

REHADAPTER™

Instructions for use



EN



EN ISO 13485

01.03.2023

00.5224EN~B



DE Scannen Sie den QR-Code mit Ihrem Telefon oder benutzen Sie den Link, um die Gebrauchsanweisung in Ihrer Sprache zu erhalten.

https://rehadapter.com/manual_de



EN Scan the QR code with your phone or use the link to download the user manual in your own language.

https://rehadapter.com/manual_en



ES Escanee el Código-QR con su móvil o utilice el enlace para acceder al Manual de instrucciones en su idioma.

https://rehadapter.com/manual_es



FR Scannez le code QR avec votre téléphone ou utilisez le lien pour obtenir le mode d'emploi dans votre langue.

https://rehadapter.com/manual_fr



IT Per ottenere le istruzioni per l'uso nella propria lingua, scansionare il codice QR con il proprio telefono o utilizzare il link.

https://rehadapter.com/manual_it



PT Digitalize o código QR com o seu telemóvel ou utilize o link para obter as instruções de utilização no seu idioma.

https://rehadapter.com/manual_pt



NL Scan de QR-code met uw telefoon of gebruik de link voor de gebruiksaanwijzing in uw taal.

https://rehadapter.com/manual_nl



DK Scan QR-koden med din telefon eller brug linket for at få vist brugsanvisningen på dit sprog.

https://rehadapter.com/manual_dk



FI Saat käyttöohjeen omalla kielelläsi linkin kautta tai skannamalla QR-koodin puhelimella.

https://rehadapter.com/manual_fi



SE Skanna QR-koden med din telefon eller använd länken för att få bruksanvisningen på ditt språk.

https://rehadapter.com/manual_se



NO Skann QR-koden med telefonen din eller bruk koblingen for å få bruksanvisningen på ditt språk.

https://rehadapter.com/manual_no



HR Skenirajte QR kod svojim telefonom ili upotrijebite poveznicu za preuzimanje korisničkog priručnika na vašem jeziku..

https://rehadapter.com/manual_hr

Instructions for use Rehadapter™

00.5224EN Rev. B

01/03/2023

All rights reserved.

Copyright © Rehadapt Engineering GmbH & Co. KG

All contents in these instructions for use, especially the text, photographs, and graphics, are protected by copyright. Unless expressly stated otherwise, the copyright lies with Rehadapt Engineering GmbH & Co. KG. Any duplication requires the prior written consent of Rehadapt Engineering GmbH & Co. KG.

This document has been created with the greatest diligence. The publisher and the author are not liable for errors, emissions, or damages resulting from use of the information contained in the document or from use of the related applications and source code. The publisher and the author are not liable for any loss of profit or other economic loss caused or alleged to be caused directly or indirectly by this document.

Subject to change without notice.

Up-to-date versions of this document are available on the official Rehadapt website:

www.rehadapt.com

Contact:

European Headquarters

Rehadapt Engineering GmbH & Co. KG

Heinrich-Hertz-Str. 104

34123 Kassel, Germany

+49 561 220 717 0

officeteam@rehadapt.com

North American Branch

Rehadapt North America LLC

40 Oser Ave, Suite 40-01

Hauppauge, NY 11788, USA

+1 888 635 6962

officeteam.na@rehadapt.com

Table of content

1	Preface	6
1.1	Symbols and Markings.....	7
1.2	Intended Purpose	8
1.3	Scope of Delivery.....	8
2	Safety Instructions	9
2.1	General Handling.....	9
2.2	Prevention of Hearing Damage	9
2.3	Charger and Battery	9
2.4	Temperature.....	11
2.5	Mounting.....	11
2.6	Emergency Situations	11
2.7	Electricity.....	11
2.8	Safety of Children and of Persons with Impaired Judgement.....	11
2.9	Repair	11
2.10	Magnetic Field / Interference with Medical Devices	11
2.11	Reporting Serious Incidents.....	12
3	Overview of the Rehadapter™	13
3.1	Rehadapter™ Overview	13
3.2	Status Indicator LED	14
4	Using the Rehadapter™ – User	15
4.1	Turning the Rehadapter™ on/off.....	15
4.2	Pairing the Rehadapter™ with the tablet	15
4.3	Unpairing the Rehadapter™ from the Tablet	16
4.4	Volume Control	16
4.5	Charging the Rehadapter™	16
4.6	Attaching Keyguards.....	17
4.7	Switch Connectors.....	17
4.8	Operating Modes.....	18
4.8.1	Lying Down	18
4.8.2	Standing.....	18
4.8.3	Adapter plate for Rehadapt UDS	19
4.8.4	More Possibilities	19
4.9	Reset.....	19
4.9.1	Resetting the Rehadapter™	19
4.9.2	Resetting the tablet	19
5	Setting up the Rehadapter™ – Authorized Distributor	20
5.1	Setting up the Rehadapter™	20
5.1.1	Opening the Rehadapter™	20
5.1.2	Inserting the Tablet	20
5.1.3	Closing the Rehadapter™	21
5.2	Attaching the Keyguards.....	21
5.3	Kickstand	23
5.3.1	Adjusting the Resistance	23
5.3.2	Removing the Kickstand	23
6	Product Care.....	24

