INSTRUCTION MANUAL

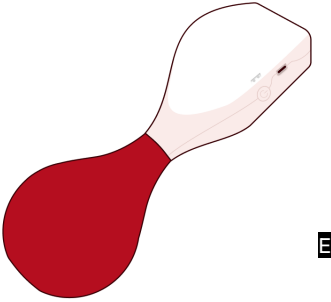
Eforto

“Digital Hand Grip Measuring Device”

Eforto® Device

REF Eforto® R1 / H1

Read Instructions before use.



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1 Introduction

Thank you for selecting the Eforto® Device R1 / Eforto® Device H1.
The digital Eforto® Device, combined with its associated software, allows users to measure hand grip strength and endurance.
Associated software can be any Smart Device App Certified by the Manufacturer to be used with the Eforto® Device.
A Smart Device can be a smartphone or tablet with the Android or iOS operating system.
All Eforto®-certified Apps can be found at https://www.eforto.com/.
Example: "Eforto® Device I/O" App

This instruction manual provides you with important safety and care information and step-by-step instructions for using the Eforto® Device. Please read and understand the manual thoroughly before using the product.

Important Notice
To ensure the safe and proper use of the Eforto® Device, READ and UNDERSTAND all of the safety and operating instructions and information. **If you do not understand these instructions or have any questions, contact the dealer whom the product was purchased from, an authorized Eforto® distributor or contact Eforto®'s Customer Service at support@eforto.com or via www.eforto.com before attempting to use the Eforto® Device. For specific information about your own grip strength measurement, consult with a healthcare provider.**
Remove the Eforto® Device from the packaging and inspect for damage. If this device is damaged, DO NOT USE and consult with your Eforto® dealer or authorized distributor.

2 Intended Use

The Eforto® Device and its associated software are designed to assess hand grip strength and endurance (muscle fatigability) in adults interested in evaluating and tracking changes in physical fitness, vitality, general health, and wellness over time.
The device captures pressure data exerted by the user's hand on the bulb, records pressure strength decay via a Smart Device application, and provides quantitative feedback on hand grip strength and muscle fatigability.

The Eforto® Device is NOT a Medical Device, it is not designed or intended for use in the diagnosis, treatment, mitigation, or prevention of any disease, medical condition, or disorder. The Eforto® Device should not be used as a substitute for professional medical advice, diagnosis, or treatment. Users should always consult their healthcare provider before making lifestyle changes or in cases of health concerns.

3 Indications for Use

Intended for use by adult users conducting self-measurements at home and health coaches or fitness trainers assisting adults in fitness and wellness center settings. The device gives users insights into their physical reserves and vitality, promoting self-awareness and a healthy lifestyle. The Eforto® Device is indicated for home and fitness use.

4 Technological Characteristics

The Eforto® Device uses air pressure from your hand grip to measure hand grip strength and endurance.
Before every measurement, the device establishes a “zero pressure” equivalent to the atmospheric pressure (i.e. the reference point).
While squeezing the bulb, the device measures the air pressure (kPa) by comparing the recorded pressure values with the reference point.

5 Important Safety Information

Read the Important Safety Information in this instruction manual before using this device. Follow this instruction manual thoroughly for your safety. Keep it for future reference. For specific information about your own grip strength, CONSULT WITH YOUR PHYSICIAN.

Any serious incident occurring in relation to the Eforto® Device should be reported to Eforto®'s Customer Service at support@eforto.com or via www.eforto.com.

5.1 Contra-indications

- ⚠ DO NOT use this device if you have a medical pre-condition on your hand/arm, an injured hand/arm, or your hand/arm is under medical treatment.
- ⚠ DO NOT use this device on a hand/arm while on an intravenous drip or blood transfusion.
- ⚠ Consult with your physician before using this device if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arteriosclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering, may affect the measurement reading.
- ⚠ Consult with your physician before using this device with a hand/arm where intravascular access or therapy, or an arteriovenous (A-V) shunt, is present.
- ⚠ Consult with your physician before using this device if you have had a mastectomy.
- ⚠ If you are allergic to Polycarbonate/Acrylonitrile Butadiene Styrene (PC/ABS) or Sarolit®, don't use this device.

