrodes |
| | Defective electrode | Replace the defective electrodes |
| UI display does not come on | Battery discharged | Recharge UI |
| Weak stimulation | Damaged or worn electrode(s) | Replace the electrode(s) |
| | Electrode placement | Ensure all electrodes are at least 1 inch apart |
| | Electrode covers are in place over electrode(s) | Remove all electrode covers prior to treatment. |
| Stimulation stops during treatment | Poor electrode contact | Reapply electrodes, secure firmly. Ensure all electrodes are at least 1 inch apart. |
| | Damaged or worn electrode(s) | Replace the electrode(s) |
| | Battery discharged | Recharge UI |
| | Poor connection | Verify proper connection of UI cable to Conductive Garment or TENS Pod |
| Stimulation weakens during treatment | This is a normal body adaptive process | Increase the intensity of the treatment using the UI |
| Stimulation is uncomfortable | Treatment intensity is too high | Decrease the intensity of the treatment using the UI |
| | Electrodes are too close together | Reposition the electrodes. Ensure all electrodes are at least 1 inch apart. |
| | Damaged or worn electrode(s) | Replace the electrode(s) |
| | Ensure proper program is being used | Refer to the User Manual for a description of all available treatment programs |
| | Dry skin | Apply electrode gel to the electrode contact area of the skin |
| Stimulation is ineffective | Improper electrode placement | Reposition electrodes. Ensure all electrodes are at least 1 inch apart. |
| | Electrode covers are in place over electrode(s) | Remove all electrode covers prior to treatment. |
| Stimulation only felt on one muscle group (VMO or Rectus Femoris) | Improper electrode placement | Reposition electrodes. Ensure all electrodes are at least 1 inch apart. |
| | Damaged or worn electrode(s) | Replace the electrode(s) |
| | Electrode covers are in place over electrode(s) | Remove all electrode covers prior to treatment. |
| Intermittent Output | Damaged or worn electrode(s) | Replace the electrode(s) |
| | Ensure proper program is being used | Refer to the User Manual for a description of all available treatment programs |
| Stimulation is not producing the usual sensation | Damaged or worn electrode(s) | Replace the electrode(s) |
| | Ensure proper program is being used | Refer to the User Manual for a description of all available treatment programs |
| | Improper electrode placement | Reposition electrodes. Ensure all electrodes are at least 1 inch apart. |
| | Dry skin | Apply electrode gel to the electrode contact area of the skin |

# 7 CUSTOMER SERVICE & MAINTENANCE

## 7.1 Customer Service

CyMedica Orthopedics Customer Service can be reached at 1-844 -CYM-2014.

Please contact Customer Service if you need assistance setting up, using, or maintaining the QB1 System or to report any unexpected operation or events.

When returning any products, please include your name, address, phone number, and Return Material Authorization (RMA) number provided by Customer Service.

All product returns should be mailed to:

CyMedica Orthopedics
Attn: RMA # _____
19120 N. Pima Rd.
Suite 135
Scottsdale, AZ 85255

## 7.2 Repair

The CyMedica Orthopedics QB1 System is not field-serviceable and has no user serviceable parts inside the device. If the device appears to be non-functional, please contact CyMedica Orthopedics Customer Service.

Do not attempt to repair any part of the CyMedica Orthopedics QB1 System. Never dismantle the QB1 UI due to risk of electric shock. CyMedica Orthopedics, Inc. declines all responsibilities for any damages or consequences resulting from unauthorized attempts to open, modify, or repair the stimulator.

## 7.3 Cleaning and Maintenance

**Conductive Garment Cleaning**

- For hygiene reasons, the Conductive Garment is intended for single person use only.
- Do not hand wash or machine wash, submerge, or dry clean the Conductive Garment
- If the Conductive Garment picks up debris or dirt, clean it using a damp and soft cloth and mild soap.

**User Interface (UI) and TENS Pod Cleaning**

- Clean the outside surface of the UI or TENS Pod gently using a damp and soft cloth when contaminated
- Do not sterilize the UI
- Do not immerse UI in liquids

**Electrodes Cleaning**

For hygiene reasons, the NMES and TENS electrodes are intended for single person use only. After each use, return the electrode to the plastic liner to maximize its useful life. If the electrode picks up small amounts of debris you may use a drop of water or the electrode gel on your finger to gently rub the debris off the electrode.

The electrodes are reusable as long as they are clean and without any sign of visible damage and still tacky. Replace the electrodes if they no longer adhere to the skin properly.

**Calibration**

The CyMedica Orthopedics QB1 System does not require equipment calibration. Each QB1 stimulator is tested prior to shipment. Its characteristics do not vary under normal operating conditions.

## 7.4 Operating Conditions

The QB1 device should be operated in temperatures between 50°F and 104°F (5°C and 40°C), atmospheric pressures between 70 and 106 kPa, and relative humidity between 15% and 93%.

### 7.5 Transportation and Storage conditions

The QB1 device should be transported and stored in temperatures between -13°F and 158°F (-25°C and 70°C), atmospheric pressures between 50 and 106 kPa and relative humidity between 10% and 93%.

### 7.6 Shelf life or Use By Date information

The shelf life or Use By Date requirement applies only to the electrodes and electrode gel. The shelf life of the electrodes and electrode gel are specified on the QB1 system package label.

### 7.7 Expected service life and disposal information

The QB1 UI, NMES Conductive Garment, and TENS are expected to provide at least one year of normal use.

Replace electrodes when they begin to deteriorate or lose adhesion. Poor contact between the electrodes and the patient's skin increases the risk of skin irritation or burns. Electrodes will last longer if used and stored according to instructions on electrode packaging.

The QB1 UI device is a piece of electronic equipment and may include substances that can damage the environment. DO NOT dispose of the device in municipal waste. Please deliver the device to a suitable collection point for recycling of electronic equipment.

When the electrodes no longer stick well to your skin, dispose of them in a receptacle out of reach of children and pets.

### 7.8 Replacement parts ordering information

To order replacement electrodes for your QB1 device, contact CyMedica Orthopedics Customer Service. Refer to Section 4.9, "QB1 System Replacement Part Numbers" of this manual for more information.

### 7.9 Limited warranty

CyMedica Orthopedics offers a warranty of 1 year for the QB1 system. Should your QB1 system develop a fault within the warranty period, CyMedica Orthopedics will replace your QB1 system free of charge, provided the system:

- has been used for its intended purpose by the original User and in the manner described in this manual
- has not been connected to an unsuitable power source
- has not been subjected to misuse or neglect
- has not been modified or repaired by anyone other than an approved CyMedica Orthopedics agent.

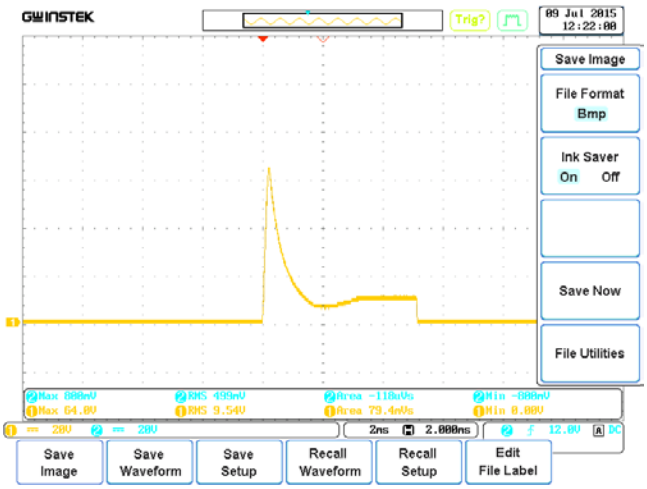
## 8 TECHNICAL SPECIFICATIONS

### 8.1 Waveform Information

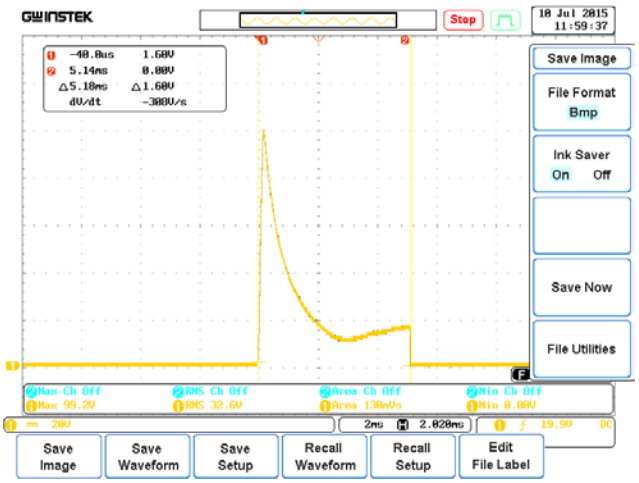
| Treatment Program | **NMES STRENGTH** | **NMES POST-OP** | **TENS** |
|---|---|---|---|
| Pulse shape | Monophasic | Monophasic | Biphasic, Symmetrical |
| Treatment duration | 20 minutes | 20 minutes | 30 minutes |
| Frequency | 50 pps | 50 pps | 100 pps |
| Pulse width | 5 ms | 5 ms | 1 ms per phase |
| Duty cycle | 25% | 25% | 20% |
| Work cycle | 12 s | 13 s | Continuous |
| Relaxation time | 10 s | 10 s | 4 ms |
| Work cycle | Work cycle – consists of five cycles of oscillating contractions per muscle group<br>Relaxation time – rest period between work cycles | Work cycle – consists of two cycles of oscillating contractions per muscle group<br>Relaxation time – rest period between work cycles | |

**NMES Waveforms**

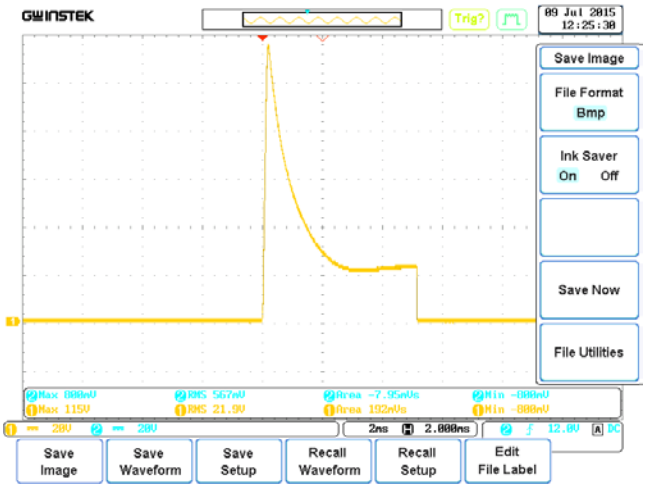
Full output, Voltage across 500Ω load




Full output, Voltage across 2,000Ω load

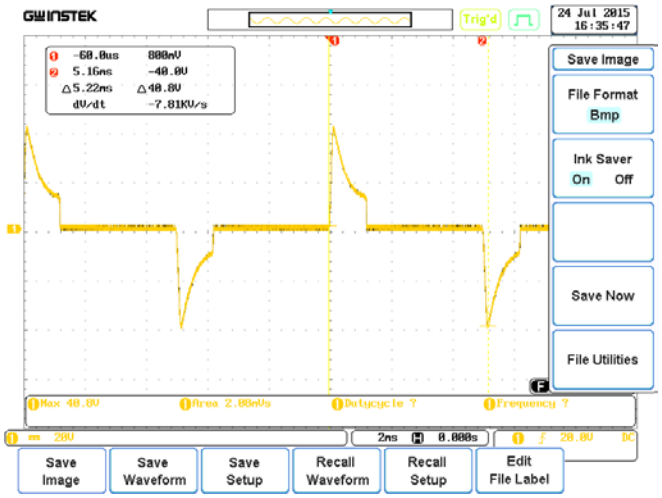



Full output, Voltage across 10,000Ω load

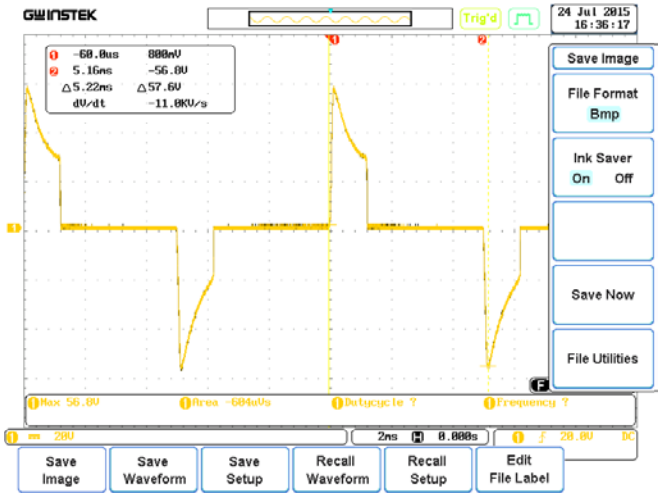



**TENS Waveforms**

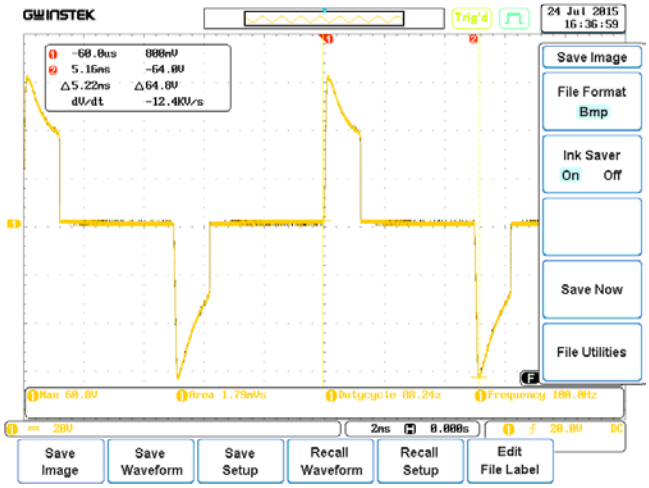
Full output, Voltage across 500Ω load




Full output, Voltage across 2,000Ω load




Full output, Voltage across 10,000Ω load



**Rated Outputs – POST-OP NMES**

| Parameter | 500 Ω | 2 kΩ | 10 kΩ |
|---|---|---|---|
| Output Voltage ($V_{RMS}$) | 3.4 V | 6.1 V | 8.5 V |
| Output Voltage ($V_{PEAK}$) | 50 V | 88 V | 107 V |
| Output Current ($I_{RMSA}$) | 6.8 mA | 3 mA | 0.9 mA |
| Output Current ($I_{PEAK}$) | 105 mA | 44 mA | 11 mA |
| Output Frequency | 50 pps | 50 pps | 50 pps |
| DC Component: Approx. | 3.5 V | 6.1 V | 8.5 V |
| Positive Pulse Width | 5 ms | 5 ms | 5 ms |
| Interphase Interval | 15 ms | 15 ms | 15 ms |
| Duty Cycle | 25% | 25% | 25% |
| Maximum Output charge | 126 µC | | |

**Rated Outputs – STRENGTH NMES**

| Parameter | 500 Ω | 2 kΩ | 10 kΩ |
|---|---|---|---|
| Output Voltage ($V_{RMS}$) | 3.4 V | 6.1 V | 8.5 V |
| Output Voltage ($V_{PEAK}$) | 50 V | 88 V | 107 V |
| Output Current ($I_{RMSA}$) | 6.8 mA | 3 mA | 0.9 mA |
| Output Current ($I_{PEAK}$) | 105 mA | 44 mA | 11 mA |
| Output Frequency | 50 pps | 50 pps | 50 pps |
| DC Component: Approx. | 3.5 V | 6.1 V | 8.5 V |
| Positive Pulse Width | 5 ms | 5 ms | 5 ms |
| Interphase Interval | 15 ms | 15 ms | 15 ms |
| Duty Cycle | 25% | 25% | 25% |
