

# Hyperice 69000 001-03 Normatec Elite Instruction Manual

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# **Hyperice**

Hyperice 69000 001-03 Normatec Elite



# **Specifications**

- Product Name: Normatec Elite
- Intended Use: Air pressure massager for temporary relief of muscle aches and increased circulation
- · Power Source: Li-ion battery
- Manufacturer Contact: +1.949.565.4994

# **Product Usage Instructions:**

# **Charging the Control Unit:**

The Normatec Elite control unit is equipped with a lithium-ion battery. To charge the battery, follow these steps:

- 1. Connect the charger to the control unit.
- 2. Plug the charger into an electrical outlet.
- 3. The battery will automatically start charging.

# **Operating the Normatec Elite:**

To use the Normatec Elite for muscle relief and increased circulation, follow these instructions:

- 1. Ensure the battery is charged.
- 2. Place the control unit in standby mode.
- 3. Attach the appropriate zones for treatment.
- 4. Adjust the settings as needed for comfort.
- 5. Start the session and monitor your comfort level.
- 6. If discomfort arises, reduce the level or stop the session.

#### FAQ:

#### What is the intended use of the Normatec Elite?

The Normatec Elite is designed as an air pressure massager to provide temporary relief for minor muscle aches and increase circulation in the treated area.

TO REDUCE RISKS OF ELECTRIC SHOCK, FIRE, AND PERSONAL INJURY, OR PROPERTY DAMAGE, THIS DEVICE MUST BE USED IN ACCORDANCE WITH THE FOLLOWING WARNINGS, CAUTIONS, AND SAFETY INSTRUCTIONS

#### **IMPORTANT SAFETY INSTRUCTIONS -**

ORIGINAL INSTRUCTIONS Read the entire instruction manual before using the Normatec Elite.

#### **WARNING**

No modification of this ME system is allowed. Do not use in or near an MRI environment.

If you experience severe pain, any unusual symptoms, or want to remove the device in an emergency during use:

- Stop the device by pressing the Start/Stop or power button.
- Remove the device from your limbs.
- Promptly consult your licensed healthcare practitioner, as required.

#### **CAUTION**

- Do not attempt to take apart the device. The device has no user-serviceable parts. When service or repairs are required, please contact customer service at +1.949.565.4994.
- Only use the charger provided with the device. Using a different charger may cause the device to operate
  incorrectly.
- To avoid risk of electric shock, do not use the device near water, such as near a bathtub, kitchen sink, laundry tub, or swimming pool.
- To avoid damage and risk of electric shock, never spill liquid of any kind on the device.
- Do not place the device or charger where they could be damaged, present a fall hazard, or become an obstruction to others.
- · Keep the power inlet free of debris.
- If the charger is damaged, the control unit is dropped or damaged, liquid is spilled on the device, or the device does not operate normally when the operating instructions are followed, turn the device off by pushing the control unit's power button and then unplugging the device from the wall outlet. Contact customer service at +1.949.565.4994 for assistance.
- Do not puncture or otherwise damage the device as this may cause it to operate incorrectly.
- To avoid risk of strangulation, do not leave a baby or child unattended with the charger.
- Choking hazard, small parts. Keep away from small children.
- Do not leave the device or charger where they could be damaged by children, pets, pests, or liquids. If you suspect your control unit is damaged, contact customer service at +1.949.565.4994 for assistance.
- Do not allow lint or dust to accumulate on the device. If lint or dust accumulates, wipe down the device with a dry cloth before use.
- The IP22 classification means the control unit is protected against the ingress of vertically dripping water and the hazardous parts are protected against access to objects equal to or larger than 12.5 mm (1/2").
- The expected service life of the device and the integrated battery is 3 years.
- Do not stand or walk while wearing the device.