5.2 Warnings

The “WARNING” sign throughout this instruction manual indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- ⚠ DO NOT use this device for infants, toddlers, children or persons who cannot express themselves.
- ⚠ DO NOT adjust medication based on readings from this grip strength measuring device. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat any diseases
- ⚠ DO NOT use this device if you have a medical pre-condition on your hand/arm, an injured hand/arm, or your hand/arm is under medical treatment.
- ⚠ DO NOT use this device on a hand/arm while on an intravenous drip or blood transfusion.
- ⚠ DO NOT use this device in areas containing high-frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, or computerized tomography (CT) scanners. Since it may result in incorrect operation of the device and/or cause an inaccurate reading.
- ⚠ This device may emit electromagnetic interference or other types of interference that could adversely affect the performance of nearby life-supporting devices. DO NOT use this device in close proximity to any critical or life-supporting equipment.
- ⚠ DO NOT use this device in oxygen-rich environments or near flammable gas.
- ⚠ Consult with your physician before using this device if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arteriosclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering, may affect the measurement reading.
- ⚠ NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- ⚠ To help avoid strangulation, keep the AC/DC adapter cable away from infants, toddlers and children.
- ⚠ This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children.

⚠ Make sure to keep breathing while performing measurements with this device.

Data Transmission

⚠ This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted. Turn off the device and unplug the AC/DC adapter when in RF-restricted areas.

AC/DC adapter Handling and Usage

⚠ DO NOT use the AC/DC adapter if this device or the AC/DC adapter cable is damaged. If this device or the cable is damaged, turn off the power and unplug the AC/DC adapter immediately.
⚠ Plug the AC/DC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
⚠ NEVER plug in or unplug the AC/DC adapter from the electric outlet with wet hands.
⚠ DO NOT disassemble or attempt to repair the AC/DC adapter.
⚠ DO NOT use the Eforto® Device while connected with the AC/DC adapter plugged into the Mains.
⚠ ONLY use the Eforto® Device with a 60601-1 certified AC/DC adapter and USB-C cable.
⚠ ONLY use a short charging cable (≤ 1 meter).

5.3 Cautions

The “Caution” sign throughout this instruction manual indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment or other property.

⚠ STOP using this device and consult with your physician if you experience skin irritation, pain or discomfort.

⚠ Consult with your physician before using this device with a hand/arm where intravascular access or therapy, or an arteriovenous (A-V) shunt, is present.
⚠ Consult with your physician before using this device if you have had a mastectomy.
⚠ STOP using the device once you are feeling pain or discomfort.
⚠ DO NOT take measurements more often than necessary because repeated tests can cause muscle and joint pain.
⚠ DO NOT use this device for any purpose other than measuring hand grip strength and endurance.
⚠ During measurement, ensure that no other electrical devices emitting electromagnetic fields are within 30 cm of this device. This may result in incorrect operation of the device and/or cause an inaccurate reading.
⚠ DO NOT disassemble or attempt to repair this device or other components. This will void the warranty, accurate measurement, and may cause injuries and harmful situations such as burn wounds, lacerations, electric shock and blast injuries.
⚠ DO NOT use this device in a location where there is moisture or a risk of water splashing this device. This may damage this device.
⚠ Dust and water may affect the performance of the device. Please consult the cleaning instructions carefully in section 8.3.
⚠ DO NOT use this device in a moving vehicle, such as in a car or an aircraft.
⚠ DO NOT drop or subject this device to strong shocks or vibrations.
⚠ This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this section 8.
⚠ DO NOT use this device in places with high or low humidity or high or low temperatures. Refer to section 10.
⚠ DO NOT use this device simultaneously with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation and/or cause an inaccurate reading.
⚠ Remain still and DO NOT talk while taking a measurement.
⚠ Ensure that this device has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. Eforto® recommends waiting for approximately 1 hour for the device to warm up or

cool down when the device is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage/transport temperature, refer to section 8.