6.1	Temperature and Humidity	24
6.1.1	General Use	24
6.1.2	Charging the Rehadapter.....	24
6.1.3	Transport and Storage.....	24
6.2	Maintenance and Care	24
6.3	Cleaning.....	24
6.3.1	General Disclaimer	24
6.3.2	Cleaning the Rehadapter™	25
6.4	Redispatch and Return	25
6.5	Disposal of the Rehadapter™	25
6.6	Disposal of the Battery	25
7	Troubleshooting.....	26
8	Customer Support, Warranty, Training	27
8.1	Customer Support	27
8.2	Warranty Policy	27
8.3	Training.....	28
Appendix A	Certification Information.....	29
A1	CE Statement.....	29
A2	FCC Statement.....	29
A2.1	Part 15 B Equipment.....	29
A2.2	Portable Devices.....	29
A3	Industry Canada Class B Compliance Statement	30
A4	Regulations, Directives and Standards	30
Appendix B	Technical Data	31
B1	Rehadapter™	31
B2.1	Medical Power Adapter EU	31
B2.2	Medical Power Adapter INT.....	32
B2.3	Medical Power Adapter US.....	32
Appendix C	Functions of the Buttons	33
Appendix D	Accessories and Replacement Parts.....	34
D.1	Accessories	34
D.2	Replacement Parts	34
Appendix E	Guidelines and Manufacturer Declaration	35

1 Preface


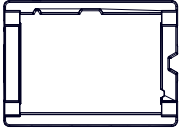

Dear customer, thank you for choosing the Rehadapter™!

To ensure optimal performance of the product, read the following instructions and follow them carefully when using the device.

Safely store the instructions for use.

























The Rehadapter™ is a communication aid for augmentative and alternative communication (AAC). It was developed and created by Rehadapt Engineering GmbH & Co. KG for people with different disabilities such as speech impediment, language impairment, physical impairment, or cognitive impairment.

The Rehadapter™ is a certified class I medical device that serves as a communication aid in combination with the following iPads:

	<i>Model</i>	<i>Version</i>	<i>Art. No.</i>	<i>Compatible tablets</i>
	Rehadapter™ Mk-I	EU	10.0000	iPad® 10.2" (7th/8th/9th generation)
		INT	10.0001	
		US	10.0002	
	Rehadapter™ Mk-II	EU	10.0004	iPad® 10.9" (10 th generation)
		INT	10.0005	
		US	10.0006	
	Rehadapter™ Pro Mk-I	EU	10.0100	iPad® Pro 11 (1st/2nd/3rd/4th generation)
		INT	10.0101	
		US	10.0102	iPad® Air (4th/5th generation)

1.1 Symbols and Markings

The following symbols can be found on Rehadapt products, accessories, instructions for use or on the packaging:

-  Indication of potential damage or malfunctions of the product in the event of non-compliance.
-  Warning of significant risk of injury for the user or damage for the product in the event of non-compliance with the warning sign.
-  Indication of significant risk of injury for the user in the event of non-compliance with the warning sign.
-  The CE marking indicates that the product complies with the applicable European safety, and environmental protection regulations.
-  The FCC mark indicates the product's conformity with the requirements provided by the U.S. Federal Communications Commission (FCC).
-  UK Conformity Assessed (UKCA) mark. Marks the product's conformity with the requirements for products sold in the UK.
-  Universal recycling label. This product can be recycled.
-  Waste Electrical and Electronic Equipment (WEEE) mark. Do not discard the device as unsorted waste.
-  The protective insulation conforms with protection class II
-  Applied part type BF according to IEC 60601-1
- IP22** The degree of protection IP22 indicates that the device is protected against foreign objects with a diameter greater than 12.5 mm, against finger access and against dripping water when the housing is tilted at 15 degrees.
-  Consult the instructions for use.
-  Article number
-  Protect against moisture
-  Suited for indoor use only
-  Date of manufacture
-  Manufacturer
-  Serial number
-  Medical device
-  Unique Device Identifier
-  Choking hazard. Small parts.
-  Bluetooth®
-  Connection for the magnetic charging cable
-  Switch connector: Space
-  Switch connector: Enter

1.2 Intended Purpose

The Rehadapter™ is a splash-, shock-, and drop-resistant tablet case that allows selected tablet models to be used as dedicated speech-generating devices.

