CyMedica Orthopedics®

e-vive NMES USER'S MANUAL

Read this manual carefully before operating the e-vive NMES System

Customer Service 1-844-CYM-2014

www.cymedicaortho.com

Please log onto www.cymedicaortho.com for more information on the e-vive system.

CY-0090-018

Rev. D

Contents

1 INTRODUCTION

The CyMedica Orthopedics e-vive system with CyMotion® technology is an electrotherapy device providing neuromuscular electrical stimulation (NMES). 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, 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 nerve-to-muscle communication.

Read this User's 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 an electrotherapy device with a neuromuscular electrical stimulation (NMES) treatment mode. The intended use of the 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

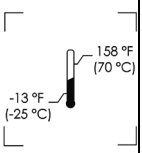
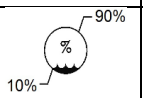
Use environment

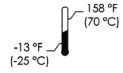
The e-vive system is a prescription device in the USA and is intended for use in accordance with the directions of a health care provider. The device may be used in a health care facility setting or by a patient or lay operator in a home environment.

3 SAFETY INFORMATION

3.1 EXPLANATION OF SYMBOLS

The following symbols are used in this user's 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
	Consult instructions for use	ISO 7000 Reg No. 1641
	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 2797	CE Marking	Medical Device Directive 93/42/EEC
EC REP	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 water drops when enclosure tilted up to 15°	IEC 60529 Edition 2.1 2001-02
	Type BF applied parts	IEC 60417.1-2004-5333
	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 Low Energy	IEEE 802.15.1-2005

3.2 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.

3.3 CONTRAINDICATION

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

3.4 WARNINGS

1. Inspect electrodes before each use. Replace electrodes frequently, when they begin to get dry, deteriorate, or lose adhesion. Electrodes dryness or poor contact between the electrodes and the patient's skin increases the risk of skin irritation or burns. Electrodes will turn dry after a few weeks of use or sometimes sooner. Dry electrodes could increase the risk of skin irritation and burn. In addition, dry electrodes reduce stimulation comfort. Apply the supplied electrode gel on the treatment area of the skin for reducing skin irritation and providing more comfort. When the device is not in use, cover the electrodes with the provided electrode covers to reduce the time before the electrodes turn dry.
2. The long-term effects of chronic electrical stimulation are unknown.
3. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
4. 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.
5. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
6. Stimulation should not be applied transcerebrally.
7. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
8. Stimulation should not be applied over, or in proximity to, cancerous lesions.

9. 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.
10. No modification of this device is allowed.
11. Use this device only with the leads, electrodes, electrode gel, and accessories recommended by CyMedica Orthopedics indicated in this User's Manual document.
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 service or perform any maintenance on device while in use.
15. Do not apply the treatment continuously more than one full cycle at a time (20 minutes for NMES treatment). Allow a minimum of three hours rest in between each treatment.

3.5 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. 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.
11. 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.
12. Keep this device out of the reach of children.
13. Do not allow any foreign bodies (soil, water, metal, etc.) to penetrate the e-vive device and the battery compartment.
14. 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.
15. Care should be used to avoid tripping on lead wires.
16. Do not operate this device while charging.
17. 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.
18. 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.
19. Never use the electrodes contra-laterally; i.e., do not use two pins connected to the same channel on opposite segments of the body.
20. For an effective stimulation and maximum comfort, follow your clinician instructions or the following guideline for placing the electrodes on the Conductive Garment.

21. Hair may be trimmed in vicinity of electrodes for additional comfort.
22. Apply electrode gel on the treatment area of the skin for maximum treatment effectiveness and comfort.
23. The following equipment or environments could generate enough electromagnetic interference to potentially create unwanted activation of your e-vive system. RF emitting equipment should be used no closer than 30 cm (12 inches) to any part of the CyMedica e-vive II NMES System.
    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).
24. 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,
25. 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 may be caused to the 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.

26. 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.

3.6 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 treatment to prevent or reduce quadriceps atrophy.

The e-vive NMES system consists of a NMES control unit, NMES conductive garment, universal USB charging cable, NMES electrodes, electrode gel, and electrode covers. 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 smart device in order to operate the control unit.

To download the app: go to the App Store (Apple) or Google Play (Android) for your device and search for “CyMedica e-vive”.

Note: Be sure to select the app with the icon shown here:

Select download/install and follow the prompts to complete your profile.

4.1 e-vive Controller

The e-vive controller is the stimulation generator that is operated through the e-vive app. By using therapy controls via the e-vive app, the controller sends the selected therapeutic program to the electrodes on the body. The controller has a single tactile power button for

on/off/pause user control, and the e-vive app controls the levels of intensity and captures progress and usage data.

On/Off/Pause Button

Battery Charge Port

e-vive app available for download

Download on the App Store

Android App available on Google play

In the ON position, the LED light on the e-vive controller will illuminate white indicating that the system is powered on and ready, but not connected to Bluetooth. The e-vive controller will turn 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 no longer illuminate. The controller will be off and will not deliver treatment.

Controller Protective Cover

A protective cover is included in the device packaging to protect it from damage due to an accidental drop and/or an accidental water spill.

Battery Charge Port

Plug the universal USB charging cord 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

When charging the controller battery, the LED light on the controller (near the USB charging port) will blink blue. When fully charged, the LED light will stop blinking and be solid blue. When the charging cable is disconnected the charging LED blue light will turn off.

The battery can be fully charged in approximately 4 hours. A fully charged controller can deliver at least three 20-minute 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. The sensor pod must not be removed from the garment.

Sensor pod

4.3 Conductive Garment

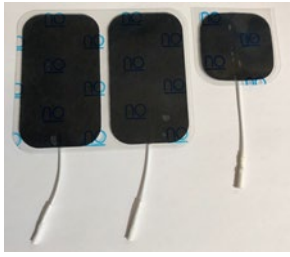
The e-vive NMES conductive garment is used to position the electrodes to your thigh during NMES treatment.

4.4 Electrodes and Covers

The e-vive system uses hydrogel electrodes to deliver the stimulation program to your thigh muscles. The NMES conductive garment employs three electrodes: two 2" x 3.5" (5 cm x 10 cm) electrodes and one 2" x 2" (5 cm x 5 cm) electrode.

Electrodes will turn dry after a few weeks of use or sometimes sooner. Dry electrodes could increase the risk of skin irritation and burn. In addition, dry electrodes reduce stimulation comfort.

Replace electrodes frequently. When utilizing stimulation at intensity levels of 60 or higher, replace electrodes more frequently to minimize risk of skin irritation or burn. Electrodes are reusable if they are clean and without any sign of visible damage, dryness, and still tacky.



NMES Electrodes

The electrode covers protect the electrodes from debris and damage while not in use. 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.

Electrode Covers

4.5 Electrode Gel

Electrode gel must be used with each treatment session to maximize treatment effectiveness and comfort, and minimize adverse effects. Utilize a small amount of gel to hydrate the skin where the electrodes will be placed on the leg.

Electrode Gel

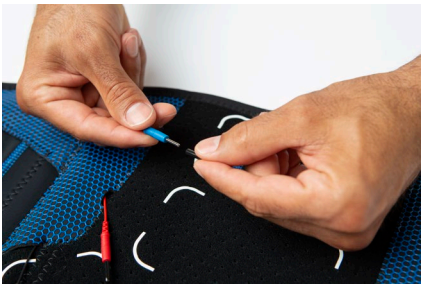
4.6 e-vive System Replacement Part Numbers

Please visit the CyMedica Orthopedics shop page at https://store.cymedicaortho.com/ to order replacement electrodes and supplies. Contact CyMedica Orthopedics (1-844-CYM-2014) if you have any questions about online ordering.

4.7 Conductive Garment Electrodes: Placement Instructions

Your garment is provided with pre-installed electrode wires with protective caps 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, unplug the existing wires and gently peel the electrodes from the garment.



Pull the white wire connected to the electrode out of garment until second wire (blue, black, red) is exposed. Unplug the white electrode wire. Position a new electrode of the same size (2” x 2” or 2” x 3.5”) so the black sticky side of electrode is facing up, the attachment side is

facing down, and firmly place within the electrode outlines on the garment. Plug in the new electrode 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 from top of electrode. After removing the clear plastic liner, place the reusable black electrode cover from packaging or the old electrode on the new electrode. Repeat the above steps for the other two electrodes.

5 e-vive OPERATING INSTRUCTIONS

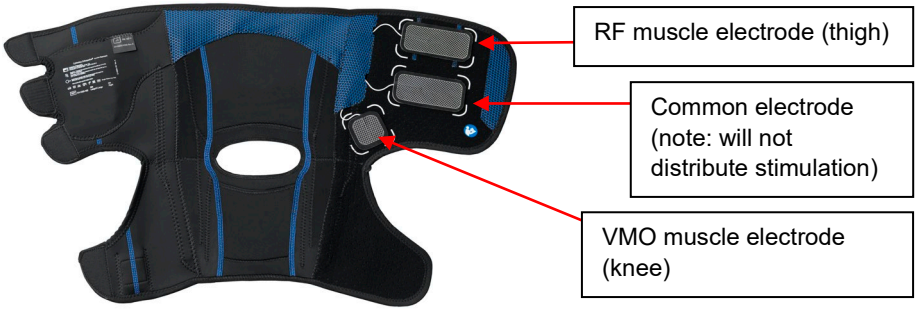
5.1 Charging and Storing the e-vive Controller

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

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 LED light (near the USB charging port) will blink blue until fully charged. Once fully charged, the blue LED light will stop blinking and remain a solid blue until the charging cable is removed.

5.2 Wearing the e-vive Conductive Garment

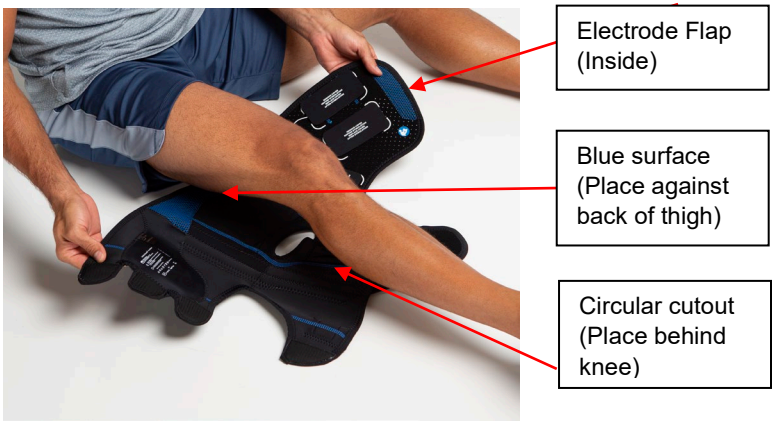
The e-vive NMES System is designed to specifically target and activate two important muscles of the quadriceps: the vastus medialis oblique (VMO) muscle located near the inner part of the upper knee area, and the rectus femoris (RF) muscle located at the top-middle part of the thigh.



Wash and dry skin. Apply a small, pea-sized amount of electrode gel to electrode area of skin. Remove electrode covers from all three electrodes.

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 for the right leg garment).



Pull garment strap 1 over the electrode flap and attach to the garment as shown.

Wrap the calf side flap over the top of the leg.

Pull garment strap 2 over the calf flap and attach as shown. Verify the front knee opening fits comfortably around the knee.

Attach garment straps 3 and 4 in order around leg ensuring a snug but comfortable fit as shown.

Wrap the electrode flap over top of thigh as shown.

Refer to the 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

STEP 1: Download the e-vive app
To download the app: go to the App Store (Apple) or Google Play (Android) for your device and search for “CyMedica e-vive™”.

Note: Be sure to select the app with the icon shown here:

Select download/install.

Important: Follow the prompts to complete your profile**.**

STEP 2: Pair the e-vive controller to your smart device

You must pair your e-vive controller with your smart device (smart phone or tablet) *before* starting a treatment. See section 9.8 for compatible mobile devices.

Once your profile has been completed, open the e-vive app, tap Stimulation Therapy or Range of Motion Test on the Dashboard and follow the on-screen instructions to pair your smart device with your controller. Bluetooth must be enabled on your smart device in order to connect to the controller. For Android devices, Location Services must also be enabled for pairing.

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 using your e-vive system.

Secure the controller into the dock on the garment and position the garment as instructed in section 5.2. The controller should be firmly seated into the dock on the garment.

STEP 3: Power on the device:

All electrodes should be in direct contact with the skin. Turn on the e-vive controller by pressing the power button. When the controller is turned on, the LED light on the controller will glow

white, indicating that the system is powered on and ready, but is not connected to Bluetooth.

The e-vive controller will turn blue when connected to Bluetooth, indicating that the mobile app and the mobile device are ready to deliver a stimulation treatment.

What do the different illuminated colors on the power button mean?

- Once you begin use, the LED light on the e-vive controller will glow yellow when a treatment is in progress and will blink yellow when the treatment is in progress and is outputting energy.
- When the LED light is alternating blue and yellow, the controller is connected but the treatment is paused. Alternating white and yellow LED lights mean the controller is not connected to Bluetooth and the treatment is paused.
- When powered off, the LED light on the e-vive controller will 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.
- If the LED on the controller flashes red contact the CyMedica Customer Service (refer Section 8.1).

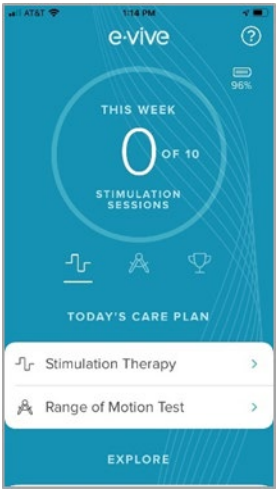
Purple	Controller is ON, not in dock
White	Controller is ON and in dock, not connected to Bluetooth
Blue	Controller is ON, in dock, connected to Bluetooth
Yellow	Treatment in progress, not outputting energy
Yellow blinking	Treatment in progress, outputting energy
Yellow/White blinking	Treatment paused, not connected to Bluetooth
Yellow/Blue blinking	Treatment paused, connected to Bluetooth
Red	Battery critically low, needs to charge
Red flashing	Failure, call Customer Service

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 smart device, you are ready to use the e-vive system.

The app home screen, or e-vive Dashboard, allows you to view your weekly progress, begin stimulation treatment for muscle strengthening, as well as test your range of motion.

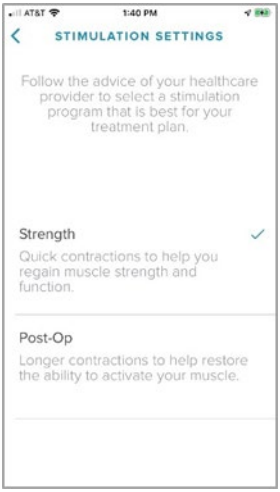
The top section of the e-vive app will display a Dashboard Ring of your daily progress. Each day you will be asked to conduct two 20-minute stimulation muscle strengthening sessions and a range of motion test.



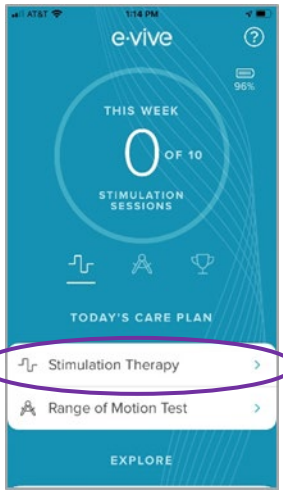
Stimulation Programs

The e-vive app offers two NMES therapy programs: Strength and Post-Op.

Note: Strength is the default program. You can select the Post-Op program instead by tapping Settings and selecting the preferred treatment under Stimulation Therapy.



STEP 4: Begin Stimulation Therapy



To start a stimulation session, simply tap Stimulation Therapy on the Dashboard screen.

Complete your Pain Assessment and proceed to the Set Stimulation Levels screen.

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.

Tap "+" to increase knee treatment intensity

Tap "-" to decrease knee treatment intensity

NOTE: It is common to have different desired intensity levels for the KNEE and THIGH.

Increase the intensity until you achieve a **strong, comfortable muscle contraction**.

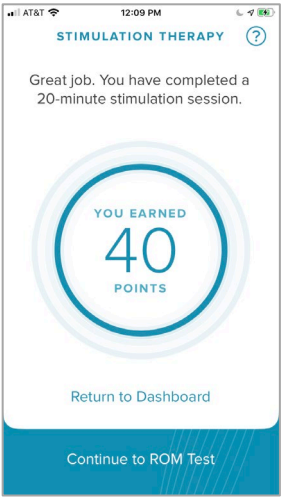
Once the intensity levels are set, tap “Start Therapy” to begin your 20-minute treatment session. Both e-vive NMES treatment programs (Strength and Post-Op) are 20 minutes long.

Note: The “hamburger icon”( ) located on the upper left of the stimulation screen allows you to navigate back to the Dashboard during stimulation therapy.

NOTE: At any time, you may tap the black “Pause” button at the bottom of the screen to interrupt the treatment program. Tap the black triangle “play” icon to resume on the screen when ready to restart your therapy session. You may terminate your stimulation session at any time by tapping the black “exit” icon ( ) on the screen. You may also pause the stimulation therapy at any time by pressing the on/off power button on the e-vive controller.

Treatment Completion

Once treatment is complete, this screen will be displayed:



5.4 Operating the e-vive device as a bilateral system (2 garments and one controller)

The bilateral e-vive system is indicated for treatment of both the left and right knee. Only one controller is needed for use with both garments. Once the device has been paired using either garment it is not necessary to pair the other garment. The e-vive controller can be interchanged with both garments. When the e-vive controller is fully seated, power the controller on, verify Bluetooth connection, select the appropriate program and begin session (see section 5.3 on how to operate the e-vive device).

5.5 Performing a 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 progress against your goals. Once daily you will be prompted to perform a range of motion test.

For accurate range of motion readings, it is important that the blue 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.

To begin the range of motion test, position yourself 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).

Extension: From a seated position at the edge of a chair, slide your heel on the floor to fully extend your leg. When you feel you have extended your leg as far as possible, while keeping your heel on the floor, gently push the back of your knee toward the ground.

In the e-vive app Range of Motion test, tap "Save" when you have reached your maximum extension.

Flexion: From a seated position at the end of a chair, slide your heel on the floor toward your buttock. When necessary, move from your heel on floor to your toe. If you feel you can achieve even greater flexion, it may be necessary to remove your toe from the ground and continue to move your heel up towards your buttock.

In the e-vive app Range of Motion test, tap "Save" when you have reached your maximum flexion.

It is important to not over-exert your range of motion beyond your comfort limits and to follow any instructions that your healthcare provider may have given to you. The knee image on the app will show the angle of your knee and resulting range of motion.

6 e-vive SYSTEM TROUBLESHOOTING

e-vive app Error Messages:

Bluetooth connection is interrupted

If during a stimulation treatment the Bluetooth connection signal is disrupted, the stimulation will continue. To pause the stimulation, momentarily press the on/off button on the e-vive controller. To stop the stimulation, press and hold the on/off button on the e-vive controller for 2 seconds to turn off the device.

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.

Troubleshooting Table

Problem	Possible cause	Solution
The Controller is not responding	Loose connection	Check the e-vive controller connection to the dock
	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 app Settings for a description of all available treatment programs
	Dry skin	Apply electrode gel to the electrode contact area of the skin. Do not shave leg before treatment.
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 app Settings 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 app Settings 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 LIST OF ERROR MESSAGES

Error Message	Solution
Cannot proceed without garment	Fully insert controller into dock 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.

8 CUSTOMER SERVICE & MAINTENANCE

8.1 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 # _____
2120 East 6th Street
Suite 8
Tempe, AZ 85281

8.2 Repair

The CyMedica Orthopedics e-vive system is not field-serviceable and has no user serviceable parts inside the device. If the device appears to be 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.

8.3 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, soft cloth and mild soap.

e-vive Controller and NMES Pod Accessory Cleaning

- Clean the outside surface of the e-vive controller or NMES 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 electrodes are intended for single person use only. After each use, place the plastic side of the supplied black electrode cover over the electrode. If an electrode picks up small amounts of debris you may use a drop of water or electrode gel on your finger to gently rub the debris off the electrode.

The electrodes are reusable as long as they are clean, still tacky, and without any sign of visible damage. Replace the electrodes frequently, and when dry or 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.

8.4 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.

8.5 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%.

8.6 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 individual package label.

8.7 Expected Service Life and Disposal Information

The e-vive controller and NMES conductive garment 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.

8.8 Replacement Parts Ordering Information

To order replacement electrodes for your e-vive device, please visit the CyMedica Orthopedics shop page at https://store.cymedicaortho.com/.

8.9 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

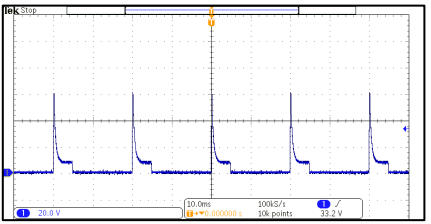
9 TECHNICAL SPECIFICATIONS

9.1 Waveform Information

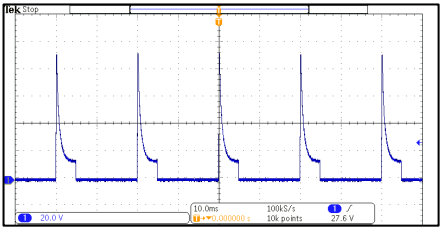
Treatment Program	**NMES STRENGTH**	**NMES POST-OP**
Pulse shape	Monophasic	Monophasic
Treatment duration	20 minutes	20 minutes
Frequency	50 pps	50 pps
Pulse width	5 ms	5 ms
Duty cycle	25%	25%
Work cycle	12 s	13 s
Relaxation time	10 s	10 s
Work cycle	Work cycle – consists of five cycles of oscillating 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

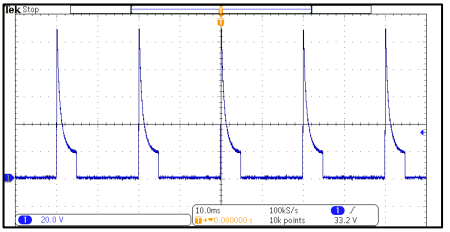
Full output, Voltage across 500Ω load



Full output, Voltage across 2,000Ω load



Full output, Voltage across 10,000Ω load



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		

9.2 Compliance Declaration

IEC 60601-1:2014, 4th Edition	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014, 4th 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: 2015	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, 2nd Edition	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

9.3 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	The e-vive is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable, battery powered	
Voltage fluctuations/ emission oscillations IEC 61000-3-3	Not applicable, battery powered	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

e-viveis 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 (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 100 kHz repetition frequency	Not Applicable – Battery powered Not Applicable – signal lines less than 3	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV	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	Voltage dips 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruptions 0 % UT; 250/300 cycle	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	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	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 V 0,15 MHz – 80MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m	**Recommended separation distances:** Portable and mobile RF communication equipment should be used no closer to any part of the e-vive device, including cables, than the recommended separation distance of 30cm (0,3m). 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.

Test Frequency (MHz)	**Band [a] (MHz)**	**Service[a]**	**Modulation[b]**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 - 390	TETRA 400	Pulse modulation[b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0,3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0,2	0,3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

9.4 FCC and IC

This device complies with Part 15 of the FCC 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 interference that may cause undesired operation.

FCC RF Radiation Exposure Statement

FCC ID: 2AU28-CY1000330
Model: e-vive II

The minimum distance of the radiating structure of this device, during normal operation, is 15mm from the body of the user (§2.1093).

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.

Note: 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. 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)

Bluetooth

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 -1.1dBm. The BLE links used in e-vive have a range of up to 10 meters (between the mobile device and controller).

Bluetooth Module: Texas Instruments CC2640R2F MCU targeting Bluetooth® 4.2
Transmit Power: -1.1dBm (controller to mobile)
Receiver Sensitivity: –97 dBm
Frequency Regulations
ETSI EN 300 328 (Europe)
EN 300 440 Class 2 (Europe)
FCC CFR47 Part 15 (US)
ARIB STD-T66 (Japan)
Frequency Range: 2,400 – 2,482 MHz
Output Watts: 0.7762 mW (-1.1 dBm)

9.5 Wireless Quality of Service and Coexistence

The e-vive system utilizes Bluetooth data transmission between your controller and your mobile device to perform the 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 forty wireless and microwave devices near the 2.4 GHz band, including 5 e-vive devices operating simultaneously within a 50 meters radius.

9.6 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, see security note for details.

The QR code of the e-vive controller provides a unique controller ID address (6-character alphanumeric code) 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 controller ID to persons that you may allow to access or control your e-vive device.

Note: Web service data transmissions use TLS 1.2 protocol with AES-256 cipher encryption.

9.7 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: 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 LED light is blue, 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-right section of the app home screen (Dashboard).
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, from the Dashboard, select 'Settings' then the 'Bluetooth Pairing' 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 Wi-Fi is enabled in your device settings and you are connected to a valid Wi-Fi connection. If a Wi-Fi 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 Wi-Fi or cellular data is not required to operate the e-vive device but is required to create and access your profile information, initially pair the device, 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. Also verify 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.

Note: Android devices require Location Services to be enabled for proper connection to the e-vive controller.

9.8 Mobile Device Compatibility

Mobile devices compatible with the e-vive system include:

Apple devices with minimum requirements:

- **OS Level**: The OS level must be at 10.0 or higher
- **Bluetooth**: The device must have Bluetooth with at least

revision 4.0 or higher

- **Memory**: At least 200MB of available RAM memory

Android devices, with minimum requirements:

- **OS Level**: The OS level must be at 6.0 or higher
- **Bluetooth**: The device must have Bluetooth with at least revision 4.0 or higher
- **Memory**: At least 200MB of available RAM memory

Note: Certain operating systems and security software can interfere with the operation of the e-vive app and the user may need to work with their phone provider to resolve any incompatibilities in operating system software with CyMedica assistance.

9.9 Measurements Accuracy

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

9.10 Materials Specifications

NMES conductive garment: Inner fabric laminate: Spandex, foam, and silicone

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

NOTE: The e-vive conductive garment and NMES electrodes are "not made with natural rubber latex".

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