- ⚠ DO NOT use this device after the service life has ended. The service life of the device may vary by the frequency of measurement and cleaning and storage state. The typical service life is 30000 squeezes of the bulb. Refer to section 10.
- ⚠ DO NOT crease the bulb excessively. ONLY squeeze the bulb with the muscle force of your hand. DO NOT apply any equipment, such as a clamp, since this can damage the bulb and the pressure sensor.
- ⚠ If the bulb does not return to its original shape after performing a calibration or measurement, there is an issue with the device. Please send the device for repair.
- ⚠ ONLY use the accessories and attachable parts specialized/authorized by the manufacturer. Otherwise, it may cause damage to the device or danger to the user. The use of unauthorized AC/DC adapters may be hazardous to this device.
- ⚠ ONLY use the approved Eforto® bulb for this device. Using other bulbs may result in incorrect readings.
- ⚠ ONLY use the approved and Eforto®-certified apps for this device.
- ⚠ Read and follow the “Correct Disposal of This Product” in section 9 when disposing of the device and any used accessories or optional parts.
- ⚠ If you are allergic to Polycarbonate/Acrylonitrile Butadiene Styrene (PC/ABS) or Sarolit®, don’t use this device.

Data Transmission

- ⚠ DO NOT turn off the Eforto® Device or the Smart Device while your readings are being transferred to your Smart Device. This may result in incorrect operation of this device and failure to transfer your measurement data.

AC/DC adapter Handling and Usage

- ⚠ Fully insert the AC/DC adapter into the outlet.

⚠ When unplugging the AC/DC adapter from the outlet, be sure to safely pull from the AC/DC adapter. DO NOT pull from the AC/DC adapter cable.

⚠ When handling the AC/DC adapter cable:

- Do not damage it. / Do not break it. / Do not tamper with it.
- DO NOT pinch it. / Do not forcibly bend or pull it. / Do not twist it.
- DO NOT use it if it is gathered in a bundle.
- DO NOT place it under heavy objects.

⚠ Wipe any dust off of the AC/DC adapter.

⚠ Unplug the AC/DC adapter when not in use.

⚠ Unplug the AC/DC adapter before cleaning.

⚠ Unplug the AC/DC adapter before using the Eforto® Device.

5.4 General Precautions

- To stop a measurement, stop squeezing the bulb and turn the device off by pressing the power button. Alternatively, you can also unpair the Eforto® Device in your Smart Device.
- Grip strength may differ between the right and left hand/arm, resulting in a different measurement value. Always use the same hand/arm to compare measurements.
- When using an AC/DC adapter, make sure not to place your device in a location where it is difficult to plug and unplug the AC/DC adapter.

6 Error Messages and Troubleshooting

If any of the below problems occur during measurement, check to ensure that no other electrical device is within 30 cm. If the problem persists, please refer to the table below.

Display / Problem	**Possible Cause**	**Solution**
The status LED is on with a red color.	The device has malfunctioned.	Press the power button again to turn the device off and on. If the status LED is still on with a red color, contact your Eforto® retail outlet, distributor or customer service.
The status LED is on with an orange color and the device is connected to the Mains.	The device is connected to the Mains and can, therefore not be used.	Unplug the device from the Mains to be able to use it.
The status LED is blinking with an orange color and the device is connected to the Mains.	The device is charging.	Unplug the device from the Mains to be able to use it.
The status LED is on with an orange color and the device is not connected to the Mains.	The battery is low.	Recharge the device. Refer to section 19.

The status LED is slowly blinking in blue.	The device is awaiting pairing with the Smart Device.	Refer to section 21 for pairing your Eforto® Device with your Smart Device, or press the power button to cancel pairing and turn your Eforto® Device off.
The status LED is on with a blue color.	The Eforto® Device is ready to transfer your readings to the Smart Device.	Open an Effort-certified app to transfer your readings.
The status LED fast blinking in blue.	Measurements are ongoing and transferred from the Eforto® Device to the Smart Device.	To stop measurements, press the power button or unpair the Eforto® Device in the mobile app.
The status LED is not on.	The battery is empty.	Recharge the device.
	The device is OFF.	Push the button.
Eforto® Device does not appear on the Smart Device to pair with.	Bluetooth is not enabled on your Smart Device.	Enable the Bluetooth on your Smart Device.
	The Eforto® Device is off.	Push the button.