It features a speaker that is connected to the tablet via Bluetooth® and includes ports for switch access. It also features a system to quickly attach and detach keyguards, as well as anchor points for attaching additional accessories such as external eye trackers or head mice.

The Rehadapter™ is not life-sustaining nor life-supporting but is intended to accompany the patient during their daily activities. To do so, it can be mounted on any Rehadapt mount featuring a Universal Device Socket (UDS), used handheld or stand-alone either simply lying on a surface or with its integrated stand.

The Rehadapter™ can be used in professional healthcare facilities as well as in home healthcare.

The tablet and software are not included. All necessary technical specifications (including the compatible tablet models) are listed in the respective product description and instructions for use.

Indications:

Persons who rely on adaptive technology to communicate (AAC).

Contraindications:

None

Patient target group:

Patients with hereditary, congenital, degenerative or acquired movement disorders, specifically in conjunction with limitations in communication; or patients with limitations in verbal speech.

Conditions include, but are not limited to:

- Cerebral Palsy
- Neuromuscular diseases such as ALS, SMA, or MS
- Acquired Brain Injuries such as Stroke, TBI or aneurysms
- Rett or Angelman syndrome, or other severe multiple disabilities
- Autism Spectrum Disorders
- Injuries or amputations

Intended users:

The Rehadapter™ is intended to be setup by a authorized distributor and used by the patient(s).

1.3 Scope of Delivery

- 1x Rehadapter™
- 1x Medical USB power adapter
- 1x RD magnetic charging cable
- 1x Set of RD soft keyguard blocks (white)
- 1x Set of RD medium keyguard blocks (grey - preassembled)
- 1x Set of RD hard keyguard blocks (black)
- 2x Reset Pin
- Tools for installation:
 - 1x Allen wrench 3 mm
 - 1x Allen wrench 5 mm
- 1x Instructions for use
- 1x Original packaging

! We recommend keeping the original packaging of the Rehadapter™. If the device is returned to Rehadapt Engineering GmbH & Co. KG for a warranty claim or a repair, use the original packaging for shipping.

2 Safety Instructions

Rehadapt products are tested to assure their compliance with all internal, industry and regulatory standards for medical devices. However, to ensure their safe operation, please comply with the following safety instructions and warnings:

2.1 General Handling

⚠ Do not use the Rehadapter™ as a life-sustaining or life-supporting device. In the event of a functional failure, the device and the software are not reliable and cannot be used.

⚠ Do not make any modifications to the product or to the accessories.

Only ever use accessories with standardized interfaces or accessories approved by Rehadapt for combination with the Rehadapter™.

⚠ Handle the Rehadapter™ with care. The device is made of metal and plastic, and it has sensitive electronic components on the inside. Do not modify it.

⚠ The Rehadapter™ consists of multiple individual parts that have been assembled to produce one complete device.

Small parts can be detached from the device, posing a potential choking hazard and other risks of accident. Small children or persons with impaired judgement should not be able to reach for or use Rehadapt products without the supervision of a caregiver.

⚠ The shoulder strap and the charging cable pose a strangulation hazard. Never leave children unattended with the shoulder strap or the charging cable.

⚠ The Rehadapter™ should only be used according to the conditions specified in this manual. Do not use the device in damp, wet, very cold, or very hot environments.

⚠ The charging connector is magnetic. Keep the charging connector away from people who use any implantable medical device (e.g. pacemakers).

2.2 Prevention of Hearing Damage

! Excessive sound volume can result in chronic hearing loss. Choose a safe volume level to avoid hearing damage.

Being exposed to loud sound continuously can inure you to harmful volume levels. This puts you at risk of damaging your hearing. Lower the volume if you notice any whistling noises in your ear. The higher the volume, the higher the risk of damaging your hearing.

To protect your hearing, Rehadapt recommends the following:

- Do not hold the Rehadapter™ directly up to your ear.
- Lower the volume if you have trouble understanding the people around you.

Follow these steps to choose a safe volume level:

- Choose a low volume level.
- Slowly increase the volume until you can hear the sound clearly.







2.3 Charger and Battery

This Rehadapt product includes a charger (which consists of a charging cable and a power adapter), and a lithium-ion battery, all intended for use with the Rehadapter™ only. Do not use the charging cable, the power adapter, or the lithium-ion battery with any other devices. Only use charging cables, power adapters, and batteries approved by Rehadapt to ensure safe and proper operation.









The proper operation of the power adapter and of the battery do not pose any danger to the customer. Misuse, improper treatment, or improper charging of the battery can result in a chemical and electrical

hazard (e.g. fire, chemical burn, heat burn, or electrocution). Follow the instructions to handle and use the power adapter and the lithium-ion battery safely.



