PONDUS[®] - INSTRUCTIONS FOR USE





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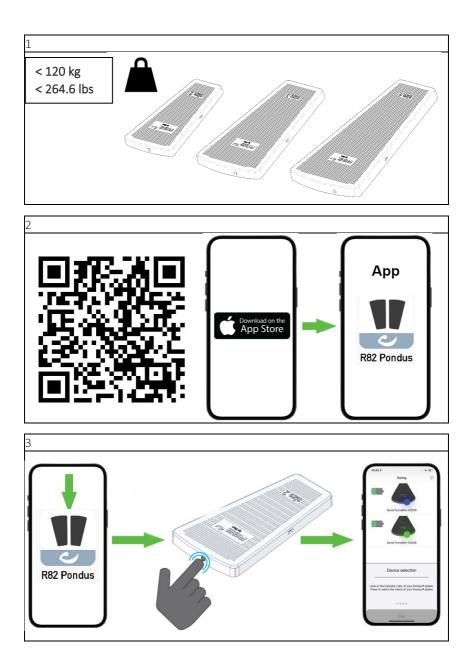
Declaration of Conformity

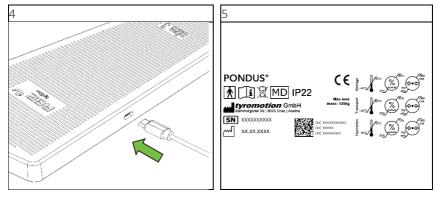
This product conforms to the requirements of the Medical Devices Regulation (EU) 2017/745. The CE mark must be removed when rebuilding the product or when using other than original PONDUS[®] accessories.

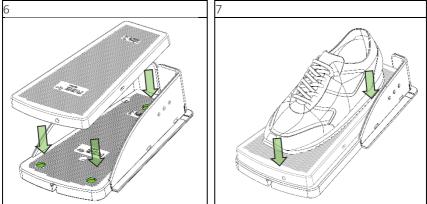
PONDUS® is a registered trademark owned by R82 A/S.

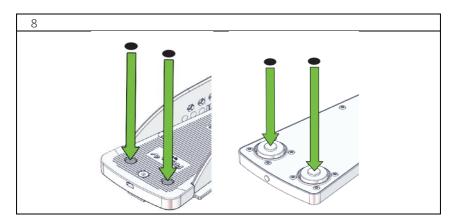
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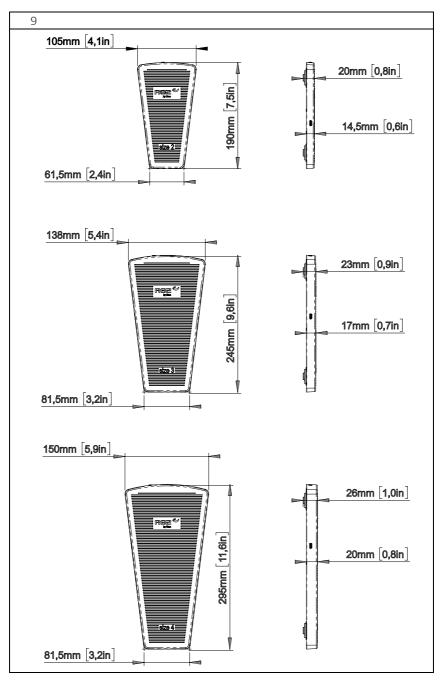
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1 Introduction

We appreciate your choice of a new product from TYROMOTION. To fully benefit from the options offered by this product please read these instructions for use and save it for future use.

1.1 Symbols

1.1.1 Symbols in the instructions for use



Warnings: This symbol indicates a possible risk of injury to your own health or to the health of others. Be especially mindful of these notices!

1.1.2 Symbols on PONDUS®

Ĩ	Follow the instructions for use
×	Applied part, type BF
	Do not discard with household waste
CE	CE mark
IP22	 Protection class against foreign objects and water: 2 means protection against penetration of solid objects with a diameter ≥ 12,5 mm 2 means protection against ingress of dripping water (15° tilt)

	Information about the manufacturer of PONDUS®, including the manufacturer's full mailing address is displayed next to the factory symbol.
	Date of manufacture
SN	Serial number of the device
MD	Medical device
10°C	Upper and lower limit of temperature Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.
30%	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

1.2 System content

PONDUS[®] consists of the following components, included in the delivery:

- 1x PONDUS[®] set (size 2, 3 or 4) consisting of two plates
- 1x Software Application
- 1x power supply
- 1x USB charging cable

- 1x Instructions for use
- 1x hook and loop adhesive pad set (for use with R82 Caribou and R82 Gazelle PS)

1.3 Intended use

PONDUS® is a medical device to support the positioning of the user in a standing frame.