- The device is designed to be used by only one person at a time.
- Product is to be used by adults only in good health.
- Consult your physician before using this product if you are under the care of a physician or have a contraindication requiring the use of any medical device.
- Consult your physician before using this product if you are experiencing inflammation, an infection, pain of unknown origin, bleeding (internal or external) at or near the site of application, or if you have a wound at or near the site of application.
- Consult your physician before using this product on sensitive skin.
- Consult your physician before using this product if you have any of the following conditions:
- · Acute pulmonary edema
- · Acute thrombophlebitis
- · Acute congestive cardiac failure
- · Acute infections
- Deep vein thrombosis (DVT)
- Episodes of pulmonary embolism
- Wounds, lesions, or tumors at or near the site of application
- Where increased venous and lymphatic return is undesirable
- Bone fractures or dislocations at or near the site of application
- Use by unconscious or incapacitated persons may be dangerous without supervision.
- Make sure the power inlet on the control unit is easily accessible at all times in order to disconnect power if required.

The Normatec Elite control unit contains a Li-ion battery. The battery must be complied with safely at an appropriate e-waste disposal or recycling facility.

# SAVE THESE INSTRUCTIONS

#### **LABELS**

The following labels and symbols appear on the control unit, attachments, and/or packaging.

Symbol	Description	Location
IP22	Degree of protection against ingress of water	On base of control unit
₿	Read instructions before use	On base of control unit and attachment tag
橑	Level of protection type BF equipment	On base of control unit
	Double insulation	On power adapter
	Direct current	On base of control unit
$\sim$	Alternating current	In manual
	Manufacturer's name and address	On base of control unit and attachment tag
~	Date of manufacture	On base of control unit
N	Separate collection for waste electrical and electronic equipment	On base of control unit
SN XXXXX	Serial number of the console	On base of control unit
¥	Fragile, handle with care	On package
<del>*</del>	Keep dry	On package
11	This side up	On package
类	Keep away from sunlight	On package
Ø	Transportation & storage humidity limitation	On package
(a)	Transportation & storage atmospheric pressure limitation	On package
7	Transportation & storage temperature limitation	On package
Ф	Place in and out of standby mode	On top of control unit
数	Do not wash	On attachment tag

(MR)	Do not use in or near an MRI environment	In manual
8	Do not dry clean	On attachment tag
1331	Do not tumble dry	On attachment tag
*	Do not bleach	On attachment tag
<b>≥</b>	Do not iron	On attachment tag
(0 <u>1</u> 1))	EU RF transmitter symbol	In manual
Æ	FCC approved equipment authorization	On control unit
8	The Bluetooth figure mark	On control unit
$\triangle$	Warning symbol to identify a hazard that may lead to death or serious injury	In manual and on control unit
$\triangle$	Caution symbol to indicate the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical control unit itself	In manual
æ	Tip to provide guidance to make use easier. Risk to user is considered negligible	In manual
REF	Indicates the manufacturer's model number so the device can be identified.	On control unit

# **INDICATIONS FOR USE**

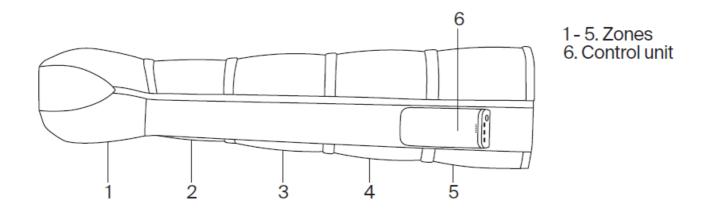
The Normatec Elite is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated area.

# **RISKS AND BENEFITS OF THE NORMATEC ELITE**

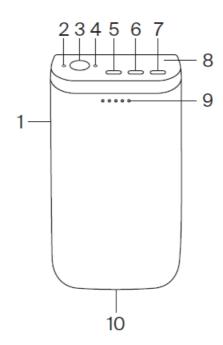
The risks and benefits of using the Normatec Elite are similar to having a massage. If the Normatec Elite massage feels uncomfortable, you can reduce the level or stop the session. Benefits include the temporary relief of minor

muscle aches and pains, and increased circulation in the area being treated. Please call customer service at +1.949.565.4994 if you have any questions.

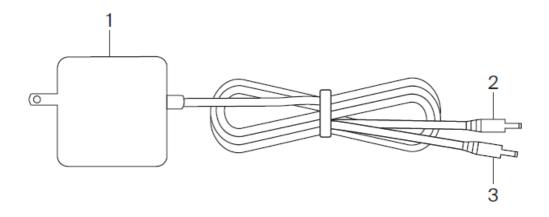
# **ILLUSTRATIONS OF ME SYSTEM COMPONENTS**



- 1. Power button Bluetooth
- 2. status indicator
- 3. Start/Stop button
- 4. HyperSync'"status indicator
- 5. ZoneBoost™button
- 6. Time adjustment button
- 7. Pressure level adjustment button
- 8. Display screen
- 9. Battery status indicator
- 10. Power jack



- 1. Wall outlet plug
- 2-3. Barrel connectors



#### **OPERATING INSTRUCTIONS**

WARNING! BEFORE OPERATING THIS DEVICE: Read all warnings at the beginning of this manual. If you do not understand these operating instructions, contact Hyperice at +1.949.565.4994. Make sure that the equipment operating environment meets the specifications otherwise unexpected consequences, e.g. damage tot he equipment, could result. The operating environment of the equipment must meet the requirements specified in this manual. If device is exposed to extreme temperatures, allow device to acclimate to ambient temperature for 30 minutes before use.

#### **SET UP THE DEVICE**

- 1. Step 1: Plug the charger into an electrical outlet and then into the Normatec Elite control unit. The charger has a bifurcated cable so you can charge your left and right Normatec Elite legs at the same time. This control unit is equipped with a lithium-ion battery. The battery automatically charges when the charger is connected to the Normatec Elite control unit and an electrical outlet. Battery status indicator lights show charge status; one light is low battery, five lights is fully charged
- 2. Step 2: Put the device on. The control units should sit towards the outside of either leg. Find a comfortable position sitting, reclined, or lying down. Never try to use the device with the zipper partially or totally unzipped—this could void your warranty.
  - Besure to zip the legs fully before starting treatment to prevent damage to your Normatec Elite
- 3. Step 3: Press the power button on the Normatec Elite control unit firmly for one second to turn on the device. While the control unit is on, the display will light up and show the current settings for Level, Time and ZoneBoost.

#### **ADJUST THE PRESSURE LEVEL**

Adjust the pressure level of the session by pressing the pressure level adjustment button on the left of the level indicators. Pressure level 1 is the gentlest setting. The massage becomes more intense as the pressure level is increased. Level can be adjusted while the session is running.

#### **ADJUST THE SESSION TIME**

Adjust the session time by pressing the time adjustment button on the left of the display screen. The session time can be set to 15, 30, 45 and 60 minutes. Time can be adjusted while the session is running. Tap the time adjustment buttons to cycle through the session time options to add or subtract time from the session.

#### **USE ZONEBOOST™**

During your session, you can increase the intensity of a single zone with the ZoneBoost feature. ZoneBoost is designed to be used when you want extra attention in a specific area. ZoneBoost will add an extra 60 seconds of massage time, as well as 10 mmHg increased pressure, in the selected zone. ZoneBoost can be enabled before

or during a session. Only one zone can be boosted at a time. To boost a zone press the ZoneBoost button until the display shows the number of the zone you want to boost. To disable ZoneBoost press the ZoneBoost button until the display shows "-".

The zones on the attachment are numbered in ascending order from distal zone to proximal zone. Zone 1 would be your foot/ankle, Zone 2 would be your calf, Zone 3 your knee, Zone 4 lower quad and Zone 5 upper quad.

#### START THE SESSION

To start the session, tap the Start/Stop button.

#### PATENTED NORMATEC PULSE MASSAGE PATTERN

Before the patented Normatec Pulse massage pattern begins, you will experience a pre-inflate cycle, during which the inflatable boots are calibrated to your exact body shape. Once the pre-inflate cycle is complete, the patented Normatec Pulse massage pattern will begin by compressing your feet. Similar to the kneading and stroking performed during a massage, each zone of the boots will first compress in a pulsing manner and then release as the compression pattern works its way up your leg. When the top zone completes its massage, there will be a brief rest period and then the cycle will begin again. This will repeat until the session time runs out. When the session is resumed after a pause, the device will perform a pre-inflate cycle before continuing.

#### STOP OR PAUSE THE SESSION

To stop the session at any time, tap the Start/Stop button. This will pause the session. To restart your paused session, tap the Start/Stop button again. If you are done using the device, turn off the device by pressing the power button and remove the inflatable boots from your limbs.

To remove the boots, fully unzip the garment and then remove.



The session will continue massaging until time runs out and the display reads Finishing Cycle. The device will continue until the current cycle is finished. When the session is completed, turn off the control unit by pressing the power button and remove the boots from your limbs.

To remove the boots, fully unzip the garment and then remove.



To turn off the device, press the power button and confirm that the LED indicators and display is off.

#### **USING HYPERSYNC™**

Your Normatec Elite devices arrive paired, which means they will inflate and deflate on the same cycle. To unpair devices, press and hold the Start / Stop button on either device until the device screen reads "Unpaired!" and the white pairing indicator light is no longer illuminated. To pair your devices, turn on both devices by pressing and holding the power (ON/OFF) button. Then press and hold Start / Stop button on either control unit until the display screen says "Pairing!" Finally, press and hold the Start / Stop button on the other device until both devices say "Pairing!" and the white pairing indicator light is illuminated.

### **CONNECTING TO THE HYPERICE APP**

Download the Hyperice App from the App Store or the Google Play Store. To connect your device to the Hyperice App via Bluetooth® make sure that your device is turned on, Bluetooth® is turned on in your phone, and your device is within range of your phone. If prompted, tap "Scan for Devices." Select your device when it pops up on the screen. The blue LED on the control unit will light up when you have successfully connected to your mobile device. Once you pair your Normatec Elite, HyperSmart™ will allow you to automatically start your session and control the within the Hyperice App.

It is recommended to configure the Hyperice App for automatic updates to ensure cybersecurity. It is also recommended to keep your Operating System up to date and to configure your Operating System for automatic updates.

#### **CLEANING THE DEVICE**

#### To clean the control unit:

- Wipe down the device with a damp, clean cloth.
- Dry thoroughly with a clean cloth.

#### Cleaning the single-person use inflatable boot:

- Wipe it down inside and out with a damp, clean cloth.
- · Dry thoroughly with a clean cloth.
- · Do not machine wash or dry.
- · Do not dry clean.

#### **MAINTAINING THE DEVICE**

The Normatec Elite requires no routine maintenance or service except for the care in this section.

#### STORING THE DEVICE

Store your Normatec Elite in a clean, dry location.

# **REPLACEMENT PARTS**

Please call customer service at +1.949.565.4994 or visit our website at <a href="https://hyperice.com">hyperice.com</a> for information regarding available replacement parts and accessories.

#### **TECHNICAL INFORMATION**

Do not attempt to take apart the device. The device has no user-serviceable parts. There are no user-replaceable fuses.

#### **BLUETOOTH WIRELESS TECHNOLOGY**

The Bluetooth word mark and logos are owned by Bluetooth SIG, Inc., and any use of such marks by Hyperice is under license. In the unlikely event of loss of a stable Bluetooth connection, the device will attempt to re-establish its connection automatically. The Normatec Elite control unit is completely autonomous, and will continue operating normally, even during a loss of connectivity. If this control unit does cause interference, which can be determined by turning the control unit off and on, the user is encouraged to try to correct the interference by reorienting or relocating the control unit, increasing the separation between equipment and the control unit, or connecting the control unit to a different outlet on a circuit if it is plugged in.

The Normatec Elite control unit uses Bluetooth 5.0 wireless technology with the following radio specifications:

	FCC ID: 2AY3Y-NTE IC: 23655-NTE	FCC ID: 2AY3Y-NTEA IC:23655-NTEA
Frequency	2402 to 2480 MHz, 433.920 MHz	
Modulations	GFSK	
Transmit Power	+4 dBm	
Security	Security AES HW	

This control unit complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1. This control unit may not cause harmful interference, and
- 2. this control unit must accept any interference received, including interference that may cause undesired operation.