Charging the Battery

-  The power supply must match the requirements of the battery, specifically the necessary nominal voltage.
-  If the device is not charging, unplug the power adapter from the power outlet and disconnect the charging cable from the device.
-  The Rehadapter™ battery is rechargeable. The performance of any rechargeable battery decreases over time. Therefore, the runtime of a fully charged used Rehadapter™ might be shorter compared to a fully charged new Rehadapter™.
-  The Rehadapter™ has an internal, lithium-ion rechargeable battery. Charging the battery can be impaired by a hot environment. For charging, the internal temperature of the battery should lie between 5 °C and 40 °C (41°F and 104°F). The battery will not charge if its internal temperature rises above 40 °C (104 °F). If the internal temperature of the battery is too hot, move the Rehadapter™ to a cooler environment for charging.
-  Inspect the charging cable regularly for signs of wear or damage. If the charging cable shows signs of wear or damage, it must be replaced. The charger does not require any other routine maintenance.
-  If the battery of the Rehadapter™ is empty and the Rehadapter™ is not connected to a power outlet using the charger, the device will shut down.

Handling/Environment

-  Only use the charger under supervision of a parent, a legal guardian, or a caregiver.
-  Do not expose the Rehadapter™ to fire or to temperatures above 40 °C (104 °F) as both can lead to battery malfunction and heat dissipation. Situations such as a car trunk on a hot day or a comparable environment might exceed the advised range of temperature. If the Rehadapter™ is stored in such environments, malfunctions may occur.
-  Special regulations apply for the transport of devices with lithium-ion batteries. Non-compliance with the transport regulations, as well as dropping, damaging, destroying, or short-circuiting a lithium-ion battery, can result in the battery emitting dangerous amounts of heat.
-  The power adapter might heat up during usage. Do not block the power adapter's air supply by touching, covering, or wrapping the power adapter, or by disturbing it in any other way.
-  Use the charger indoors only. The charger is not intended for outside use.
-  Do not expose the charger to external heat sources. Do not expose the charger to direct sunlight for extended periods of time.
-  Do not bring the charger near heat sensitive materials.
-  Do not drop or overload the charger. Do not subject the charger to excessive shaking.

Exchanging/Replacing the Battery

-  Do not attempt replacing the Rehadapter™ battery yourself as the Rehadapter™ and the battery can be damaged in the process. Damaging the battery by attempting to replace it can lead to injury and to overheating of the device. The battery may only be replaced by the Rehadapt Service Center.
-  Do not use the Rehadapter™ or its accessories in case of mechanical damage.

- ! If the battery is damaged, handle it with utmost caution. If you come into contact with the battery contents (electrolyte), immediately clean the affected areas with soap and water. If the battery contents get into your eyes, rinse them for 15 minutes using warm water and consult a doctor.

2.4 Temperature

- ⚠ Using the Rehadapter™ in direct sunlight or in another hot environment can lead to the device surfaces becoming very hot.

- ⚠ Do not expose the Rehadapter™ to fire or to temperatures above 40 °C (104 °F) as both can lead to battery malfunction and heat dissipation. Situations such as a car trunk on a hot day or a comparable environment might exceed the advised range of temperature. If the Rehadapter™ is stored in such environments, malfunctions may occur.

2.5 Mounting

- ⚠ Mount the Rehadapter™ according to the instructions of the respective mounting system. The user is responsible and liable for any risks of mounting as well as for any personal injury or damage to property caused by the improper usage of the mount. The user and the distributor are responsible and liable for the mount's assembly and operation.

2.6 Emergency Situations

- ! Do not use the Rehadapter™ as the only option for emergency calls. We recommend having multiple alternative communication aids ready for emergency situations.

2.7 Electricity

- ⚠ Do not open the casing of the Rehadapter™. Opening the Rehadapter™ casing can lead to an electrical hazard. The device does not contain any serviceable components.

2.8 Safety of Children and of Persons with Impaired Judgement

- ⚠ The Rehadapter™ and its accessories are not toys and must not be used for play by children or persons with impaired judgement. Using the Rehadapter™ or its accessories as a toy for children or persons with impaired judgement poses a risk of injury or of damaging the Rehadapter™ or its accessories.

The Rehadapter™ consists of multiple individual parts that have been assembled to produce one complete device. Small parts can detach from the device, posing a potential choking or other hazard. Small children or persons with impaired judgement should not be able to reach for or use the Rehadapter™ or its accessories without the supervision of a caregiver.

2.9 Repair

- ⚠ Do not attempt to open the Rehadapter™ or to repair the Rehadapter™ yourself. Disassembling the Rehadapter™ can lead to permanent damage to the device and to injury. Contact Rehadapt Engineering GmbH & Co. KG if the Rehadapter™ is damaged or if it does not function properly. Do not use the Rehadapter™ or its accessories if the Rehadapter™ or its accessories are mechanically damaged. Repairs may only be carried out by the Rehadapt Service Center.