	Other cause.	If the error persists after checking the above solutions, contact your Eforto® retail outlet, distributor or customer service.
Error message “The calibration for the Eforto® Device failed.” or “The calibration for the Eforto® Device failed three times in a row.”	The user touched/squeezed the device during calibration.	Retry the calibration. Put the device on a flat surface and don’t touch it. If the error persists after retrying, contact your Eforto® retail outlet, distributor or customer service.
Readings appear too high or too low.	Grip strength varies constantly. Many factors including your health status, time of day, and/or how you hold the Eforto® Device, may affect your grip strength. Review section 23 and section 24.	
Any other communication issue occurs.	Follow the instructions shown in the application on the Smart Device, or visit the “Help” section in the Eforto®-certified app for further help. If the problem still persists, contact your Eforto® retail outlet, distributor or customer service.	
Any other problem occurs.	Press the power button to turn the device off, then press it again to take a measurement. If the problem persists, contact your Eforto® retail outlet, distributor or customer service.	

7 Limited Warranty

Thank you for buying an Eforto® product. This product is constructed of high-quality materials, and great care has been taken in its manufacturing.
It is designed to give you every satisfaction, provided it is properly operated and maintained as described in the instruction manual.
The proper construction, workmanship and materials of this product are warranted by UniWeb BV for a period of 2 years after the date of purchase. During this period of warranty UniWeb will, without charge for labor or parts, at our option, repair or replace the defective product or any defective parts. Repair or replacement is our only responsibility and your only remedy under the warranty.

The warranty does not cover any of the following:
A. Transport costs, taxes and risks of transport.
B. Costs for repairs and/or defects resulting from repairs done by unauthorized persons.
C. Periodic check-ups, calibration services and maintenance.
D. Failure or wear of replaceable parts or other attachments other than the main device itself, unless explicitly warranted above.
E. Replaceable parts (eg bulb). They have a one (1) year warranty from the date of purchase.
F. Costs arising due to non-acceptance of a claim (those will be charged for).
G. Damages of any kind including personal caused accidentally or from misuse.

Should warranty service be required, please apply to the dealer whom the product was purchased from, an authorized Eforto® distributor or contact the customer service for information on www.eforto.com
Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.
The warranty will be granted only if the complete product is returned together with the original invoice/cash ticket issued to the customer by the retailer.
⚠ Do not attempt to remove the sticker or disassemble the device, as this will void your warranty and result in permanent damages.

8 Maintenance

To obtain the best performance, please follow the instructions below.

8.1 General

To protect your device from damage, follow the directions below:
Changes or modifications not approved by the manufacturer will void the user warranty.

⚠ Caution

- ⚠ DO NOT disassemble or attempt to repair this device or other components. This may cause an inaccurate reading.
- ⚠ DO NOT remove the sticker from the device.
- ⚠ DO NOT shake the Eforto® Device violently. Avoid intense shaking or collisions.
- ⚠ DO NOT let the Eforto® Device under strong shocks, such as dropping the device on the floor.
- ⚠ Before using the Eforto® Device, check for defects such as cracks in the bulb. If there are any defects, contact the dealer whom the product was purchased from, an authorized Eforto® distributor or contact Eforto® customer service.

8.2 Storage

- Keep your device and other components in the storage case when not in use
- Store your device and other components in a clean, safe location.

- Care should be taken to prevent pressure to the bulb when putting it in the box, as this may damage or deteriorate the workings of the Eforto® Device.

⚠ Do not store your device and other components:
  - If your device and other components are wet.
  - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
  - In locations exposed to vibrations or shocks.

8.3 Cleaning

- Use a soft dry, or moist cloth moistened with mild (neutral) detergent to clean your device, then wipe it with a dry cloth.
- For high-use environments, the Eforto® Device can easily be wiped with isopropanol or, we recommend Bacillol AF or Bacillol 30 wipes (30% alcohol)

⚠ DO NOT wash or immerse your device or other components in water or other liquids. Clean with a dry cloth if wet.