1.4 Warranty and legal disclaimer

TYROMOTION GmbH issues a warranty to the original system purchaser that the system shall be free of material and qualitative processing defects for a period of 12 months under normal usage conditions from the date of installation on the owner's premises and that the system complies with the mechanical and electrical specifications published by TYROMOTION. This warranty is granted under the provision that the system is installed, operated and maintained in accordance with the instructions for use. The customer must submit all warranty claims to TYROMOTION in written form within 60 days of the occurrence of the problem and before the expiry of the warranty. TYROMOTION is exclusively obligated to repair, exchange or correct faulty or non-compliant parts at its own discretion in accordance with the warranty. TYROMOTION has no further obligations to the owner in regard to these parts after the repair or exchange of faulty or non-compliant parts. All repairs or maintenance work must be performed by an authorized TYROMOTION service representative in accordance with this warranty. The above mentioned warranty becomes null and void if repairs, maintenance or other work is performed by third parties. Moreover, problems resulting from accidents, improper use, incorrect application, storage damage, negligence as well as system or component modifications are excluded from the warranty.

The above mentioned warranty is granted in place of all other warranties, rights or conditions, and the system is delivered "without deficiency warranty" apart from the limited warranty. TYROMOTION and its third-party suppliers specifically and unreservedly reject all other explicit or implicit warranties held by the owner, his personnel and patients, customers, users and any third parties, unreservedly including all warranties for marketability, applicability for a specific purpose, non-infringement and any warranties resulting from performance development, business trends or commercial customs. TYROMOTION and its

third-party suppliers do not provide declarations or warranties for system compliance with the owner's requirements or for functionality without interruption, errors or deficiencies.

TYROMOTION is in no way liable for indirect, incidental, specific or consequential damage or for punitive damage compensation including, among other things, the loss or absence of profits, yield, goodwill or usage, which the owner or third parties may incur or for damage to connected equipment, costs for replacement products, installations, servicing, exchange elements or idle time or for claims from patients, customers, visitors, the owner's employees or other persons, regardless whether submitted within the context of a contractual claim, due to unauthorized behavior, strict liability or imposed by law or otherwise even when TYROMOTION has been informed about the possibility of such damages. TYROMOTION's liability for damages resulting from or in connection with this contract may not in any event exceed the purchasing price of the system.

Some jurisdictions limit or exclude the extent of restrictions, the exclusion of legal means, compensation or liability, such as liability for gross negligence or willful misconduct according to or in the abovementioned extent or do not permit the exclusion of implicit warranties. In such jurisdictions, the restriction or exclusion of warranties, legal means, compensations or liabilities described above may not be valid for the owner. Such restrictions or exclusions apply according to the highest legally permitted extent even if they are not valid according to the legally prohibited extent. The owner may also have other rights that vary depending on the specific country or other jurisdictions.

2 Technology

2.1 Overview

Device name:	PONDUS®
Classification:	PONDUS [®] is a medical device class I according to medical device regulation (EU) 2017/745, rule 13.
Type of applied part:	Typ BF
Protection against electric shock:	Internally powered medical device

Electromagnetic compatibility:	Class B device (CISPR 11) PONDUS® is suitable for usage in all establishments including residential areas and areas that are directly connected to the PUBLIC SUPPLY GRID, which also supplies residential buildings.
Country of origin:	AUSTRIA
Power supply voltage:	100 – 240V alternating current
Supply frequency:	50/60Hz
Electricity/Power consumption:	5V DC / 100mA charging
Battery:	Polymer-lithium-ion battery, 3.7V, 470mAh The battery must not be replaced.
Radio transmission frequency:	ISM Band (Bluetooth BLE)
Radiated transmission power:	Max. 10mW Operational area: 10 meters given uninterrupted view between PONDUS® plates and used Tablet/Smartphone
Operating type:	Continuous operation

2.2 Area of application

The product is for indoor use.



PONDUS[®] is classified as a medical electronic device and therefore subject to specific precautionary measures relating to electromagnetic compatibility (EMC). It is absolutely imperative to observe the stated indications for EMC. Portable and mobile HF communication devices may affect the PONDUS[®].

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS

PONDUS® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of PONDUS® must ensure that it is used in such an environment.