For more information about the Rehadapt Service Center, visit the Rehadapt website: www.rehadapt.com

2.10 Magnetic Field / Interference with Medical Devices

- ⚠ The Rehadapter™ and some accessories contain components that have magnets attached to them and that create a magnetic field. Do not bring the Rehadapter™ or its accessories closer than 1cm [0.40"] of a person who uses implantable medical devices. Do not place the Rehadapter™ or its accessories on any medical device that can be or might be influenced by electromagnetic or magnetic radiation. We recommend keeping the Rehadapter™ and its accessories at a safe distance to other medical devices to avoid any possible electromagnetic interferences.

- ! During use, the Rehadapter™ may only be touched in the designated areas. Keep 1cm [0.40"] between the casing and the user in the area surrounding the kickstand.
- ! It is required to keep 30cm [12"] between the Rehadapter™ and any mobile transmitter for standard-conforming use.
- ! Using the Rehadapter™ in combination with or near high-frequency surgical instruments is prohibited.

2.11 Reporting Serious Incidents

Report all incidents to the following email address: customercare@rehadapt.com. "Incident" refers to a malfunction or a decrease of the attributes or the performance of the Rehadapt product, including application errors caused by ergonomic features, as well as inadequacy of the information provided by Rehadapt or the distributor, and any unwanted side effects.

All serious incidents involving the product or occurring in connection with the product must be reported to Rehadapt.

3 Overview of the Rehadapter™

3.1 Rehadapter™ Overview

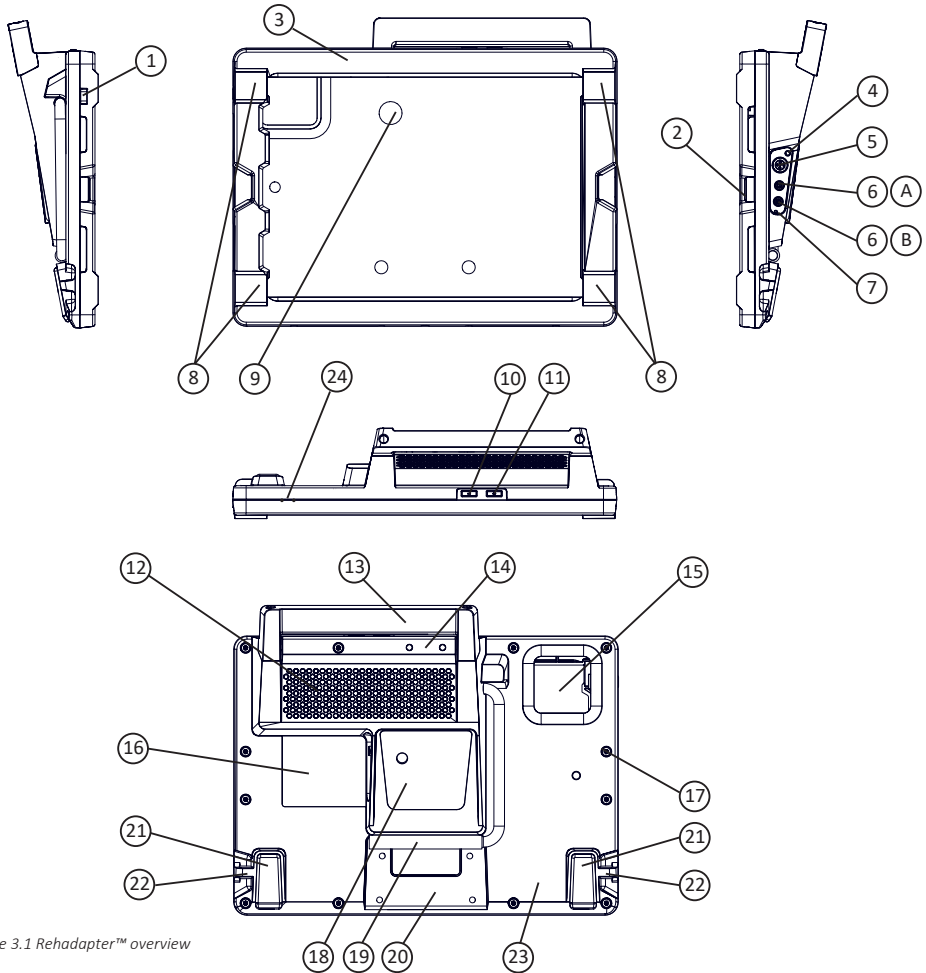


Figure 3.1 Rehadapter™ overview

Pos.	Description
1	Tablet On/Off button
2	Cutout for charging port tablet
3	Front casing
4	Status indicator LED
5	Magnetic charging port
6A	3.5 mm switch connector – Space
6B	3.5 mm switch connector – Enter
7	Reset
8	Keyguard click system
9	Kickstand fixation bolt
10	Volume Down (-)
11	Volume Up (+)
12	Speaker