| Maximum Output charge | 126 µC | | |

**Rated Outputs – TENS**

| Parameter | 500 Ω | 2 kΩ | 10 kΩ |
|---|---|---|---|
| Output Voltage ($V_{RMS}$) | 0.18 mV | 0.19 mV | 0.20 mV |
| Output Voltage ($V_{PEAK}$) | 38 V | 56 V | 65 V |
| Output Current ($I_{RMSA}$) | 0.36 mA | 0.10 mA | 0.02 mA |
| Output Current ($I_{PEAK}$) | 76 mA | 28 mA | 6.5 mA |
| Output Frequency | 100 pps | 100 pps | 100 pps |
| DC Component: Approx. | 0 V | 0 V | 0 V |
| Positive Pulse Width | 1 ms | 1 ms | 1 ms |
| Pulse Width (at 50% of max amplitude) | 700 µs | 800 µs | 800 µs |
| Interphase Interval | 4 ms | 4 ms | 4 ms |
| Duty Cycle | 20% | 20% | 20% |
| Maximum Output charge | 43 µC | | |

## 8.2 Compliance Declaration

| | |
|---|---|
| IEC 60601-1:2005, 3rd Edition | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2: 2007, 3rd Edition | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| IEC 60601-1-6: 2010, 3rd Edition | Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability |
| IEC 60601-1-11: 2011 | Medical electrical equipment - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment used in the home healthcare environment |
| IEC 60601-2-10: 2012, 2nd Edition | Medical electrical equipment - Part 2-10: Particular requirements for basic safety and essential performance of nerve and muscle stimulators |
| CENELEC EN60601-1: 2006 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| AAMI ES60601-1: 2005 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| CSA C22.2 #60601-1: 2008, 3rd Edition | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |

## 8.3 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

- The QB1 device needs special EMC precautions and must be installed and started according to the EMC information supplied in this manual.
- Portable and mobile RF communications equipment could affect the QB1 device. For example mobile phones can affect the QB1 device. Avoid placing a mobile phone in direct proximity to the QB1 device.
- Warning: The use of accessories, other than those recommended by the manufacturer, may result in stronger emissions or reduce the immunity of the QB1 device.
- Warning: The QB1 device should not be used beside or stacked on top of any other equipment. If you must use it side by side or on top of another system, you should check that the QB1 device works properly in the chosen configuration.
- Meeting the emissions levels shown in the first table is considered to be essential performance of the QB1 device.

<table>
<tr><th colspan="3">GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">QB1 is intended for use in the electromagnetic environment specified below. The customer or user of the QB1 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guide</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The QB1 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">QB1 is suitable for use in any establishment, other than a private dwelling or a place connected directly to the low voltage<br>mains supply which powers residential buildings.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Not applicable, battery powered</td></tr>
<tr><td>Voltage fluctuations/ emission oscillations IEC 61000-3-3</td><td>Not applicable, battery powered</td></tr>
</table>

| GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| QB1 is intended for use in the electromagnetic environment specified below. The customer or user of the QB1 should assure that it is used in such an environment | | | |
| **Immunity test** | **Test level IEC 60601** | **Compliance level** | **Electromagnetic environment - recommendations** |
| Electrostatic discharge (DES) CEI 61000-4-2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±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<br>±1 kV for input/ output lines | Not Applicable – Battery powered<br>Not Applicable – signal lines less then 3 meters | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line to line<br>±2 kV line to earth | Not Applicable – Battery powered | 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 $U_T$<br>for 0.5 cycle<br>40% $U_T$ (60% dip in $U_T$)<br>for 5 cycles<br>70% $U_T$ (30% dip in $U_T$)<br>for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$)<br>for 5 s | Not Applicable – Battery powered | Mains power quality should be that of a typical commercial or hospital environment. If the user of the QB1 requires continued operation during power mains interruptions, it is recommended that the QB1 be powered from an uninterruptible power supply or a 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 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 MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY**

The QB1 is intended for use in the electromagnetic environment specified below. The customer or the user of the QB1 should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - recommendations |
|---|---|---|---|
| | | | Portable and mobile RF communication equipment should be used no closer to any part of the QB1 device, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distances** |
| Conducted RF IEC 61000-4-6 | 3 Vrms<br>150 kHz to<br>80 MHz | 3 Vrms | $d = 1.2 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80 MHz to<br>2.5 GHz | 3 V/m | $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz<br>Where P is the maximum output power of the transmitter in Watts (W) according to the transmitter manufacturer and where *d* is the recommended separation distance in meters (m).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |

NOTE 1 At 80 MHz and at 800 MHz ,the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by ab- sorption 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 QB1 device is used exceeds the applicable RF compliance level above, the QB1 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re orienting or relocating the QB1 device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

**RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE QB1**

The QB1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the QB1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the QB1 as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter**<br><br>**W** | **Separation distances according to frequency of the transmitter**<br><br>**m** | | |
|---|---|---|---|
| | **From 150 kHz to 80 MHz**<br>$d = 1.2 \sqrt{P}$ | **From 80 kHz to 800 MHz**<br>$d = 1.2 \sqrt{P}$ | **From 800 MHz to 2.5 GHz**<br>$d = 2.3 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.20 | 1.20 | 2.30 |
| 10 | 3.79 | 3.79 | 7.27 |
| 100 | 12.00 | 12.00 | 23.00 |

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 modified by absorption and reflection from structures, objects and people.

## 8.4 Measurements Accuracy

Duration of treatment is accurate within ± 1 minute.

## 8.5 Materials Specifications

USB Wall Charger:

| | |
|---|---|
| Manufacturer/Model: | Emerson / DCH3-050XX-0002 (Note: XX can be US, EU, or UK) |
| Protection Class: | Class II |
| Input Voltage / Current: | 110-230V~, 50/60Hz, 120mA |
| Output Voltage / Current: | 5VDC, 500mA |
| Continuous usage | |

Conductive Garment: Inner fabric laminate: Spandex, foam, and silicone.

NMES and TENS electrodes: Conductive silicon rubber layer (skin contact) and a conductive hydrogel layer (fabric contact)

**NOTE:** The QB1 Conductive Garment and NMES / TENS electrodes are “not made with natural rubber latex”.

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