This control unit complies with Innovation, Science and Economic Development Canada's license-exempt RSS standard(s). Operation is subject to the following two conditions:

- 1. this control unit may not cause interference, and
- 2. this control unit must accept an interference, including interference that may cause undesired operation of the device.

This equipment complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This equipment has very low levels of RF energy that are deemed to comply without testing of specific absorption rate (SAR).

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.

# INTERNAL BATTERY INFORMATION

This Normatec Elite control unit is equipped with a rechargeable lithium-ion battery. The internal battery is designed to allow use of the Normatec Elite anywhere—even when power outlets aren't available. The Normatec Elite control unit may need to be plugged in before first use. A fully charged battery will provide power for 3+ hours of continuous use. It takes approximately 5 hours to fully charge the battery when the control unit is plugged in and not in use. The rechargeable lithium-ion battery is intended to be changed only by authorized service personnel with the use of a special service tool. Battery voltage and capacity: 7.2V, 5000 mAh / 7.38V, 4800 mAh

#### PRODUCT SPECIFICATIONS

- Normatec Elite Model: JPN11 -SH, JPN11-ST, JPN11-TL, JPN11-PH, JPN11-PS, JPN11-PT
- Hardware versions: V1.3, V1.4, V1.5, V1.6, V1.7, V1.8, V1.9, V1.10, V1.11, V1.12, V1.13, V1.14
- Normatec Elite Dimensions: 4" (width), 4" (depth), 8.5" (height); [10.2 cm (width), 10.2 cm (depth), 21.6 cm (height)]
- Normatec Elite Weight: 3.2 lbs [1.45 kg]•
- Normatec Elite electrical requirement: 12V DC 4 A•

- Maximum Air Pressure: 110 mm Hg
- Temperature (operating): +41° F to 104° F [+5° C to +40° C]
- Temperature (storage): -13° F to +158° F [-25° C to +70° C]
- Relative Humidity (operating): 15% to 93%, non-condensing
- Relative Humidity (storage): -25° C without relative humidity control; +70° C at relative humidity up to 93%, noncondensing
- Atmospheric pressure (storage and transportation): 190hPa to 1060hPa
- Atmospheric pressure (operating): 700hPa to 1060hPa

#### **AC-DC ADAPTER**

WARNING! Only use the AC-DC adapter model number SMS-01120400-S68 provided with the device. Using a different adapter may cause the device to not operate correctly.

Input: 100-240V - 1.5 A 50/60 Hz
 Output: 12V = DC minimum 4 A

#### **ELECTROMAGNETIC COMPATIBILITY**

The information contained in this section (such as separation distances) is in general specifically written with regard to the Normatec Elite. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

#### **GENERAL NOTES**

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use of this control unit.

#### **WARNING!**

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas)
   should be used no closer than 30 cm (12 inches) to any part of the Normatec Elite, including cables specified by
   the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The Normatec Elite should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Normatec Elite should be observed to verify normal operation. If operation is not normal, the Normatec Elite or the other equipment should be moved.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this
  equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this
  equipment and result in improper operation.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as antitheft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

#### **ELECTROMAGNETIC EMISSIONS**

Emissions	Compliance According To	Electromagnetic Environment	
RF emissions (CISPR 11)	Group 1	The equipment 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.	
CISPR emissions classification	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage charger network	
Harmonic emissions (IEC 61000-3-2)	Class A	that supplies buildings used for domestic purposes.	
Voltage fluctuations/ flicker (IEC 61000-3-3)	Complies		

# **ELECTROMAGNETIC IMMUNITY**

During the immunity testing described below the Normatec Elite continued to provide therapy normally. This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

Immunity Against		Compliance Level (of this control unit)	Electromagnetic Environment	
Electrostatic discharge, ESD (IEC 61000-4-2)		± 8 kV Direct ± 2,4,8,15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.	
Electrical fast transients/bursts (IEC 61000-4-4)		± 2 kV	Mains power quality should be that of a typical clinic, hospital, athletic training, or home environment.	
RF Proximity (IEC 61000-4-3)		27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 28 V/m 9 V/m	Equipment with high RF emissions should be kept at a distance to reduce the likelihood of interference.	
	Surges on AC mains lines (IEC 61000-4-5)	±1kV	Mains power quality should be that of a typical clinic, hospital, athletic training, or home environment.	
	Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	30 A/m	Equipment that emits high levels of power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference.	
	Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	0.5 cycles 1 cycle 25 cycles (50 Hz) 30 cycles (60 Hz) 250 cycles (50 Hz) 300 cycles (60 Hz)	Mains power should be that of a typical clinic, hospital, athletic training, or home environment. If you require continued operation during power mains interruptions, ensure that batteries are installed and charged. Ensure that battery life exceeds longest anticipated power outages or provide additional uninterruptible power source.	
	Conducted RF RF coupled into lines (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	This device is suitable for the electromagnetic environment of typical clinic, hospital, athletic training or home environments.	
	Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz		

# **EQUIPMENT CLASSIFICATION**

• Protection against electric shock: Class II/internally powered equipment

- Degree of protection against electric shock: Type BF applied part (device and inflatable boots)
- Ingress protection: IP22
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Continuous operation

#### **TROUBLESHOOTING**

Problem	Possible Causes	Solutions
The device does not start	Power is not turned on Charger is not securely connected	Press the power button to turn the control unit on.  Check that the battery is charged or that the charger is securely connected to the Normatec Elite control unit and the electrical outlet.  Check that the wall outlet works.
The attachment does not inflate	The session has not been started  The attachment has been damaged	Check that the Start/Stop LED is ON and the timer is counting down. If not, press Start/Stop button to start or resume session.  Check that there is no air leak error message on the display screen.

The device stopped pumping	The session has been stopped or ended	Check that the Start/Stop LED is ON and the timer is counting down. If not, press Start/Stop button to start or resume session.  Check that there is no air leak error message on the display screen.  Check that there is no Low Battery message on the display screen.
		Giopiay Gorecon.
Message: Air Leak	Air leak	Check for punctures in the attachment.
Message: Low Battery	Battery needs to be charged	Plug in the control unit to charge the battery
Cannot establish or maintain a Bluetooth connection	Bluetooth is turned off on mobile device	Turn on Bluetooth on mobile device attempting to connect with the Normatec Elite
Devices not synching settings and/or treatment	Devices are not paired	Check that the white pairing indicator light is illuminated on both devices. If not, your devices are not paired. Follow the "Using HyperSyncTM" instructions in the Operating Instructions to pair your devices.

Call Hyperice customer service at +1.949.565.4994 if further assistance is needed.

#### WARRANTY INFORMATION

• Normatec Elite Limited One-Year Warranty The Normatec Elite control unit is warranted by Hyperice, Inc. a California corporation ("Hyperice"), against manufacturing defects in material and workmanship for a period of one year from the date of purchase from Hyperice. In the event of any such defect occurring during the warranty period, Hyperice will, at its option, (a) correct the defect by repair or by replacement of the applicable part or component that fails as a result of such defect, without charge for parts and labor; or (b) replace the

control unit with one of the same or then current design.

- The foregoing Warranties do not cover normal wear and tear or cosmetic damage, and are void if the control unit and/or the attachments and other accessories (collectively, the "product") are not used in accordance with the user manual, are otherwise misused or modified in any way, and/or are repaired or altered by anyone other than an authorized service representative of Hyperice. These Warranties expressly exclude transportation, shipping or insurance costs, or defects, damages, or failure resulting from misuse, abuse, improper or abnormal usage, or neglect.
- EXCEPT AS PROVIDED ABOVE, HYPERICE MAKES NO EXPRESS WARRANTIES OR ANY IMPLIED
  WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR
  PURPOSE OR USE, AND ARE LIMITED IN DURATION AS STATED ABOVE. EXCEPT AS EXPRESSLY
  STATED ABOVE, HYPERICE SHALL HAVE NO LIABILITY OR RESPONSIBILITY TO ITS CUSTOMER OR
  ANY OTHER
- PERSON OR ENTITY WITH RESPECT TO ANY LIABILITY, LOSS, OR DAMAGE CAUSED DIRECTLY OR INDIRECTLY BY USE OR PERFORMANCE OF THE PRODUCT OR ARISING OUT OF THE USE OR INABILITY TO USE THE PRODUCT OR ANY BREACH OF THESE WARRANTIES, INCLUDING BUT NOT LIMITED TO ANY DAMAGES RESULTING FROM INCONVENIENCE, LOSS OF TIME, PROPERTY, OR INCOME, OR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND.
- Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above
  limitations or exclusions may not apply to you. These Warranties give you specific legal rights, and you may
  also have other rights, which vary from state to state. In the event of a product defect covered by the foregoing
  Warranties during the applicable warranty period, contact Hyperice at +1.949.565.4994 or
  customersupport@hyperice.com

All replaced parts and products become the property of Hyperice. New or reconditioned parts and products may be used in the performance of Warranty service. Repaired or replaced parts and products are warranted for the remainder of the original warranty period only. You will be charged for repair or replacement of parts and products made after the expiration of the applicable Warranty period.

#### **RETURN POLICY**

This policy is only applicable if you are an end user and you purchased the equipment directly from Hyperice. In the unlikely event that you are not satisfied with your purchase, you may return it within thirty (30) days of the purchase date. All returns are subject to the conditions listed below.

- Returns must have a Return Merchandise Authorization (RMA) number. Obtain an RMA number by contacting
  us at +1.949.565.4994 or <u>customersupport@hyperice.com</u> Returned items without an RMA number will not
  be eligible for a credit to your account.
- Returns must be shipped within 30 days of the purchase date.
- Products and packaging must be returned in new and undamaged condition. Any products showing signs of
  wear or being soiled in any way will be deemed "unacceptable," and you will be so notified. Unacceptable
  returns may be reshipped to you following payment of an inspection/shipping fee.
- If you refuse delivery of your order for any reason, you will be refunded the cost of your order less shipping fees.
- All partial or full refunds will be posted to the credit card used for purchase.
- Hyperice is not responsible for items lost or damaged during shipping.

#### RECYCLING

Please visit <a href="https://hyperice.com/recycling">https://hyperice.com/recycling</a> for information about recycling this packaging.

#### **FDA INFORMATION**

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 FDA evaluate your report. However, we understand that for a variety of reasons, you may not wish to have the form filled out by health care 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 acknowledgment from 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:

- Report online at: <a href="https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home">www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home</a>
- 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
- Call FDA at 1-800-FDA-1088 to report by telephone

Reporting Form FDA 3500 commonly used by heath professionals. The form is available at: <a href="https://www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm163919.pdf">www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm163919.pdf</a>
Hereby, Hyperice Inc decalres that the radio equipment contained in the Normatec Elite is in complinace with the Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: <a href="https://hyperice.zendesk.com/hc/en-us">https://hyperice.zendesk.com/hc/en-us</a>

#### FOR MEXICO ONLY

- This device is not intended for use by persons (including children) whose physical, sensory or mental capabilities are different or reduced, or who lack experience or knowledge, unless such persons have been given supervision or training in the operation of the device by a person responsible for their safety.
- Children should be supervised to ensure that they do not use the devices as toys.
- The device must only be powered at the safety extra-low voltage indicated on the device.
- The device must only be used with the charger unit provided with the device.
- The battery must be removed from the device before disposal. The device must be disconnected from the charger when the battery is removed. The battery is removed for safe disposal.

#### hyperice.com

NormaTec Industries, LP 480 Pleasant Street Watertown, Massachusetts 02472 USA

#### **Documents / Resources**

Normatec Elite

<u>Hyperice 69000 001-03 Normatec Elite</u> [pdf] Instruction Manual 69000 001-03 Normatec Elite, 69000 001-03, Normatec Elite, Elite

#### References

- " hyperice.com
- MedWatch Online Voluntary Reporting Form
- <u>hyperice.com/recycling</u>
- User Manual

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