Pos.	Description
13	Handle
14	TOP accessory anchor point
15	Cutout for the camera of the tablet
16	Device identification label
17	Casing bolts (12x)
18	Adapter plate for Rehadapt UDS
19	Kickstand
20	BOTTOM accessory anchor point
21	Rubber feet
22	Eyelets for shoulder strap
23	Back casing
24	Optional cutouts for volume buttons of the tablet

3.2 Status Indicator LED

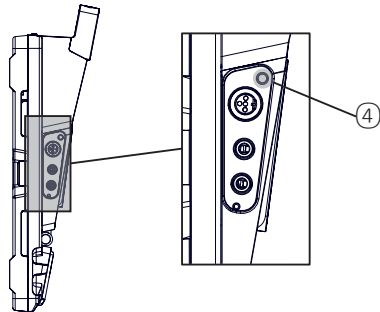


Figure 3.2 Detail – position of the Status Indicator LED

The light of the Status Indicator ④ signalizes the following status information:

Status	Status Indicator LED
Connecting	Blinking blue (slow)
Connected	Solid blue
Pairing Mode	Blinking blue (fast)
Connecting (Battery Low)	Blinking yellow (slow)
Connected (Battery Low)	Solid yellow
Charging (Power Off)	Blinking purple (slow with long pause)
Charging (Connecting)	Blinking purple (slow)
Charging (Connected)	Solid purple
Charger Error	4x blinking red, pause, repeating
Amplifier Error	3x blinking red, pause, repeating
Reset	Indicating device versions (Contact Rehadapt Engineering for more information)

4 Using the Rehadapter™ – User

This section includes the instructions for use for the end-user. It includes all the information the end-user needs to know to use the Rehadapter™ according to its intended purpose (as defined in Section 1.2). For information about the initial setup of the Rehadapter™, refer to *Chapter 5*.

- ! Before using the Rehadapter™ for the first time, fully charge the battery (*Section 6.1.2 Charging the Rehadapter™*).
- ! Only authorized distributors may set up and adjust the Rehadapter™. This is to avoid the risk of damaging the Rehadapter™.
- ! Comply with any notices and signs that limit or prohibit the use of mobile devices (for example in healthcare facilities). Notwithstanding the fact that the Rehadapter was designed, tested and manufactured to comply with regulations regarding radio frequency emissions, such emissions may affect the operation of other electronic equipment and cause them to malfunction.

4.1 Turning the Rehadapter™ on/off

Turn on

To turn on the Rehadapter™, press and hold the volume up button ⑪ for 3 seconds (*Fig. 3.1 Rehadapter™ Overview*).

Turn off

To completely turn off the Rehadapter™, press and hold both volume buttons ⑪ and ⑫ for 5 seconds.

- ! The Rehadapter™ will shut down by itself if there is no Bluetooth® connection with the tablet for 10 minutes.

4.2 Pairing the Rehadapter™ with the tablet

To initially pair the Rehadapter™ with the tablet via Bluetooth®, follow the steps below:

1. Turn on the tablet.
2. On the tablet, turn on Bluetooth®.
3. Turn on the Rehadapter™ (*Section 4.1 Turning the Rehadapter™ on/off*).
4. Activate Pairing Mode: Press and hold one volume button ⑪ or ⑫ while slowly pressing the other volume button for 4 times one second each. When the status indicator starts blinking quickly in blue, let go of both buttons.
5. On the tablet, go to Bluetooth® settings, and tap the name of the Rehadapter™ (✱Rehadapter-XXXXXX as shown on *Fig. 4.1*). The Rehadapter™ is now paired with the tablet. The status indicator LED is solid blue.

- ! Pairing is only possible for 1 minute.
- ! If the Rehadapter™ is not paired with a new device within 1 minute, the Rehadapter™ will shut down by itself.
- ! The Rehadapter™ can only be connected with one tablet at the time.

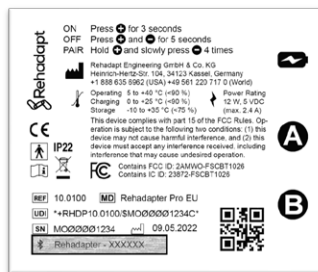


Figure 4.1 Device identification label ⑯ on the back of the Rehadapter™

4.3 Unpairing the Rehadapter™ from the Tablet

To unpair the Rehadapter™ from the tablet, go to Bluetooth® settings on the tablet and remove the Rehadapter™ (Rehadapter-XXXXXX) from the tablet's list of paired devices.

- ! Pairing the Rehadapter™ with a new tablet removes the tablet previously paired from the Rehadapter™ memory.

4.4 Volume Control

To adjust the volume, press the respective volume button ⑪/⑫ on the top side of the Rehadapter™ (*Fig. 3.1 Rehadapter™ Overview*).