⚠ DO NOT use any abrasive or volatile cleaners.

⚠ DO NOT use gasoline, thinners or similar solvents to clean your device or other components.

8.4 Calibration and Service

- The accuracy of this Eforto® Device has been carefully tested and is designed for long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy.
  Please consult your Eforto® dealer or the Eforto® customer service at the address on the packaging or attached literature.

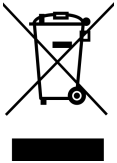
8.5 Charging

- Charging the Eforto® Device must be done in a temperature range of 10°C-45°C.

8.6 Changing the bulb

- If you need to detach the bulb of the Eforto® Device, do it carefully by rotating the bulb and pulling it off gently.
- If you need to attach the bulb to the Eforto® Device, do it carefully with your entire hand around the bulb, moving the bulb towards the device in a rotating fashion without squeezing the bulb.

9 Correct Disposal of This Product (Waste Electrical & Electronic Equipment)



Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal.
This marking on the product or its literature, indicates that it should NOT be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of waste and recycle it responsibly to promote the sustainable reuse of material resources. Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling. Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

This product complies with RoHS Directive 2011/65/EU and Amendment (EU) 2015/863.

10 Specifications

Product description	Digital Hand Grip Measuring Device
Model (code)	Eforto R1 / Eforto H1
Air pressure sensor range	0 to 689 kPa ± / over pressure limit: 1700 kPa
Measurement range	Hand grip pressure: 0 kPa ~ 200 kPa Overpressure limit: 1700 kPa
Accuracy according to Sensor Specifications	Accuracy; ±0.25 %FSS BFSL (Full Scale Span Best Fit Straight Line) Total error band: ±1% (Full Scale Span)
Measurement method	Pneumatic
Device classification	Battery Powered Mode: Internally Powered Medical Electrical Equipment AC/DC Adaptor charged Mode: Class II Medical Electrical Equipment (the AC/DC Adaptor shall comply with the requirements of IEC 60601-1)

Wireless data transmission method	Bluetooth Low Energy (BLE) Operating Frequency: 2402 MHz – 2480 MHz Frequency range: 2.4 GHz (2400 MHz - 2483.5 MHz) / Modulation: GFSK Transmission power: max. 4 dBm Effective radiated power: < 20 dBm
Operating mode	Continuous operation
IP classification (Ingress Protection)	IP2X
Applied part / Degree of Protection	Type BF applied part (Bulb)
Power source	3.7V 900mAh Built-in rechargeable Power supply li-polymer battery, 5V 1A AC Adaptor
Service life	Eforto® Device: 2 years / Bulb: 1 year
Normal Working conditions / Operating conditions	A temperature range of: +0°C to +40°C A relative humidity range of 15% to 90%, non-condensing,

	but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of: 700 hPa to 1060 hPa
Storage / Transport conditions	Temperature: -5°C to +50°C A relative humidity range of ≤ 85%, non-condensing, at a water vapour pressure up to 50hPa
Contents	Eforto® Device (REF: Eforto H1 or Eforto R1), Premounted Bulb (REF: B1), and instruction Manual Not included: Storage case and AC/DC adapter
Protection against electric shock	Internally powered ME equipment Class II ME equipment (optional AC/DC adapter)
Weight	Total:Device (with bulb) ±100g / Device: ± 57g (without bulb) / Bulb: ± 43g
Dimensions (approximately value)	Device: 80 mm (L) × 50 mm (H) × 28 mm (W) Hand grip bulb: 77 mm × 60 mm Diameter: 60 mm (size 5)

11 EMC and RF statements

The Eforto® Device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.

The device is suitable for home healthcare environments.

The Eforto® Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Interference may occur in the vicinity of equipment marked with the following symbol

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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.

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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Eforto® Device is not suitable for use in MRI (Magnetic Resonance Imaging) environments.

12 Important Information Regarding Electromagnetic Compatibility (EMC)

Eforto® Device R1 and Eforto® Device H1 conform to the EN60601-1-2:2015 Electromagnetic Compatibility (EMC) standard.
Further documentation in accordance with this EMC standard is available at www.eforto.com.

13 Network Security Recommendations

The following warnings detail security measures that Eforto® users should follow to ensure appropriate protection of their personal data. Failure to comply with these warnings may lead to user personal data leakage or destruction.

Only use mobile applications authorized by Eforto®. Eforto® only makes its mobile applications and subsequent updates available on official app stores (i.e. Google Play Store and Apple App Store).

14 Guidance and Manufacturer's Declaration

This device complies with the following regulations and normative documents/standards:

EU RED STATEMENT: Hereby, UniWeb BV, declares that the device is in compliance with the essential requirements and other relevant provisions of RE Directive 2014/53/EU.

EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 80601-2-30:2009+A1:2013 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

• Hereby, UniWeb BV., declares that the radio equipments type Eforto® Device R1 and Eforto® Device H1 are complied with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.eforto.com
• This Eforto® product is produced under the strict quality system of UniWeb BV, Belgium. The Core component for the Eforto Device is the Pressure Sensor, is produced in Japan.
• Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

15 Trademarks, Patents and Options/Variants

Eforto® is a registered Trademark in the Benelux.
Eforto Device Patent pending at Belgian Patent Office

Tradenames for the Eforto Device:
Eforto monitor, Eforto dynamometer, Eforto vigorimeter, Eforto vitalitymeter, Eforto Grip

The Eforto Devices (H1 and R1) are available in: white (XX-01), black (XX-02), gray (XX-03) and blue (XX-04)

The Bulbs (B1) are available in: black (XX-02), gray (XX-03), blue (XX-04) and red (XX-05)

16 Terms of use, reverse engineering, patent

By using the Eforto® Device the user authorizes the Manufacturer to collect anonymized measurement data for improvements to the Eforto® Device, it's Algorithms and the accompanying Eforto®-certified applications.
It's strictly forbidden to reverse engineer the Eforto® Device, the Eforto® Firmware, the Eforto® Algorithms and the Efoto®-certified Apps.

17 Symbols Description

The signs below might be in the user manual, labeling or other component with your Eforto® Device.

	Indicates the medical device manufacturer		Indicates that the instruction manual/booklet must be read
	Indicates the date when the medical device was manufactured		Identifies a type BF applied part complying with IEC 60601-1
	Indicates the manufacturer's catalog number so the medical device can be identified		Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions
	Indicates the manufacturer's serial number so that a specific medical device can be identified		Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. that intentionally apply RF electromagnetic for diagnosis or treatment

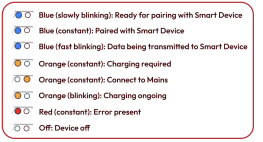
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005	IP2X	Protected against solid objects over 12.5mm (e.g., a finger)
CE	CE marking indicates that a product complies with applicable European Union regulations		
	The “Caution” sign throughout this instruction manual indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment or other property.		The “WARNING” sign throughout this instruction manual indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

18 Package Contents

Your Eforto® Device is supplied in a box containing the following items:

1x Eforto® Device with pre-mounted hand grip bulb

1. Pre-mounted hand grip bulb
2. Enclosure
3. LED indicators
4. Power button
5. Charging port



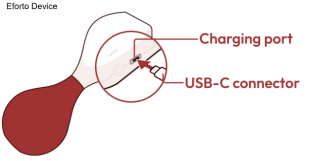
Note: the colors for the bulb and enclosure in this instruction manual may be different from the colors of your Eforto® Device.

1x User Manual

Latest version of the Eforto® Device user manual can also be found online at: www.eforto.com

19 Power Supply and Charging

The battery of the Eforto® Device is a built-in rechargeable lithium-polymer battery.
The battery capacity is 3.7V 900mAh.
If charging for the first time (immediately after purchase or after not having used it for a long time), or if the battery stops working while using the device, make sure to charge it fully.



To charge your device:
1. Connect the USB-C connector of the USB cable to the Eforto® Device's charging port.
2. Connect the USB-A connector of the USB cable to the 60601-1 certified AC/DC adapter.

Charge the battery under following circumstances:

- When the orange status LED is blinking, the battery power is low.
- When powering on the device, the status LED does not light up.

Note: Charge at least once every three months. If the battery completely loses all charge, it may not be rechargeable anymore.

Note: Only use a 60601-1 certified AC/DC adapter and cable.

The Eforto® Device shall not be exposed to excessive heat such as direct sunshine, fire, or other similar situations.
The battery could explode causing injury or death.

Do not attempt to replace the device battery: it is built-in and not changeable. Only charge the battery in accordance with the user instructions supplied with the device. Do not use the device while charging. Do not clean the device when it is being charged.

Avoid prolonged skin contact with the USB-C connector and the charging cable, especially when the charging cable is connected to a power source.

20 Body Posture during Measurements

Make sure you follow these guidelines when performing measurements. Failing to do so may lead to inaccurate results or cause the measurements to fail.

Please sit down and relax for 5 minutes before starting the measurements.

1. Sit upright with your back straight, your shoulder adducted and your feet flat on the floor.
2. Bend your dominant arm at the elbow, so the upper arm makes a straight angle (90 degrees) with the lower arm. Your forearm should be horizontal to the ground and unsupported as shown in the picture.
3. Close the fingers of your dominant hand around the bulb of the Eforto® Device, so the thumb is on one side and the other fingers are on the opposite side.
4. Hold the Eforto® Device so that the wide end of the bulb is at the bottom and the enclosure is at the top.
5. Take the measurement in a calm and quiet area.
6. Stay still, and do not talk. Make sure to keep breathing while performing the measurements.

In some situations, this position will not be possible. In this case, a physician should advise you on the position you should adopt for your usage of the Eforto® Device.

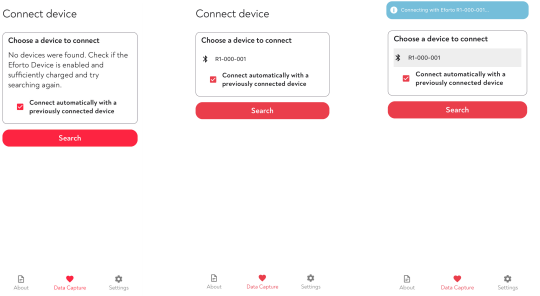
Note: Grip strength measurements can be affected by the position of the Eforto® Device and your physiological and emotional condition.

21 Start the Measurement

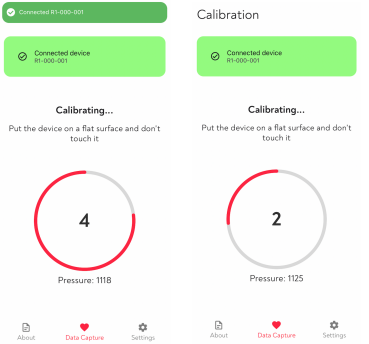
The screenshots used in this instruction manual are from the Eforto® Device I/O App v1, which is the most basic version of the Eforto®-certified applications. Similar functionalities/screens are available in the other Eforto®-certified apps.

1. **Download the free Eforto® Device I/O App or any other Eforto®-certified App.**
   Go to the Google Play store or Apple App Store, then download and install the free Eforto® Device I/O App or any other Eforto®-certified App.
2. **Unplug your Eforto® Device from the Mains and turn it on by pressing the power button.**
   The device's LED should start blinking slowly with a blue color, indicating that the Eforto® Device is ready to be paired with a Smart Device. Make sure the Eforto® Device and the Smart Device are sufficiently charged before starting a measurement.

3. **Pairing your Eforto® Device with your Smart Device.**
Enable Bluetooth on your Smart Device and keep the Eforto® Device close to your Smart Device (in the same room and within 10 meters of the device). Open the Eforto® Device I/O App on your Smart Device, then tap “Search” to find nearby Eforto® Devices. The Eforto® Device’s model number (e.g. R1) followed by the serial number will appear in the list. Click this identifier to start the pairing procedure. Wait until pairing is confirmed by the Eforto® Device I/O App and the LED is a constant blue.



4. **Calibrate your Eforto® Device.**
Place the Eforto® Device on a flat service and don't touch the device until the self-calibration finishes. The app will count down as long as the calibration process is ongoing. At 0, the calibration is finished. When the calibration is done, the app will automatically navigate to the app's Data capture screen.



5. **Prepare for measurement.**
Position yourself before starting the measurement (see section 20). You can now start performing measurements, results are sent via Bluetooth to the connected Smart Device and displayed in the Eforto® Device I/O App. The LED is fast blinking in a blue color to indicate data transmission.

6. **Turn off and store your Eforto® Device.**
Turn your Eforto® Device off by pressing the power button and store it as described in section 8.2.

22 Important Facts about Hand Grip Strength

Read more about hand grip strength and the Eforto® Device in the following publication:

De Dobbeleer L, Swart MM, Geerds MAJ, Baggen RJ, Jansen AS, Tielemans R, Silva H, Lieten S, Barbé K, Peeters G, Vollenbroek-Hutten MMR, Melis RJF, Bautmans I. Validity and reliability of Eforto, a system to (self-)monitor grip strength and muscle fatigability in older persons. Aging Clin Exp Res. 2023 Apr;35(4):835-845. doi: 10.1007/s40520-023-02365-3. Epub 2023 Mar 10. PMID: 36897558; PMCID: PMC10115702.

23 How to Evaluate your Hand Grip Strength

The Eforto® Device is not intended to be a diagnostic device. Self-diagnosis of measurement results and self-treatment are potentially dangerous. You should always consult your doctor for relevant interpretation and diagnosis based on your personal hand grip strength results.

The Eforto® Device I/O App displays the measurement results in the “Data Capture” tab.

In the “Pressure” table, the current hand grip strength value measured by the Eforto® Device is displayed in kPa (kilopascal).

In the “Accelerometer” table, the current values of the accelerometer of your Eforto® Device are displayed in m/s2 (meters per second squared). These values represent the acceleration of the device, which is used to sense and quantify acceleration or changes in motion. The X, Y and Z values represent the acceleration or changes in motion along three perpendicular axes in three dimensions:

X: represents the horizontal axis - Y: represents the vertical axis - Z: represents the depth or forward-backwards axis

The values for hand grip strength and the acceleration are constantly updated (every 32 ms) until you navigate away from the “Data Capture” tab in the app or turn off the Eforto® Device.

You can compare your personal hand grip strength (pressure values) with the reference values that can be found on the website www.eforto.com. These charts are not intended to provide a basis for any type of diagnosis or emergency assessment; these charts only depict different classifications of hand grip strength.

⚠ Various factors such as age, gender and health condition should be considered for a correct evaluation.
Consult with your physicians for an accurate assessment and diagnosis of your health condition.

24 Some Frequently Asked Questions

Why do my hand grip strength measurements differ throughout the day?

Individual hand grip strength naturally varies through regular daily life. It is also affected by the way you hold the Eforto® Device and your measurement position, so please try to take the measurements under the same conditions. If you are under treatment or prescription of drugs, your hand grip strength may vary more.

Why do I get a different hand grip strength measurement at home compared to when a physician assesses it?

Your hand grip strength is different even throughout the day due to exercise, tiredness, etc. Also, when your physician assesses your hand grip strength, you might put more effort in the measurement and thus get a higher hand grip strength.

What do you need to pay attention to when you measure your hand grip strength?

- Correct body posture during the measurement (refer section 20).
- Correct way to hold the Eforto® Device (refer section 20).
- You are relaxed. Waiting for 5 minutes before beginning will yield a more accurate measurement.

Is the result the same if measured on the left/right arm?

Your hand grip strength can vary considerably between your left and right hand/arm. It is recommended to measure the hand grip strength of your dominant hand. If this is not possible, you can deviate from it and measure your hand grip strength for your non-dominant hand. In general, we suggest you measure on the same arm/hand every time.

25 Unpair your Device

During the pairing procedure, the Eforto® Device is linked to your Smart Device. In case you wish to abort the pairing and allow another person to use the device, you must disconnect the Eforto® Device in the Settings. Alternatively, the pairing can be stopped by turning the Eforto® Device off.

Eforto® Device (Model H1 / R1)
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