CyMedica Orthopedics®

e-vive™ USER'S MANUAL

Read this manual carefully before operating the e-vive 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 e-vive system.

CyMedica ORTHOPEDICS

CY-0090-001

Rev. G

Contents

1 INTRODUCTION

The CyMedica Orthopedics e-vive™ system with CyMotion technology is an electrotherapy device with two treatment modes: neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). The e-vive 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 e-vive closed loop system provides strong yet comfortable muscle activation. In NMES mode, pulses stimulate motor points of target muscles causing a contraction. The e-vive has two different NMES treatment programs: Post-Operative treatment and Strength Building. Each program treats atrophy and re-educates muscles.

The e-vive 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 e-vive TENS program for immediate and long-term pain relief.

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 e-vive 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 e-vive NMES device, including any indications for use, is limited to use in rehabilitation, including providing adjunctive therapy in rehabilitation for medical purposes.

In addition the e-vive device is intended to evaluate joint function by measuring and recording range of motion.

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

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

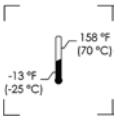
- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain

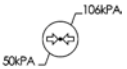
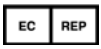
Use environment

The e-vive 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
	Serial Number	ISO 7000:2014-2498
	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) 5.3.7
	Humidity Limitation	ISO 7000:2014-2620
	Temperature Limitation	ISO 7000:2014-0632

	Pressure Limitation	ISO 7000:2014-2621
	Keep the device away from sunlight	ISO 15223-1:2012(E) 5.3.2
	Keep the device dry	ISO 15223-1:2012(E) 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
	Do not dry clean	ISO 7000:2014-3114
	CE Marking	Medical Device Directive 93/42/EEC
	Authorized Representative	ISO 15223-1:2012(E) 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) 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
IP22	Protection against medium-sized foreign bodies with a diameter > 12 mm; Protection against vertically falling	IEC 60529 Edition 2.1 2001-02

	water drops when enclosure tilted up to 15°	
	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
	Wireless	ISO 7000:2014-3600
	Bluetooth	IEEE 802.11-2012

3.1 DEFINITIONS

- Applied Parts – Part of the medical equipment, which is designed to come into physical contact with the patient, or parts that are likely to be brought into contact with the patient. For example, the electrodes are an example of an applied part.

SAFETY INFORMATION

3.2 CONTRAINDICATION

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

3.3 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 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.
12. 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.
13. Do not service or perform any maintenance on device while in use.
14. Do not apply the treatment continuously more than one full cycle at a time (20 minutes for NMES treatment and 30 minutes for

TENS treatment). Allow a minimum of three hours rest in between each treatment.

3.4 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 e-vive 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 e-vive device and the battery compartment.
15. Do not use the e-vive 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 e-vive 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 e-vive 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 e-vive 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 e-vive controller, e-vive cradle, or electrode wires by pests, pets, or children. If there is evidence of damage, the system should be returned to CyMedica Orthopedics.
27. Device contains small parts, which may present a choking hazard to small children. Keep the e-vive device and its accessories away from small children.

3.5 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.

3.6 ADVERSE REACTIONS

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

4 E-VIVE SYSTEM COMPONENTS

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

The e-vive NMES system consists of a NMES control unit, universal USB charging cord, NMES conductive garment, NMES electrodes, and electrode gel. The user interface is controlled by a proprietary smart phone or tablet CyMedica e-vive application (app) that must be downloaded from an App store and installed to your personal device in order to operate the control unit. To download the app go to the App Store for your device and search for “CyMedica e-vive”. Select download/install and follow the prompts.

The e-vive TENS system consists of a control unit, universal USB charging cord, TENS Pain Control Pod accessory, TENS electrodes, and electrode gel. The user interface is controlled by a proprietary smart phone or tablet CyMedica e-vive application (app) that must be downloaded from an App Store and installed to your personal device in order to operate the control unit. To download the app go to the App Store for your device and search for “CyMedica e-vive”. Select download/install and follow the prompts.

4.1 E-VIVE CONTROLLER

The e-vive controller is the stimulation generator and the e-vive app controls the device for the e-vive system. It sends the selected therapeutic program to the electrodes on the body. The controller has a single tactile power button for on/off user control, the e-vive app controls the levels of intensity and captures rehabilitation and usage data.