4.5 Charging the Rehadapter™

The Rehadapter™ has an internal battery. The Rehadapter™ shuts down if its battery is not sufficiently charged.

Use only the included power adapter and charging cable. The magnetic charging port ⑤ is on the backside of the Rehadapter™ (*Fig. 3.1 Rehadapter™ Overview*).

1. Connect the charging cable to the magnetic charging port ⑤ of the Rehadapter™ and to the power adapter. The magnetic plug adjusts itself to the port by slightly rotating it.
2. Plug the power adapter to a power outlet.
3. Charge the Rehadapter™ until the battery is fully charged. When the battery is fully charged, the status indicator LED ④ will be solid blue.
4. After the battery is fully charged, disconnect the charger from the Rehadapter™ and from the power outlet. The battery cannot be overcharged.

- ! Do not let the power plug come into contact with persons who use implantable electronic medical devices (such as pacemakers) as the charging plug is magnetic.

- ! If the battery of the Rehadapter™ is empty, the tablet will automatically use its own speakers.

- ! The battery performance may decrease over time due to internal chemical reactions. If you do not comply with the instructions mentioned in Sections 2.3 and 2.4, the battery life might decrease and the Rehadapter™ might be damaged. The battery may need to be replaced if the battery discharges rapidly even after correct charging. Contact the Rehadapt Service Center if the battery discharges irregularly rapidly.

- ⚠ Do not attempt replacing the Rehadapter™ battery yourself as the Rehadapter™ and the battery can be damaged in the process. Damaging the battery by attempting to replace it can lead to injury and to overheating of the device. The battery may only be replaced by the Rehadapt Service Center.

- ⚠ Do not use the Rehadapter™ or its accessories in case of mechanical damage.

For information regarding the storage and the charging temperatures of the battery, see *Section 2.3 Charger and Battery*.

The status indicator LED ④ is solid yellow if the battery is low (*Section 3.2 Status Indicator LED*).

You can see the battery level in the header or the widget menu of the tablet, as shown on *Fig. 4.2*. The Rehadapter™ is displayed as an audio accessory (headphones symbol) in the header and widget menu of the tablet.



Figure 4.2 Battery level of the Rehadapter™ shown on the tablet (a) widget menu, and (b) header

4.6 Attaching Keyguards

Keyguards are positioned on top of the screen and secured to the front casing ③ of the Rehadapter™. Attach the keyguard as shown on **Fig. 4.3**. Slide the keyguard into the keyguard click system ⑧ on one side, then push them down on the other side, and they will snap into place.

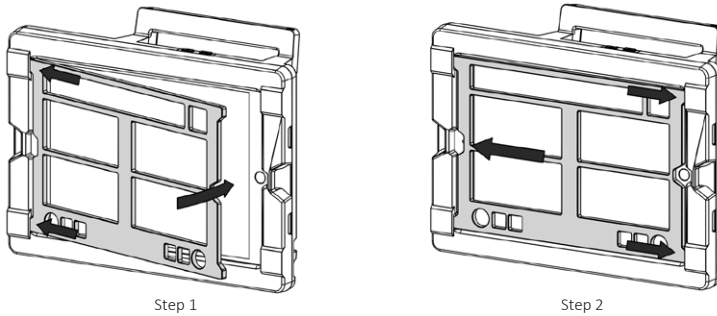


Figure 4.3 Attaching keyguards

To detach the keyguards perform the steps in reverse order.

The keyguard click system ⑧ can be set in 3 levels of hardness by using the different sets of keyguard blocks (included). Only authorized distributors may replace the keyguard blocks on the Rehadapter™.

4.7 Switch Connectors

You can connect up to two switches to the Rehadapter™, which are attached to the 3.5 mm ports ⑥ (A) and ⑥ (B) on the back casing (**Fig. 3.1 Rehadapter™ Overview**).

Their function is adjustable and depends on the software used.

These are the default switch functions:

- ⑥ (A) Space
- ⑥ (B) Enter

4.8 Operating Modes

You can use the Rehadapter™ by itself in two primary positions: lying down (**Section 4.8.1**) and standing (**Section 4.8.2**). You can operate the Rehadapter™ using touch, scanning or alternative input methods in both positions. Additionally, the Rehadapter™ can be used handheld, or mounted on any Rehadapt mounts featuring a UDS (**Section 4.8.3 and 4.8.4**).

4.8.1 Lying Down

The Rehadapter™ can be lie down on a flat surface. In this case, the screen has an angle of use of 10°, as illustrated on **Fig. 4.4**.