Interference emission measurements	Agreement	ELECTROMAGNETIC ENVIRONMENT – Guidelines	
HF emmissions according to CISPR 11	Group 1	PONDUS® exclusively uses HF energy for its internal FUNCTIONS. HF emissions are very low and unlikely to disrupt electronic devices within range.	
HF emissions according to CISPR 11	Class B	PONDUS [®] is suitable for usage in all establishments including residential areas and areas that are directly connected to the PUBLIC	
Harmonics emissions according to IEC 61000-3-2	Not applicable		
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	SUPPLY GRID, which also supplies residential buildings.	

Table 1: Guidelines and manufacturer's declaration – electromagnetic emissions

Guidelines and MANUFACTURER's declaration – ELECTROMAGNETIC IMMUNITY

PONDUS® is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of PONDUS® must ensure 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines Not applicable	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV differential mode Not applicable	± 1 kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U _T (> 95 % dip in U _T) für 0.5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles < 5 % U _T (> 95 % dip in U _T) for 5 s	< 5 % U _T (> 95 dip in U _T) for 0.5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles < 5 % U _T (> 95 % dip in U _T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	Not applicable	Not Applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage before application of the test level.

Table 2: Guidelines and manufacturer's declaration – electromagnetic immunity

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC IMMUNITY

PONDUS[®] is designed for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or user of PONDUS[®] must ensure that it is used in such an environment.

Portable and mobile RF communications 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.

Immunity Test	IEC 60601-Test Level	Compliance Level	ELECTROMAGNETIC ENVIRONMENT - Guidance
			Recommended Separation Distance:

Conducted RF IEC 61000-4-6	6 V _{rms} 150 kHz to 80 MHz	6 V	$d = 0.58 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d=0.35\sqrt{P}$ 80 MHz to 800 MHz
			$d=0.7\sqrt{P}$ 800 MHz to 2.5 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:
			$(((\bullet)))$

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.

- 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 PONDUS® system 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 reorienting or relocating the PONDUS® system.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [4] V/m.

Table 3: Guidelines and manufacturer's declaration – electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and PONDUS®

PONDUS[®] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this 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 maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = 0.58 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
0.01	0.058	0.035	0.07
0.1	0.18	0.11	0.22
1	0.58	0.35	0.70
10	1.83	1.11	2.21
100	5.80	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.

- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and PONDUS®

3 Clinical Application

3.1 Indications/Contraindications

In principle, for PONDUS[®] the same indications and contraindications apply as for the standing frames it is used in combination with. Knowledge of the contraindications is essential in order not to put the patient at risk. Before applying PONDUS[®] in combination with a standing frame to a patient, check carefully if one or more contraindications exist. Also, be aware that your patient may have additional indications and/or contraindications that have not been listed here but may be relevant. The following listings have no claim to completeness.

Indications

PONDUS[®] can be used by children and adults with disabilities using a standing frame. The target group for the PONDUS[®] is based on functional ability and anthropometry. It is not based on a specific health condition or age.

The user is the person standing in the frame in which PONDUS® plates are mounted. The caregiver is the person operating the frame and PONDUS®. Never leave the user unattended in a standing frame. Ensure permanent supervision by a caregiver. The use of the PONDUS® and standing frame will be discontinued more times during the day where the user will be lying down or sitting in another assistive device or a conventional product.

Contraindications

There are no known contraindications. However, you must familiarize yourself with the contraindications of the specific standing frame model the PONDUS[®] is used in combination with.

Precautions

Be aware of the height of the PONDUS[®] plates. When placed in the foot holds of a standing frame, it positions the user approx. 20 mm higher, and thus the mounted standing frame accessories should be adjusted accordingly to support the user properly. Special attention should be given to the considerations about

the configuration of the standing frame and the use of standing frame accessories for users with limitation in their:

- sensory functions and the sensation of pain, consider extra checks of the pressure caused by the support provided by the standing frame and its accessories.
- movement function (e.g., experience involuntary movements), pay special attention when using a standing frame
- ability to maintain a standing position, use the product with standing frame accessories (e.g., chest or back support).
- ability to maintain the position of their head, consider using standing frame accessories or to use a standing frame that provide support to the positioning of the head.

3.2 Safety

3.2.1 Safety concept

In order to prevent problems with the use of the device the following instructions for proper use are also to be adhered to.



Caregivers are obligated to familiarize themselves with these safety instructions and avoid conditions that may lead to injuries or damages.

Caregiver

- Every caregiver must have read the instructions for use prior to using PONDUS®. TYROMOTION GmbH rejects any liability for damages to persons or material if safety regulations and instructions relevant to the usage of PONDUS® are not observed!
- Only use original accessories from the manufacturer that are supplied in the system contents.
- The caregiver must take appropriate measures to stabilize the user during use.
- PONDUS[®] must not be charged during use.
- If there is any doubt as to the continued safe use of PONDUS[®] or if any parts should fail or become defective, stop using the product immediately and contact TYROMOTION GmbH or your local dealer.

• The cleaning instructions stated in these instructions for use must be strictly observed.

Environment

• Do not use PONDUS[®] in combination with standing frames that have not been recommended by TYROMOTION GmbH. Unforeseen risks could arise for people and equipment.

PONDUS® may only be used in combination with the following standing frames:

- o R82 Meerkat
- o R82 Rabbit Up
- o R82 Toucan
- o R82 Caribou
- o R82 Gazelle PS

Product

- No modifications of PONDUS® are allowed.
- Always contact the manufacturer for repairs!

3.2.2 Residual risk

An unpredictable residual risk remains despite all safety precautions. In rare cases, the user may experience minor pinching or crushing injuries even during proper operation. However, the probability of such injuries is very low, and the injuries should not be severe as long as all safety instructions in the present instructions for use are observed. TYROMOTION GmbH can provide a detailed risk analysis upon request.

If you think that you or someone who used PONDUS® has experienced an injury due to the use of PONDUS® please report this to the manufacturer and to your national health authority.

4 PONDUS®

4.1 First steps



The time required for PONDUS® to warm/cool from the min./max. storage temperature between uses until the system is ready for its intended use at ambient temperature is **one hour**. Please wait for this period of time before operating the unit.

4.1.1 Charging PONDUS®

The PONDUS[®] system is equipped with a rechargeable battery. Before using PONDUS[®] for the first time, fully charge the system using the supplied USB cable and power supply unit (figure 4). The charging time is 3 hours when the battery is completely empty.

4.1.2 Installation PONDUS® App

Install the PONDUS[®] app directly from the respective app store or scan the QR code (figure 2) using your smartphone or tablet.

4.2 Use of PONDUS®

To use PONDUS[®], carry out the following steps:

- 1 Switch on the two plates of the PONDUS® system by pushing the LED button on the front panel of the plates (figure 3). They should now start flashing yellow, which means they are in paring mode.
- 2 Place the plates in the sandals provided on the standing frames. Make sure that the plates are engaged in the designated indentations of the sandals (figure 6). If you use PONDUS[®] in combination with the standing frames R82 Gazelle PS or R82 Caribou, you can also use the additional hook and loop adhesive pad set (figure 8).
- 3 Now put the user on the plates and fix the feet in the sandals (figure 7).
- 4 The plates must be paired to the PONDUS® App. For this, the Bluetooth function of your smartphone or tablet must be activated. For a successful Bluetooth connection, the plates must be positioned within a radius of 10m (in the same room) from the smartphone/tablet.

- 5 Start the PONDUS[®] App on your smartphone/tablet (figure 3).
- 6 The App should automatically find the two plates. If not, drag down from the top in the list view.
- 7 Select the two devices matching the colors of your plates.
- 8 Now the LED button on the front side of the plates should change color to green and blue, indicating left and right and the PONDUS[®] plates (figure 3).
- 9 The plates are now connected to the PONDUS® App and PONDUS® is ready to use.
- 10 Follow the instructions in the PONDUS[®] App.

Error messages are displayed directly in the app and errors can be corrected interactively. If necessary, restart the app and plates and follow the steps described above again.

If the PONDUS® plates are not connected to the PONDUS® App, they switch off automatically after 10 minutes.

4.3 Shutdown of PONDUS®

Follow these steps to shut down PONDUS®:

- 1 Release the patient from the sandals of the standing frame.
- 2 End the Bluetooth connection by closing the PONDUS[®] App.
- 3 Take the plates out of the sandals and switch off the PONDUS® plates by pushing the LED button on the front panel for at least 3 seconds (figure 3).

4.4 LED Status PONDUS®

Observe the LED button on the front side of the plates (figure 3). This provides information on the status of PONDUS[®].

LED-Display	Meaning
Flashing YELLOW	Waiting for a connection
Solid COLOR	A smartphone/tablet was connected and set a color for identification
Flashing in-between ORANGE	Battery below 10%

Solid GREEN	PONDUS® plate is connected to a smartphone/tablet	
Solid BLUE	PONDUS® plate is connected to a smartphone/tablet	
Flashing GREEN	PONDUS [®] plate is sending data to a connected smartphone/tablet	
Flashing BLUE	PONDUS® plate is sending data to a connected smartphone/tablet	
Solid ORANGE	PONDUS [®] plate is charging or fully charged	
No light	PONDUS® plate is turned OFF. Click the button to switch it ON	

4.5 Battery

Charging battery:

The integrated battery can be charged via power supply included in the system content (figure 4). PONDUS[®] switches into the charging mode automatically.

Duration of Charging:

The duration of charging depends, among other things, upon whether the battery was fully uncharged at the start of the charging process or not. The charging only lasts at most 3 hours and thus should be done within 3 hours.

Charging Cycles and Lifespan:

Due to the use of high-quality lithium-polymer batteries, it is ensured that the battery running times still meet the requirements even after many charging cycles. Nevertheless, no guarantee can be given for the lifespan of batteries going beyond 12 months after the date of purchase.

If you adhere to the following advice, you can certainly save the battery of your device and thereby extend its lifespan:

• Avoid direct exposure on PONDUS® to sunlight in order to prevent the battery inside the device from becoming too hot.

• Use exclusively the power supply provided by TYROMOTION GmbH for the recharging of the battery.

Battery life:

In use, the battery operating time is minimum 8 hours (when fully charged).

5 Service information

Maintenance of a medical device is wholly the responsibility of the owner of that device. Failure to maintain a device in accordance with the instructions for use may invalidate the device's warranty. Furthermore, failure to maintain a device may compromise the clinical condition or safety of users.

5.1 Monthly functionality check

The functionality checks described here must be performed monthly. Perform the checks even if PONDUS[®] indicates a malfunction (e.g., in case of unusual sounds, elementary damages, etc.).

Inspection:	Malfunction:	Resulting measure:
Protective covers	Covers shake	• Further use is prohibited
	Covers missing	Contact TYROMOTION
	Covers damaged	GmbH
Externally visible deformations	 Parts bent out of shape Parts asymmetrical Parts defective 	 Further use is prohibited Contact TYROMOTION GmbH

Table 5: Inspection points

5.2 Periodic check

The periodic test differs from the tests in chapter 5.1 in that the test described here can be required by law, whereas the tests specified in chapter 5.1 serve, amongst other things, to determine acute damage or the need for replacement of wear parts. The operating company of the device itself is responsible for carrying out both tests.

An interval of one year is defined by TYROMOTION GmbH for carrying out the periodic tests.

5.3 Lifetime

The lifetime of this product in normal use is 5 years if all maintenance and servicing is carried out in accordance with the manufacturer's instructions.

5.4 Cleaning instructions

The following instructions apply to the manual cleaning of medical devices by Tyromotion GmbH.

Thorough cleaning and wiping is essential for the first time and reuse of reusable medical devices. Effective cleaning must be performed to achieve adequate decontamination.

The goal of cleaning is to remove any visibly sticky soil and reduce the number of particles and microorganisms.

Cleaning must be carried out in a manner that minimizes the risks posed by pathogens.

The devices of the Tyromotion GmbH must be cleaned and disinfected after delivery before the first and any further use on the user.

5.4.1 Disinfection

The product can be disinfected with a 70% disinfectant IPA solution. It is recommended to wipe off any residue and dirt from the product, using a cloth with warm water and a mild detergent/soap without chlorine and let it dry before disinfection.

5.4.2 Cleaning process

To minimize the risk of germ transmission, all surfaces that are touched by the user should be periodically cleaned and disinfected and at least before any further use on the user.

- 1. If the user perspires heavily during use, dry the PONDUS[®] components after use before disinfecting them.
- 2. Moisten the disposable cloth, according to the product information leaflet, only slightly with disinfectant. Wipe the PONDUS® components

with the clean, soft and lint-free cloth. Observe the contact time of the disinfectant used according to the label and product information.

- 3. Dry the area with a clean, non-abrasive, soft, lint-free cloth.
- 4. Always store the PONDUS® components in clean and dry rooms or facilities after use.

5.5 Repair

Always contact the manufacturer for repairs!

5.6 Disposal

The PONDUS[®] must not be disposed of as household waste according to the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE-RL) and the respective national legislation. The product must be disposed of at the intended collection point or at a collection point approved for the recycling of waste electrical and electronic equipment. It can also be returned to TYROMOTION GmbH.



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