On/Off Button

Battery Charge Port

e-vive app available for download

In the ON position, the LED light on the e-vive controller will illuminate green indicating that the system is powered on and ready but, not connected to Bluetooth. The e-vive controller will flash blue when connected to Bluetooth, indicating the mobile e-vive app and the mobile device are ready to deliver stimulation treatment. In the OFF position, the LED light on the e-vive controller will illuminate white and then no longer illuminate. The controller will be off and will not deliver treatment.

Controller Protective Cover

A protective cover is included to protect it from damage due to an accidental drop and/or an accidental water spill. ***Do not remove the protective cover as it is used to protect the controller.***

Battery Charge Port

The universal USB charging cord will plug into a standard 5V USB wall charger adapter and then plug into the e-vive controller micro USB port to recharge the e-vive controller

Charging the Controller

The battery can be fully charged in approximately four hours. While the battery is being charged, the charger LED light on the controller will turn blue. When fully charged, the charger LED light will turn off. On the mobile App, when the battery has less than 5% charge the battery icon will flash Red. When the battery has a change of 5% and less than 15%, the battery icon is a constant yellow. When the battery has a charge of 15% - 100% the battery icon is a constant green.

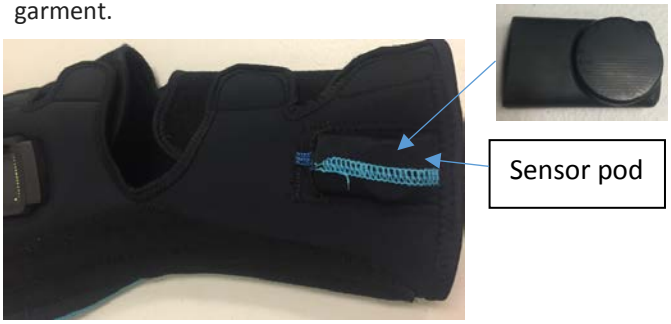
The battery can be fully charged in approximately 4 hours. A fully charged controller can deliver at least three 20 minutes treatment programs before it needs to be charged again.

Universal USB cord

The universal USB charging cord should be plugged into a standard 5V USB Wall adapter to charge the e-vive controller. A power supply is not provided with the e-vive system.

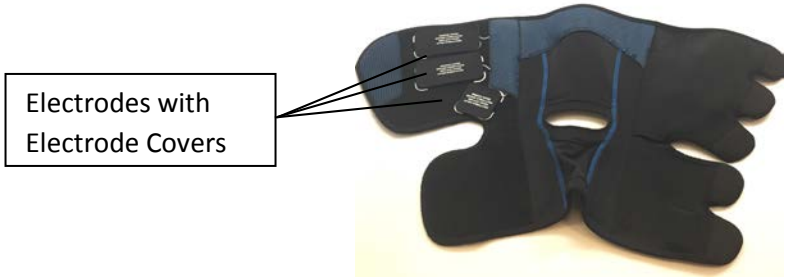
4.2 Range of Motion Sensor Pod

The e-vive Range of Motion Sensor is used to evaluate the full movement potential of the knee joint, usually its range of flexion and extension, and is contained in a small pocket of the conductive garment.



4.3 Conductive Garment (NMES mode only)

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



4.4 Electrodes and Covers

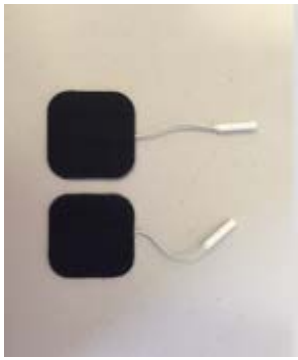
The e-vive system uses hydrogel electrodes to deliver the stimulation program to your leg. The NMES Conductive Garment employs three electrodes: two 2" x 4" (5.1 cm x 10.2 cm) electrodes and one 2" x 2" (5.1 cm x 5.1 cm) electrode. The e-vive TENS employs two 2” x 2” (5.1 cm x 5.1 cm) electrodes.

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 clear plastic covers so the electrodes can contact the skin. After treatment, place the plastic side of the supplied black electrode cover over the electrode.

NMES Electrodes

TENS Electrodes



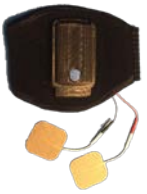
Electrode Covers

4.5 Electrode Gel (Both NMES & TENS applications)

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

4.6 TENS Pain Control Pod Accessory (TENS mode only)

The e-vive TENS Pain Control Pod accessory is used for the delivery of a transcutaneous electrical nerve stimulation (TENS) signal for pain management therapy.



4.7 E-VIVE 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	CY-1000-019
TENS Electrodes Set	CY-1000-021

4.8 NMES Garment Electrodes Replacement Instructions

Your garment is provided with pre-installed electrode wires with protective cap covering the metal conductive pins. Follow these instructions to initially place or change your electrodes with a new set. Acquire an electrode set. If this is the first time you are placing electrodes on your garment, remove the plastic electrode pin covers. If you are replacing electrodes already on your garment, gently peel the existing electrodes from the garment.

Pull white wire connected to electrode out of garment until second wire (blue, black, red) is exposed. Unplug the white 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. Rotate electrode so the black sticky side of electrode is facing up, the hook side is facing down, and firmly place within the electrode outlines on the garment.

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

5 E-VIVE OPERATING INSTRUCTIONS

5.1 Charging the e-vive Controller

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

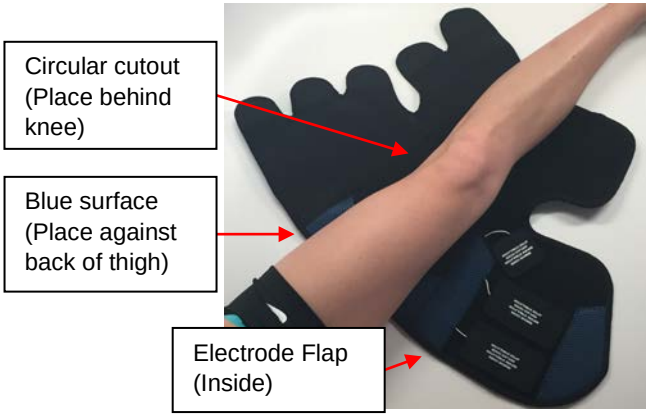
When not in use, the e-vive controller can be stored in the docking pod attached to the conductive garment or pod accessory.

To charge the controller, undock it from the docking pod and attach the supplied USB charging cord to a standard 5V wall adapter charger. Plug the small, micro USB end of the USB cable into the side of the e-vive controller. While charging, the controller will remain powered on, as indicated by the illuminated button, and charging progress may be monitored within the e-vive app.

5.2 Wearing the NMES Conductive Garment- NMES Treatment

Note: Place electrodes on the garment and 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 cutout behind the knee.
(Note: The pictures shown here are the left 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 e-vive post-operative range of motion knee brace.

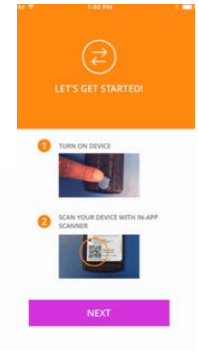
5.3 Operating the e-vive Device for NMES Treatment

All electrodes should be in direct contact with the skin. Turn on power to the e-vive controller by pressing the power button. When the controller is turned on, the LED light on the controller will glow green, indicating that the system is powered on and ready but not connected to Bluetooth. The e-vive controller will flash blue when connected to Bluetooth indicating that the mobile app and the mobile device are ready to deliver a stimulation treatment. When powered off, the LED light on the e-vive controller will illuminate white and then turn off. The controller will be off and will not deliver treatment. After powering off, wait at least 5 seconds before turning the controller back on.

Pairing Your e-vive Controller & Mobile Device

Important:
You must pair your e-vive controller with your mobile (smart phone or tablet) device *before* it is inserted into the NMES conductive garment. The required mobile device to operate e-vive system is iPhone model 4 and above. The Operating System requirement is iOS 9.35 and above.

Ensure your controller is turned on, then open the app and follow the on-screen instructions to pair your smart device with your controller.



Notes:

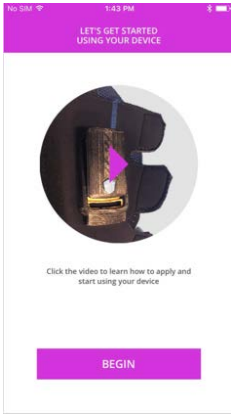
- Once paired, your e-vive controller and smart device should connect automatically every time they are both switched on with Bluetooth® enabled.
- If the pairing fails, your smart device will advise you of this and prompt you to retry the process.