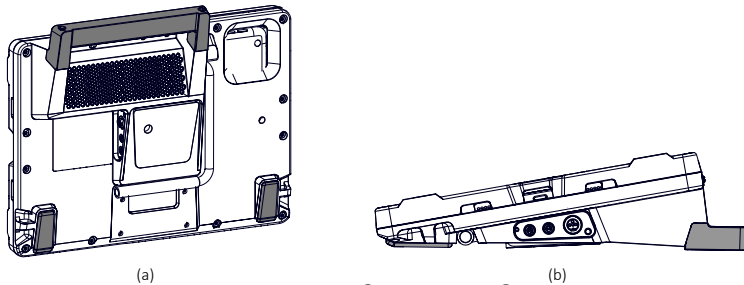


Figure 4.4 Lying Down (a) contact points (Handle ⑬ and Rubber Feet ⑳), and (b) angle of use 10°

4.8.2 Standing

With its kickstand ⑲ the Rehadapter™ can stand up on a flat surface at a variable angle from 35° to 45°, as shown on **Fig. 4.5**. The rubber feet and kickstand ensure slip resistance.

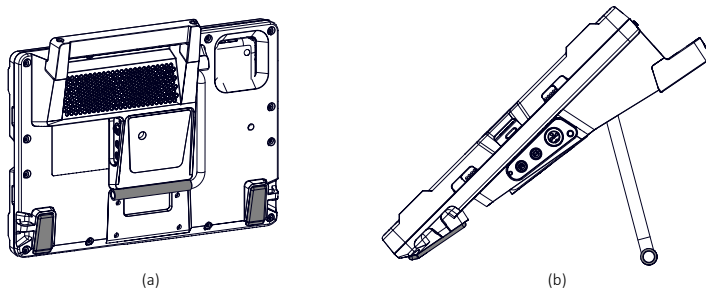


Figure 4.5 Standing (a) contact points (Kickstand ⑲ and Rubber Feet ⑳), and (b) angle of use 35°-45°

- ! Make sure the kickstand is sufficiently unfolded and the hinge is working, otherwise the Rehadapter™ might not be standing stable.

4.8.3 Adapter plate for Rehadapt UDS

In addition, the Rehadapter™ can be mounted on any Universal Device Socket (UDS) manufactured by Rehadapt Engineering using the device adapter plate ⑱ (Fig. 3.1 Rehadapter™ Overview), as illustrated on Fig. 4.6.

- ! Choose a Rehadapt mount taking into consideration the weight of the Rehadapter™ and do not exceed the load capacity of the mount. The mount can be purchased from your distributor.
- ! Observe the instructions for use included with the mount.

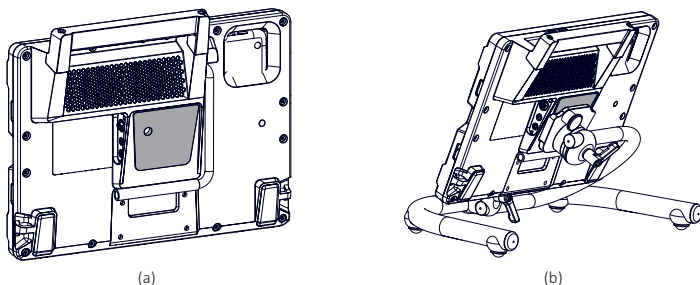


Figure 4.6 (a) UDS adapter plate ⑱, and (b) Rehadapter™ mounted on a Rehadapt table stand°

4.8.4 More Possibilities

In addition, the Rehadapter™ can be used handheld, carried by its handle, or with a shoulder strap. When carrying it using a shoulder strap, it is upside down. Attach a shoulder strap using the designated eyelets ⑳ on the back of the Rehadapter™.

- ! The shoulder strap is not included with the Rehadapter™. It can be purchased separately from your distributor.

4.9 Reset

The Rehadapter and the tablet require different procedures for a reset.

4.9.1 Resetting the Rehadapter™

If the Rehadapter™ does not operate as usual, reset the Rehadapter™. To do so, press the reset button ㉑ using a long, narrow, blunt object (for example the included reset pin). The reset button ㉑ is located inside the casing (Fig. 3.1 Rehadapter™ Overview).

4.9.2 Resetting the tablet

If the volume buttons of the tablet need to be accessed for resetting the tablet use the included reset pins and insert them in the optional cutouts ㉒ as show in Fig. 4.7.

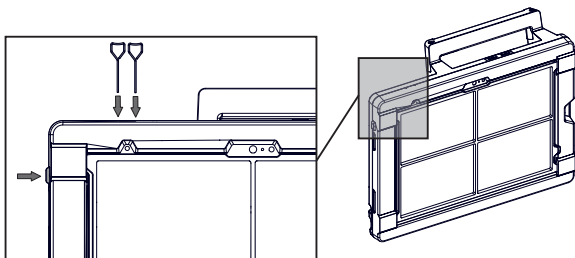


Figure 4.7 Using the reset pins

5 Setting up the Rehadapter™ – Authorized Distributor

! Only authorized distributors may set up and adjust the Rehadapter™. