Therabody

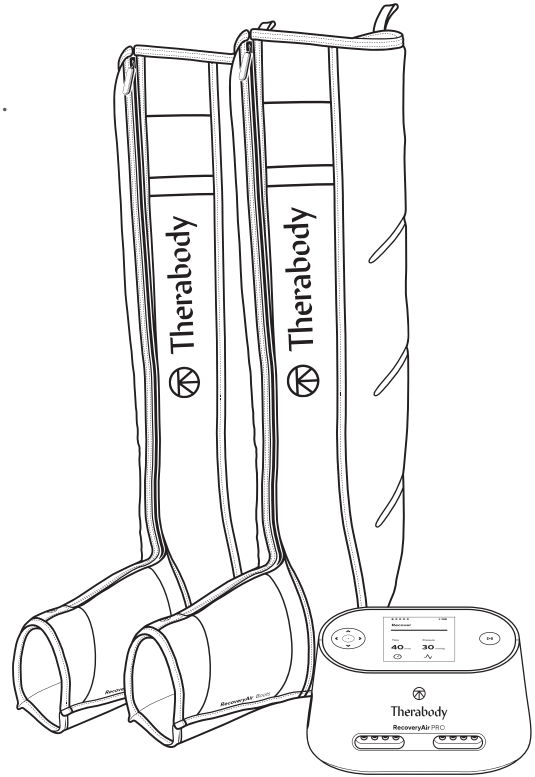
RecoveryAir PRO

Personalized Recovery.

RecoveryAir PRO

Fully customizable pneumatic compression system.

Your RecoveryAir PRO pneumatic compression system comes with a pump, a pair of compression boots, a blocker plug, a DC power adapter, and a carrying pouch for both the pump and boots.



See Warnings on pg. 16 for important safety instructions.

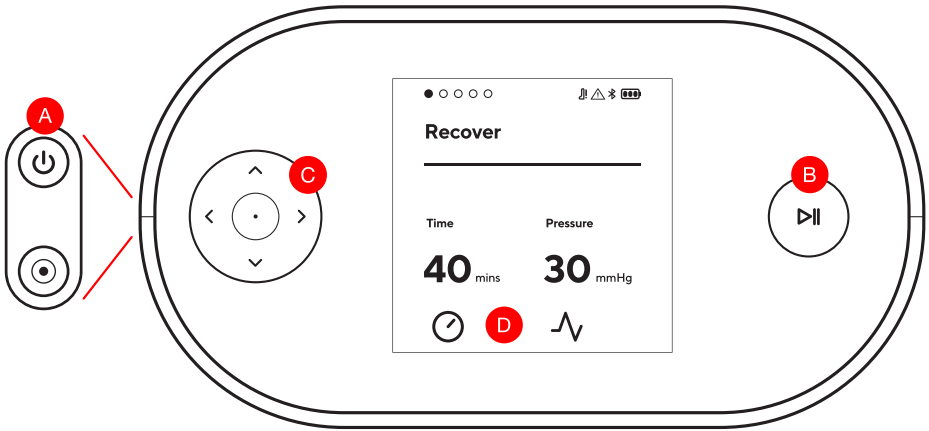
Getting started

1. To turn on the RecoveryAir PRO pump, press and hold the power button.
2. To get started, put your boots on first before attaching them to the pump. This allows you to get into the most comfortable position and avoid any disruption in the air flow connection.
3. Next, plug in the connector from the boots into the pump. Make sure you hear a “click” so that you know the RecoveryAir PRO is fully connected, is plugged in, and there is a proper seal.
4. Once connected and comfortable, you are ready to customize your treatment.

Customizing your treatment

1. To turn on the RecoveryAir PRO pump, press and hold the power button.
2. Customize your treatment from the pump interface.
3. Using the left & right arrows in the 4-way button, scroll through the 5 preset treatment options: Recover, Warm-up, Isolation, Interval, and PRO Mode (Custom).
4. Once you have chosen your desired treatment preset, use the up & down arrows in the 4-way button to adjust the pressure setting.
5. To create a custom routine, simply press the select button until a new screen appears.
6. Then, use your select and arrow buttons to navigate the options such as Pressure, Time, Hold, Release, and Gradient, creating a fully personalized routine.
7. Once you have selected the treatment options that are right for you, push play, relax, and you’ll be on your way to recovery in no time. You can also share your routines with other RecoveryAir users easily through the Therabody app.

Feature Callouts



Buttons

A *Power Button*

B *Start/Pause/Stop Button*

C *4-way Buttons*

C *Select Button*

D Settings (Adjustable Range)

Pressure Setting

Adjustable Pressure Range (20-100 mmHg) in increments of 5 mmHg. Adjustable pressure changes in increments of 1 mmHg while in Gradient Setting.

Time Setting

10min-90min in steps of 5min or continuous.

E Indicators

Warning Indicator

Indicator lights up solid ON or blinking when a device malfunction is detected

Bluetooth Indicator

Indicator turns ON only when connected to the App

Battery Indicator

3 LED lights to indicate battery life

Air loss/Leakage Indicator

RecoverAir PRO Programs

About negative gradient for all programs:

The RecoveryAir PRO's unique true negative gradient of pressure sequentially travels up the limb from the foot toward the heart in four internal overlapping chambers. The spiraling overlap of chambers safely maximizes circulation.

- The pressure can be the same in two consecutive chambers, but the pump won't allow a back chamber to have a higher pressure than a front chamber.
- The minimum pressure level of each chamber is 20 mmHg.

Recover and Warm-Up preset programs

- The Recover program is the perfect go-to when experiencing fatigue, tension, or soreness brought on by your everyday activities or post workout.
- The Warm-Up program is recommended for use before a workout.
- The only difference between the two programs is the default pressure level and treatment time.

Sequential inflation cycle

Both the Recovery and Warm-Up preset programs use the Sequential inflation cycle.

- A directional massage is applied, starting at the base of the treated area, and progresses upwards towards the torso and then releases. (see Figure 1)
- Starting with Chamber 1, once the inflating chamber has reached its preset pressure level, the pressure level for that chamber is held and the next chamber begins inflating.

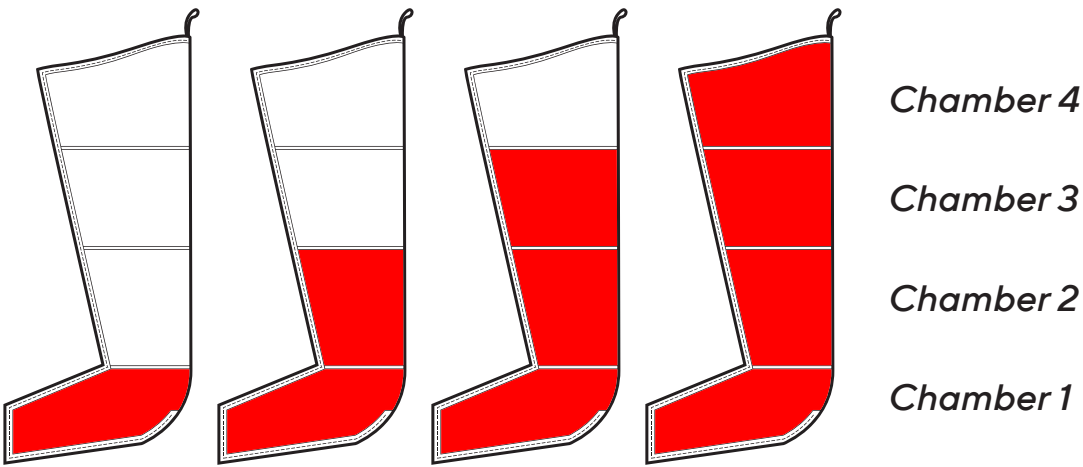


Figure 1 – Sequential Cycle Mode

RecoverAir PRO Programs

Isolation preset program
The Isolation program is recommended when needing to treat a specific, isolated area of your choosing.

Isolation inflation cycle (ISO)
The Isolation program provides targeted compression to a selected zone.

- A directional massage is applied to a smaller, isolated area.
- Inflation starts with the front chamber.
- The next chamber starts to inflate after a few seconds.
- Until both chambers reach the set pressure and deflate at the same time, the cycle will start again after a short pause (see Figure 2).

Isolated Areas:

- Full Distal Zone – Chamber 1, 2, & 3
- Distal Zone – Chamber 1 & 2
- Mid Zone – Chamber 2 & 3
- Proximal Zone – Chamber 3 & 4
- Full Proximal Zone – Chamber 2,3, & 4

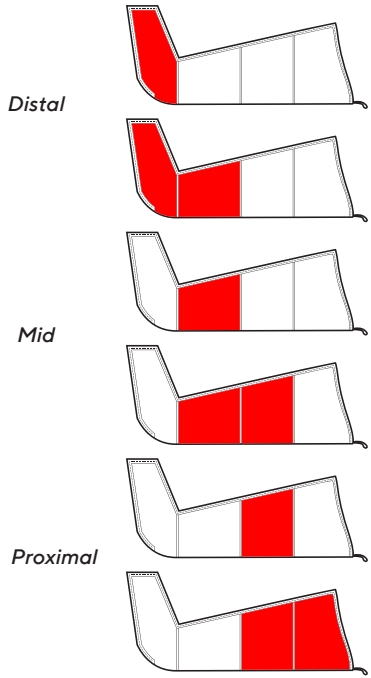


Figure 2 - ISO Cycle Mode

Interval preset program

The Interval program allows for a cycle to turn on and then off in a sequential selected amount of time.

- A directional massage is applied with a sequential cycle, and alternates between intervals of being under treatment (Time On) and no treatment (Time Off).
- Start by selecting the Time On (in minutes), the Time Off (in minutes), and the total Interval program time (in hours).
- The treatment begins with the selected Time On, and after this treatment is completed, the pump pauses for the selected amount of Time Off, and then back to the selected Time On.
- This Time On/Time Off interval continues automatically until the total treatment time is completed (up to 8 hours).

Time On	Time Off	Total (hrs)
10 – 90 min (5min per step)	10 – 90 min (5min per step)	1 – 8 hours (1hr per step)

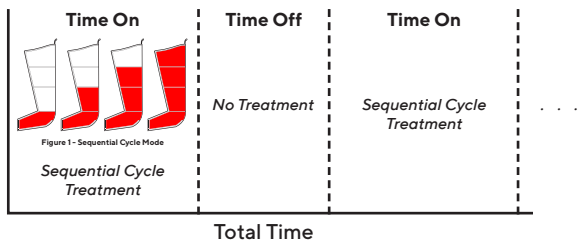


Figure 1 - Sequential Cycle Mode

PRO Mode (Custom)

The PRO Mode allows you to create a fully customized program that's unique to you.

- You can use the Pretreatment program or you can choose from four inflation cycles: Sequential, Isolation, Wave, or Flow.
- During your treatment, you can change the treatment parameters, but you can't change the selected inflation cycle and can't turn the pre-selected program ON/OFF.

Pretreatment (See Figure 3)

- Pretreatment treats the proximal areas first.
- A specific pattern is applied, and the duration varies according to garment size (5–12 minutes) with a preselected pressure of 30 mmHg in all chambers that cannot be changed.
- Sequence 1 is carried out six times.
- Sequence 2 and Sequence 3 are carried out only once.

Sequential inflation cycle (see page 5)
Isolation inflation cycle (see page 7)

Wave inflation cycle

- The Wave inflation cycle starts at the base of the limb, over the foot.
- As one chamber inflates, the previous chamber starts deflating, so at any one time a small area is being compressed.
- For example: When chamber 2 is full, then chamber 1 starts to deflate, while chamber 3 starts to inflate, so for a moment, there are 2 chambers reaching the target pressure at the same time. (See Figure 4)

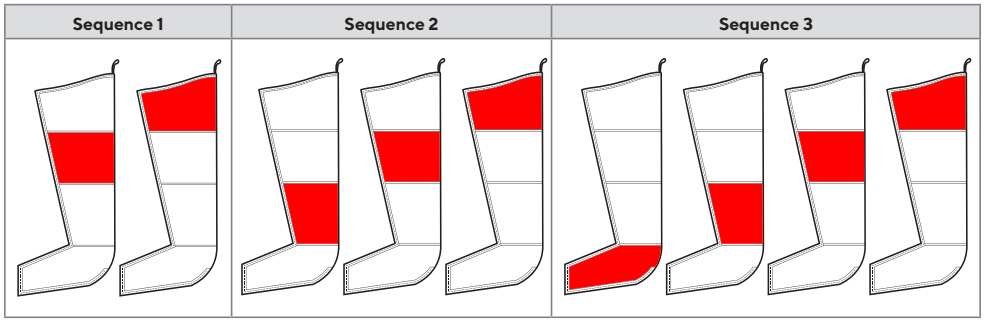


Figure 3 - Pretreatment Sequences

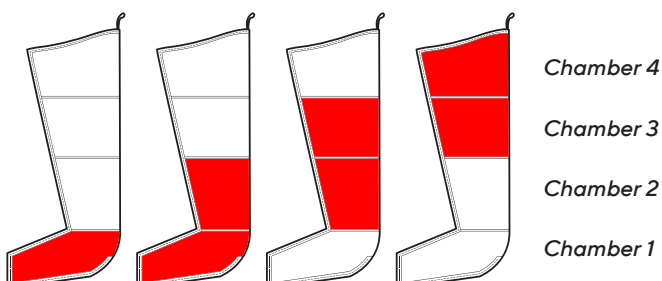


Figure 4 - Wave Cycle Mode

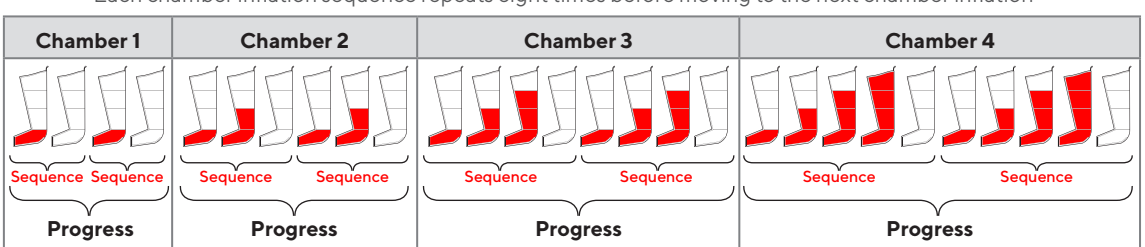
PRO Mode (Custom)

Flow inflation cycle

- Four sequences exist within the Flow inflation cycle. Each sequence is determined by the last chamber inflated.
- The Flow inflation cycle has an associated Frequency parameter, which determines the number of sequences within the cycle.
- You can set the Frequency to be between 1 and 8.
- The default Frequency setting is 2.

Examples

- Frequency 1
  Each chamber inflation sequence happens once before continuing to next chamber sequence
- Frequency 2
  Each chamber inflation sequence repeats twice before continuing to next chamber sequence
- Frequency 8
  Each chamber inflation sequence repeats eight times before moving to the next chamber inflation



Superior, hygienic design

The RecoveryAir PRO compression boots have non-porous medical grade material that helps prevent bacteria buildup and provides a resistant surface. Our internal overlapping chambers provide a smooth surface to clean, which means no wiping under chamber flaps where bacteria can build up. This also means no smells.

How to Clean

Here are simple steps to cleaning your RecoveryAir PRO compression boots:

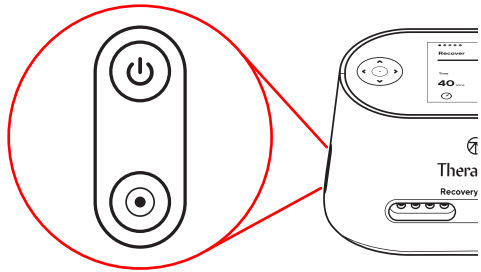
1. Unzip the boots completely and lay them on a flat surface.
2. Take a disinfectant wipe or spray, and gently clean the inside of the boots. Avoid any oil based cleaning product.
3. Once you have cleaned your garment, make sure to fully dry the surface by hanging them up or wiping them down.
4. We also recommend you wipe down the exterior of the pump to reduce surface contaminants.

What it is and why it's important:

We use medical-grade material covering the internal chamber to help reduce the potential for microbial growth and moisture retention. Whether you are an individual, or a clinic, our boots are designed to help limit the potential for bacterial transmission.

Charging the RecoveryAir PRO

1. After turning off the pump, plug the power adapter into the charging port of the RecoveryAir PRO pump.
2. You can continue to use the RecoveryAir PRO while charging.
3. Charging is complete when all 3 LED lights of the LED battery indicator are lit.



Traveling with your RecoveryAir PRO Compression System

When traveling with your RecoveryAir PRO Compression System, we recommend:

- Roll the hose tightly and slide it into the foot section of your garment. It is important to keep the hose from creasing to protect the hose's integrity and its ability to properly distribute airflow.
- Once you secure the hose, simply fold your garment to fit into your travel bag or carry-on luggage.
- Secure your pump in the provided carrying pouch.

Lock & unlock feature:

1. To lock or unlock the pump, press and hold the select and up arrow at the same time.
2. You will then see a padlock icon appear on the main screen.

Factory reset

You can perform a factory reset to change all customized programs back to the original default setting by following this easy step:

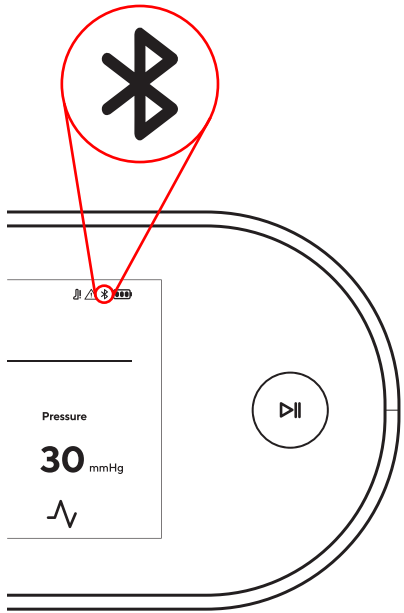
1. Press and hold the select and play/stop buttons.

Select Button *Start/Pause/ Stop Button*

Smart Features

The RecoveryAir PRO also connects to the Therabody app via Bluetooth, giving you total control of your RecoveryAir PRO session from the convenience of your smartphone.

Not only can you easily access options like individual chamber pressure, but you can create and share custom routines with your friends, clients, or patients directly from the app via text message or email.



Scan the QR code to get started.

Download on the App Store

GET IT ON Google Play

Important Safety Information

Read all instructions before using the RecoveryAir PRO Compression System for the first time.

Warning

- This system is intended for use by people in good health. This system is not recommended for people who have heart problems, or vascular problems, have a condition requiring the use of any medical device, or have any condition that may affect their normal well-being.
- If you are, or may be, pregnant, consult with your physician before use.
- Do not use this system over insensitive or numb areas, or in the presence of poor circulation. Do not use if you have been diagnosed with blood clots, deep vein thrombosis or phlebitis. This system should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain.
- Consult your physician prior to use.

Safety Warnings and Precautions

Warning:

- **Explosion Hazard:** Do not use the RecoveryAir PRO Compression System in the presence of flammable gases, including flammable anesthetics.
- **Electric Shock Hazard:** Do not allow liquid to enter any part of the RecoveryAir PRO Compression System pump. Do not immerse in water or liquid. To clean, follow instructions found on page 13.
- **Electric Shock Hazard:** To prevent electric shock, do not open the pump. Do not attempt to service the pump yourself. All repairs should be performed only by Therabody trained and authorized service personnel. Service by unauthorized personnel will void any warranty.
- Stop using the system if there is any change in RecoveryAir PRO Compression System's performance.
- Do not modify any part of the RecoveryAir PRO Compression System.
- The RecoveryAir pneumatic compression system includes small parts that could cause choking in children. Keep away from children and pets.
- Do not inflate the garment without wearing it over the intended body area or with open zippers. Doing so can damage the garment.
- Do not apply excessive force to the garment straps. Do not use the straps for any purpose other than intended by the manufacturer. Use of excessive force and/or misuse shall void the manufacturer's warranty.
- Do not stand or walk while wearing the garment.
- Disconnect the pump from the electrical outlet before cleaning and let it dry completely before reconnecting it to the electrical outlet.

Caution

- Do not operate the RecoveryAir PRO Compression System while operating a vehicle.
- Do not store or transport the RecoveryAir PRO Compression System beyond the specified temperature, humidity, and atmospheric pressure range.
- Do not use the RecoveryAir PRO Compression System beyond the specified temperature range: 10 to 30°C (50 to 86°F).
- Do not use the RecoveryAir PRO Compression System beyond the specified humidity range: 30%rH–75%rH, non-condensing.
- Only use the RecoveryAir PRO Compression System up to 3000m above mean sea level.
- To prevent any damage to the RecoveryAir PRO Compression System, keep it away from dust, lint, and dirt. Keep away from sources of heat or moisture.
- To prevent any damage to equipment, use only accessories, detachable parts, and materials described in this User Manual.
- While in use, place the pump on a horizontal firm surface only. Do not place the pump on a bed, blanket, mattress, pillow, or soft furniture. Do not cover the pump.
- The equipment is to be installed and put into service according to the EMC information provided in Chapter 11 - EMC Manufacturer Declarations.
- Portable and mobile RF communication equipment might affect the equipment.
- For indoor use only.
- Use only the DC power adapter provided with the pump.
- When the system has been stored in extreme temperature conditions of -20°C (-4°F) or 70°C (158°F) between uses, wait for two (2) hours before using the system.
- The massage sensation should be pleasant and comfortable. If you experience pain or discomfort during or after the massage or if there is onset of bruising or irritation during or after the massage, discontinue use and consult your physician.
- Do not hand or machine wash. Surface wipe only.
- Do not allow liquid to get into the air inlets.
- Do not use bleach.
- Do not dry clean.
- Do not wring, iron, tumble, or force heat dry.

Labels

The following labels and symbols appear on the pump, garments and/or packaging.

Label	Description	Location
IP 22	Degree of protection against ingress of water	On console base
	Read instructions before use	On console base
	Read instructions before use (for China only)	On console base
	Level of protection type BF applied part	On garment label
	Class III equipment Equipment relying on limitation of voltage to extra-low-voltage (ELV) values as provision for basic protection and with no provision for fault protection.	On console base
	Manufacturer's name and address	On garment label and console base.
	Unique Device Identification (UDI)	On garment label and package, and garment bag and package

Label	Description	Location
	Separate collection for waste electrical and electronic equipment **Note:** For more information about disposal of equipment, its parts and accessories, please contact your local distributor.	On console base
	In accordance with Directive 2014/35/EU electrical equipment designed for use within certain voltage limits, and Directive 2014/30/EU electromagnetic compatibility	On console
	Do not wash	On garment tag
	Do not dry-clean	On garment tag
	Do not tumble dry	On garment tag
	Do not bleach	On garment tag
	Do not iron	On garment tag

Indications for Use

RecoveryAir is indicated for the temporary relief of minor muscle aches and pains, and for the temporary increase in circulation to the treated areas in people who are in good health. RecoveryAir simulates kneading and stroking of tissues by using an inflatable garment.

Note

- The pump is "multi-voltage" and can be used for travel.
- An appropriate socket adapter must be used in countries with incompatible wall outlets.
- Use only RecoveryAir garments with the RecoveryAir pump.
- When immediate garment deflation is necessary, disconnect the garment hose bundle from the pump to immediately deflate the air pressure in the garment.

Troubleshooting

Note	Possible Cause	Action
The pump is not working.	No electricity	Inspect the electrical wall outlet.
	DC power adapter	Verify that the DC power adapter cable is connected to the DC adapter socket on the console, and the DC power adapter is connected to the 100-240 Volt wall outlet.
	DC power adapter cable	Examine the cable for any defects.
The Status Indicator is On in yellow	Malfunction	Contact Therabody.
The pump starts working and stops immediately.	The air cannot move through the garment hose.	Examine hoses for kinks, twists and folds.

Note	Possible Cause	Action
One garment inflates but the second one does not.	The second garment does not receive air.	Examine its hoses for kinks, twists and folds.
The pump stops working, the Status Indicator turns On in yellow.	Hose is not connected properly to garment or pump, or prong plug is not inserted into unused air outlet.	Examine and fasten all air connections. When treating only one limb, always plug the unused air outlet with the prong plug provided with the pump. If all air connections are OK and the problem persists, contact Therabody.
The pump works at a very low pressure, regardless of the pressure set by the user.	Defective garment	Replace garment and check again.
	Internal malfunction	Contact Therabody.
An irregular noise.	Pump transferring vibrations to a surface	Make sure the pump is standing evenly on all four of its bumpers.
	Internal malfunction	Contact Therabody.

Warranty

For full warranty information, please visit www.therabody.com/warranty. To request a copy of the warranty by mail, you may send a request to the following address:

Therabody - WarrantyAttn: Customer Service
6100 Wilshire Blvd.,
Los Angeles, CA 90048

Please note, this is not a return address or a retail location. No products or packages will be accepted at this location.

Bluetooth Wireless Technology Information

Bluetooth Compliance	Version 4.2 low energy
Operating Frequency	2.402–2.480 GHz
Output Power	0 dBm
Operating Range	3-meter radius (line of sight)

Network Topology	Star - bus
Operation	Slave
Antenna Type	Integrated chip type antenna
Modulation Type	Adaptive Frequency Hopping
Data Rate	Over the air: 1 Mbit/second Application throughput: 0.27 Mbit/s
Data Latency	6 ms
Data Integrity	Adaptive Frequency Hopping
Robustness	24-bit CRC (cyclic redundancy check) 32-bit message integrity check
Quality of Service	This device uses Bluetooth smart technology for wireless communication, which allows for reliable communication in electrically noisy environments. If connection is lost, the device will automatically reconnect in a few seconds.
Bluetooth Profiles Supported	GAP, GATT, SM, L2CAP and Integrated Public Profiles
Authentication and Encryption	Supported

EMC Manufacturer Declarations

Electromagnetic Compatibility (EMC) Statement for Home Healthcare Environment

The RecoveryAir PRO system has been evaluated to international standard IEC 60601- 1-2 "General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests".

The Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here within the accompanying documents.

Portable and mobile RF communication can affect the Medical Electrical Equipment. See below recommended separation distances between portable and mobile RF communication equipment and the RecoveryAir PRO system.

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3.3 m away from the system.

Rated Maximum Output Power of Transmitter (W)	Separation Distance* according to Frequency of Transmitter (m)
0.01	0.23
0.1	0.73
1	2.3
10	7.3
100	23

*Note: The distance calculated from 800 MHz to 2.5 GHz

Caution: Basic Safety and Essential Performance

- This system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this system should be observed to verify normal operation in the configuration in which it will be used.
- The essential performance of the RecoveryAir PRO system as evaluated in IEC 60601-1-2 includes treatment completing cycle, presentation on the display is not interfered, and treatment parameters are not changed unintentionally.
- The following, but not limited to, are unacceptable risks that are not allowed: malfunction, non-operation when operation is required, unwanted operation when no operation is required, deviation from normal operation that poses unacceptable risk to operator or user, component failure, change in programmable parameter(s), change in operation mode, reset to factory defaults, and false positive or false negative alarm.
- Do not apply the device near any devices with Electromagnetic Interference (EMI), such as cell phones, Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio

Frequency Identification (RFID), etc. or MR environment. EMI, RF devices or MR environments may affect the normal function of the device or would cause user injury.

Guidance and Manufacturer's Declaration – Electromagnetic Emission

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

Emission Test	Compliance	Electromagnetic Environment – Guidance
The device 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.		
IEC 61000-3-3	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The RecoveryAir PRO device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	2, 4, 6, 8 kV contact 2, 4, 8, 15 kV air	2, 4, 6, 8 kV contact 2, 4, 8, 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 for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	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% UT(>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% UT(>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted Immunity 61000-4-6	3 Vrms/m for 0.15MHz to 80MHz 6 Vrms/m for ISM & amateur radio band.	3 Vrms/m for 0.15MHz to 80MHz 6 Vrms/m for ISM & amateur radio band.	Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance = 1 . 2 = 1 . 2 80 MHz to 800MHz = 2 . 3 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a) should be less than the compliance level in each frequency range(b) . Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated Immunity 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
(a). Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
(b). Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the Device

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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 Watt (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Reporting adverse events to FDA

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help the FDA evaluate your report. However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting adverse event reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1. Report Online at: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
2. Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at: www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf
3. Call FDA at 1-800-FDA-1088 to report by telephone.
4. Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

Storage environment shall be expressed:

- The pump can be transported or stored for short periods of time within:
  - Temperature range of -4 - 158°F (-20 - 70°C)
  - Humidity range of 10-93% RH non-condensing
  - Atmospheric pressure range of 190 - 1060hPa
- Allow the pump to reach a reasonable room temperature of 50 - 86°F (10 - 30°C) before operating.
- When the system has been stored in extreme temperature conditions of -20°C (-4°F) or 70°C (158°F) between uses, wait for two (2) hours before using again.

FCC compliance statement

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. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

ISED compliance statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:
(1) This device may not cause interference.
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Radiation Exposure statement

This equipment complies with FCC/IC RSS-102 radiation exposure limits set forth for an uncontrolled environment.

RecoveryAir

by Therabody

Born in Los Angeles, CA.
Designed for every***body.***

@Therabody