Once the controller and the app on your smart device are successfully paired you may start the using your e-vive system.

First, snap the controller in to the cradle on the garment and secure the garment as instructed in section 5.2. The controller should be firmly seated into the cradle on the garment.

App Home Screen Overview

Now that you have secured your garment properly to your leg and have paired your e-vive controller to the e-vive app on your mobile device, you are ready to use your e-vive system. Press the begin button to go to your main home screen.



This home screen or e-vive app "my dashboard" screen allows you to view your results, perform electrical stimulation for muscle strengthening as well as test your range of motion.

The top section of the e-vive app will display your daily progress. Each day you will be asked to conduct three, 20 minute stimulation muscle strengthening sessions and one range of motion test. To start a stimulation session, simply press "session 1, 2 or 3 icon"

The Menu bar at the bottom of the e-vive app will appear on most of your screens. This menu bar was designed to allow you convenient access to the most-used features of your e-vive application. It's important to remember that the home icon on this menu bar will always take you back to this "my dashboard" home screen.

You may also use the icons on the bottom menu to start a muscle stimulation treatment session.

The e-vive app will display the available treatments: NMES POST-OP and STRENGTH.

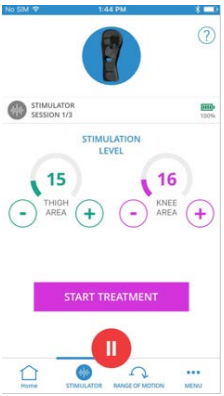
Select the treatment prescribed by your medical professional.

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.



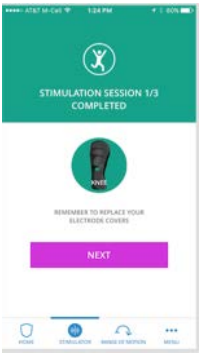
Once the intensity levels are set, select the “START TREATMENT” button. NMES treatment programs are 20 minutes long.

NOTE: At any time, you may press the red “Pause” button at the bottom of the app to interrupt the treatment program. Press the orange “play icon triangle” to resume on the app when ready to restart your treatment session. You may terminate your therapy session at any time by pressing the orange “stop X” icon on the screen. You may also terminate/stop the stimulation treatment at any time by pressing the on/off power button on the e-vive controller.

To pause treatment, press the Pause button on the e-vive app. To resume treatment, press the RESUME button the touchscreen.

Treatment Completion

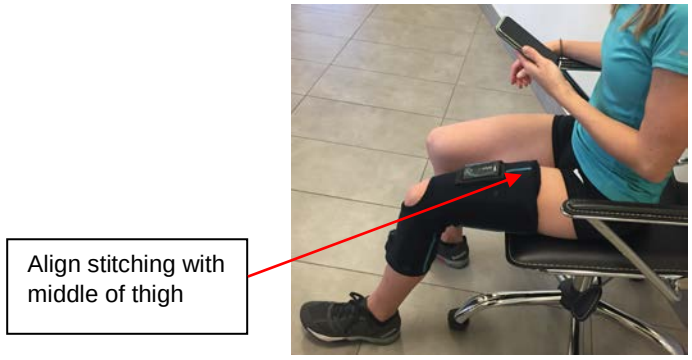
Once treatment is complete, this screen will be displayed:



5.3.1 Performing Range of Motion Test

In addition to electrical stimulation, the e-vive system incorporates range of motion sensing technology. The range of motion test is easy to perform and will allow you and your healthcare provider to track your rehabilitation progress against your goals. Once daily you will be prompted to perform a range of motion test.

To begin the range of motion test, be seated at the edge of the seat, in a chair where your knee can extend and bend comfortably. It is important that the garment be adequately secured to your leg as described in section 5.2 (wearing the NMES conductive garment).



For accurate range of motion readings, it is important that the stitching on the top of the thigh area on the garment be aligned with the middle of your thigh. Similarly, the stitching on the bottom area of the garment below the knee should be aligned with the center of your shin. Adjust the garment as needed for proper orientation.

If deemed necessary by your medical professional, the range of motion test may be calibrated within the e-vive app to accommodate different body types by adjusting the slider (-20 to +20 degrees). For example, if your leg is extended to 0 degrees, but the system extension reading is -5 degrees, the slider may be moved to +5 degrees to calibrate the reading to 0 degrees.

After pressing the pink “start test” button, the system will connect to the range of motion sensors and will say Connecting, Starting, and then Measuring when ready to measure. Slowly extend (straighten) and flex (bend) your leg to the extents that you can achieve. Once you have a realistic measurement, select capture to record the measurement.

It is important to not over-exert your range of motion beyond your comfort limits and to follow any instructions that your doctor may have

provided to you. The knee image on the app will show the angle of your knee and resulting range of motion.

5.4 Operating the e-vive Device- TENS Treatment

The e-vive transcutaneous electrical nerve stimulation (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 Pain Control Pod accessory into one of the electrodes.
Note: Make sure to fully seat the pin into the electrodes. A bare metal pin can cause skin burn.

5.4.2 Operating e-vive Device for TENS Treatment

Connect the e-vive controller into the TENS Pain Control Pod accessory by snapping the controller into the cradle on the TENS Pain Control Pod accessory.

6 THE E-VIVE APP WILL RECOGNIZE THE PAIN CONTROL POD AND WILL DISPLAY THE TENS TREATMENT PROGRAM ONCE YOU SELECT THE SIMULATOR ICON. CHANGE THE INTENSITY LEVEL BY PRESSING “+” OR “-“ BUTTONS. ONCE THE INTENSITY LEVEL IS SET, SELECT THE “START” BUTTON TO BEGIN YOUR 30-MINUTE TENS TREATMENT.

7 E-VIVE SYSTEM TROUBLESHOOTING

e-vive app Error Messages:

The e-vive controller is not connected to an accessory.

If the e-vive controller is powered ON but not communicating with the cradle pod on the NMES Conductive Garment or a TENS Pain Control Pod accessory, this screen will appear. Verify that the e-vive controller is fully seated into the cradle of the conductive garment or pod accessory.

Bluetooth connection interrupted

If during a stimulation treatment, the Bluetooth™ connection signal is disrupted, the stimulation will continue. To stop the stimulation, press the on/off button on the e-vive controller.

Battery discharged

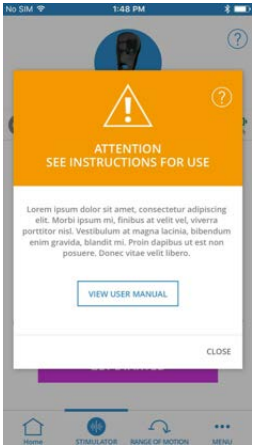
Should the e-vive controller internal battery become discharged, a screen will be displayed on the e-vive app once treatment is complete. The e-vive controller needs to be recharged before the next treatment. Refer to Section 5.1, “Charging the e-vive controller” for battery charging instructions.

Attention: See Instructions for Use.

The app will display this screen when an error within the e-vive System exists. Should this screen appear, all stimulation will halt immediately.

Below are examples of failure modes that would result in the display of this screen:

- The e-vive controller is unable to communicate properly with the Conductive Garment or TENS Pain Control Pod Accessory
- The e-vive controller has an internal problem



Troubleshooting Table

Problem	Possible cause	Solution
The Controller is not responding	Loose connection	Check the e-vive controller connection to the cradle
	Battery discharged	Recharge e-vive controller
	Bad connection	Verify the connection of lead wires to electrodes
	Defective electrode	Replace the defective electrodes
	Damaged or worn electrode(s)	Replace the electrode(s)
Weak stimulation	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 the e-vive controller
Stimulation weakens during treatment	This is a normal body adaptive process	Increase the intensity of the treatment using the e-vive mobile app
Stimulation is uncomfortable	Treatment intensity is too high	Decrease the intensity of the treatment using the e-vive mobile app
	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

8 LIST OF ERROR MESSAGES

Error Message	Solution
Cannot proceed without Garment	Fully insert Controller into cradle on conductive garment and make sure Controller is on.
Over temperature condition detected	Shut down controller and mobile application, allow to cool, and turn power back on.
Failed to configure Controller	Reconnect your mobile device with your controller by re-scanning the garment.

9 CUSTOMER SERVICE & MAINTENANCE

9.1 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 e-vive 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

9.2 Repair

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

Do not attempt to repair any part of the CyMedica Orthopedics e-vive System. Never dismantle the e-vive controller 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.

9.3 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.

e-vive Controller, TENS Pain Pod Accessory and NMES Pod Accessory Cleaning

- Clean the outside surface of the e-vive Controller, TENS or NMES pod accessories gently using a damp and soft cloth when contaminated
- Do not sterilize the e-vive Controller
- Do not immerse e-vive Controller 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 e-vive System does not require equipment calibration. Each e-vive stimulator is tested prior to shipment. Its characteristics do not vary under normal operating conditions.

9.4 Operating Conditions

The e-vive 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 90%. If the device has been stored or transported at the extremes of the recommended storage temperatures, the user should allow the unit to acclimate at room temperature for about 45 minutes prior to operating the device.

9.5 Transportation and Storage Conditions

The e-vive 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 90%.

9.6 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 e-vive system package label.

9.7 Expected Service Life and Disposal Information

The e-vive controller, NMES Conductive Garment, and TENS Pain control Pod accessories 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 e-vive controller and sensor in the NMES conductive garment 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.

9.8 Replacement Parts Ordering Information

To order replacement electrodes for your e-vive device, contact CyMedica Orthopedics Customer Service. Refer to Section 4.7, "e-vive System Replacement Part Numbers" of this manual for more information.

9.9 Limited warranty

CyMedica Orthopedics offers a warranty of 1 year for the e-vive system. Should your e-vive system develop a fault within the warranty period, CyMedica Orthopedics will replace your e-vive 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 exposed to water damage
- has not been modified or repaired by anyone other than an approved CyMedica Orthopedics agent.

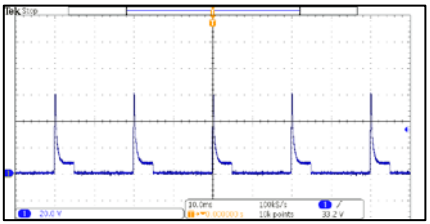
10 TECHNICAL SPECIFICATIONS

10.1 Waveform Information

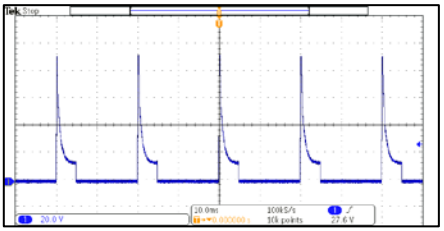
Treatment Program	**NMES STRENGTH**	**NMES POST-OP**	**TENS**
Pulse shape	Monophasic	Monophasic	Biphasic, Symmetrical
Treatment duration	20 minutes	20 minutes	30 minutes
Frequency	50 pps	50 pps	100 pps
Pulse width	5 ms	5 ms	1 ms per phase
Duty cycle	25%	25%	20%
Work cycle	12 s	13 s	Continuous
Relaxation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

NMES Waveforms

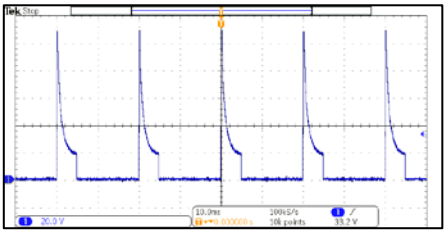
Full output, Voltage across 500Ω load



Full output, Voltage across 2,000Ω load

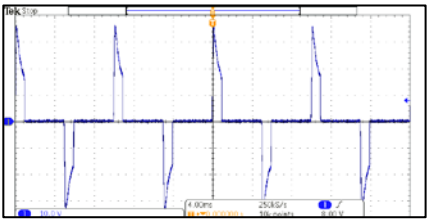


Full output, Voltage across 10,000Ω load

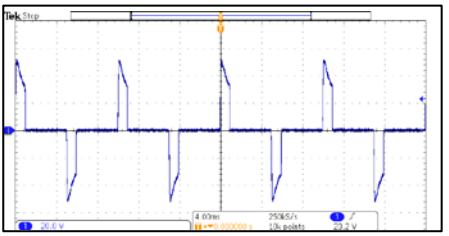


TENS Waveforms

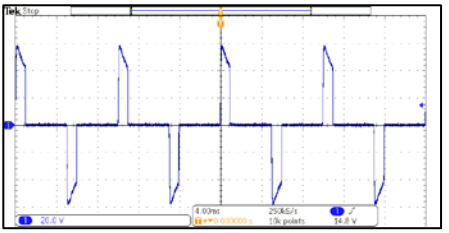
Full output, Voltage across 500Ω load



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})	9.2 V	16.4 V	21.3 V
Output Voltage (V_{PEAK})	64 V	96 V	111 V
Output Current (I_{RMS})	18.3 mA	8.2 mA	2.1 mA
Output Current (I_{PEAK})	128 mA	48 mA	11 mA
Output Frequency	50 pps	50 pps	50 pps
DC Component: Approx.	3.4 V	7.0 V	9.0 V
Positive Pulse Width	5 ms	5 ms	5 ms
Interphase Interval	15 ms	15 ms	15 ms
Duty Cycle	25%	25%	25%
Net Charge	366 µC		

Rated Outputs – STRENGTH NMES

Parameter	500 Ω	2 kΩ	10 kΩ
Output Voltage (V_{RMS})	9.2 V	16.4 V	21.3 V
Output Voltage (V_{PEAK})	64 V	96 V	111 V
Output Current (I_{RMS})	18.3 mA	8.2 mA	2.1 mA
Output Current (I_{PEAK})	128 mA	48 mA	11 mA
Output Frequency	50 pps	50 pps	50 pps
DC Component: Approx.	3.4 V	7.0 V	9.0 V
Positive Pulse Width	5 ms	5 ms	5 ms
Interphase Interval	15 ms	15 ms	15 ms
Duty Cycle	25%	25%	25%
Net Charge	366 µC		

Rated Outputs – TENS

Parameter	500 Ω	2 kΩ	10 kΩ
Output Voltage (V_{RMS})	10.9 V	17.9 V	21.7 V
Output Voltage (V_{PEAK})	37 V	52 V	59 V
Output Current (I_{RMS})	21.9 mA	9.0 mA	2.2 mA
Output Current (I_{PEAK})	75 mA	26 mA	6 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
Interphase Interval	4 ms	4 ms	4 ms
Duty Cycle	20%	20%	20%
Net Charge	0 µC		

10.2 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

10.3 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

- The e-vive device needs special EMC precautions and must be installed and started according to the EMC information supplied in this manual.
- Warning: The use of accessories, other than those recommended by the manufacturer, may result in stronger emissions or reduce the immunity of the e-vive device.
- Warning: The e-vive 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 e-vive device works properly in the chosen configuration.
- Meeting the emissions levels shown in the first table is considered to be essential performance of the e-vive device.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic environment - guide
RF emissions CISPR 11	Group 1	The e-vive 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	e-vive is suitable for use in any establishment, other than a private dwelling or a place connected directly to the low voltage mains supply which powers residential buildings.
Harmonic emissions IEC 61000-3-2	Not applicable, battery powered	
Voltage fluctuations/ emission oscillations IEC 61000-3-3	Not applicable, battery powered	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
e-vive is intended for use in the electromagnetic environment specified below. The customer or user of the e-vive system 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 ±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	Not Applicable – Battery powered 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 ±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 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 s	Not Applicable – Battery powered	Mains power quality should be that of a typical commercial or hospital environment. If the user of the e-vive requires continued operation during power mains interruptions, it is recommended that the e-vive 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 e-vive is intended for use in the electromagnetic environment specified below. The customer or the user of the e-vive should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - recommendations**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the e-vive device, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distances** $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz 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). 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 at 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-VIVE device is used exceeds the applicable RF compliance level above, the e-vive 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 e-vive 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 E-VIVE

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

Rated maximum output power of transmitter W	**Separation distances according to frequency of the transmitter**		
	From 150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**From 80 kHz to 800 MHz** $d = 1.2\sqrt{P}$	**From 800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
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.

10.4 FCC and IC

This device complies with Part 15 of the FCC Rules and with RSS-210 of the IC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including any interference that may cause undesired operation.

FCC RF Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter meets both portable and mobile limits as demonstrated in the RF Exposure Analysis.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules and to RSS-210 of the IC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. (Part. 15.21)

The e-vive system contains the following Bluetooth transmitter module:
FCC ID: S9NSPBTLERF
IC: 8976C-SPBTLERF
IC: ATCB017288

Bluetooth®

The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by CyMedica Orthopedics, Inc. is under license. Communication between the e-vive Device and the Smartphone is via Bluetooth.

Bluetooth Specifications:
Bluetooth Low Energy (BLE) modulation (as defined in the Bluetooth Core Specification) is Gaussian (shaped, binary). Frequency Shift Keying (GFSK) with a modulation index of 0.5 using frequency hopping in bursts of 1 mega-symbols/second on 2 MHz spacing within the 2.402 to 2.440 GHz band. BLE employs both FDMA (frequency division) and TDMA (time division) multiple-access schemes.

The BLE maximum output power levels in e-vive are -2.1dBm from the Controller (to the Mobile Device or the Sensor Pod) and -4.9dBm from the Sensor Pod (to the Controller). The BLE links used in e-vive have a range of up to 10 meters (between the Mobile Device and Controller) and up to 1 meter (between the Controller and Sensor Pod).

The coexistence of the e-vive wireless system has been tested for up to five e-vive devices operating simultaneously within a 50 meters radius.

Bluetooth Module: ST Microelectronics BLE SPBTLE-RF Bluetooth® Module with Bluetooth® 4.1 low energy radio
Transmit Power: 0 dBm (Controller to Mobile); -18 dBm (Controller ☐ Sensor Pod)
Receiver Sensitivity: -88 dBm
FCC Rules: Part 15 B and C
Frequency Range: 2,400 – 2,482 MHz
Output Watts: 1 mW (0 dBm); 0.126 mW (-18 dBm)

10.5 Wireless Quality of Service and Coexistence

The e-vive system utilizes Bluetooth data transmission between your Controller and your mobile device as well as between your Controller and Sensor Pod to perform intended device function. All data sent over BLE is either acknowledged or transmitted often enough that transient data is regularly updated. The wireless Quality of Service in the e-vive device is entirely managed by the Bluetooth Standard Technology and does not require you to configure any settings to perform device functions.

The coexistence of the e-vive wireless system has been tested for up to thirty wireless and microwave devices near the 2.4 GHz band, including 5 e-vive devices operating simultaneously within a 50 meters radius.

10.6 Recommendations for Safe Wireless Connections

The e-vive system utilizes encrypted Bluetooth wireless data transmission to protect information. Additionally, the e-vive system uses Wi-Fi or cellular data connections to transmit usage information via web service data transmissions that are encrypted and decrypted using SSL AES-128 methods to ensure data security.

The QR code of the e-vive Controller provides a unique device ID address that allows only mobile devices that have been paired to the e-vive controller to connect to and operate the e-vive device. To prevent any un-authorized access, only provide your QR code or device ID to persons that you may allow to access or control your e-vive device.

Security: Encryption: Link Layer: AES-128 encryption and decryption

10.7 Wireless Connections Troubleshooting

In the event that your e-vive Controller is not connecting to your mobile device, take the following steps:

1) Ensure that your Bluetooth is enabled in your device settings. Note that you will not see the e-vive device listed in your Bluetooth connected device list.
2) Ensure that your mobile device is on, has sufficient battery, and that you have opened your e-vive App.

3) Ensure that your Controller is powered on and you have paired the e-vive controller to your mobile device.
4) If the Controller light is pulsing a dark blue light, this indicates that your mobile device is connected via Bluetooth. You should see the App recognize the Controller and indicate the Controller battery level in the top section of the App home screen.
5) If the Controller and mobile device are still not connected via Bluetooth, reconnect the Controller to your mobile device by the following: In the e-vive mobile app, click on the Menu '…' button, select 'Settings' and push the 'Reconnect' button. The app will walk you through connecting your Controller to your mobile device.

In the event that your e-vive mobile app is not connecting to the internet, take the following steps:

1) Ensure that your WiFi is enabled in your device settings and you are connected to a valid WiFi connection. If a WiFi connection is not available, ensure that your cellular data is turned on and that you have authorized the e-vive app to use cellular data.
2) Open your e-vive App.

Note: An internet connection via WiFi or cellular data is not required to operate the e-vive device, but is required to access your Profile information and to communicate your rehabilitation results with your healthcare provider.

If you are still experiencing wireless connection issues, verify that your device is compatible per section 9.8 below and that you have installed your latest mobile device operating system updates and the latest e-vive mobile app from the app store. If you are still experiencing difficulties, call CyMedica Orthopedics customer service.

10.8 Mobile Device Compatibility

The required mobile device to operate the e-vive system is iPhone model 4 and above. The Operating System requirement is iOS 9.35 and above.

10.9 Measurements Accuracy

Duration of treatment is accurate within ± 1 minute.
Range of motion is accurate within ± 2 degrees.

10.10 Materials Specifications

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

NMES and TENS electrodes: Conductive silicon rubber layer and a conductive hydrogel layer

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

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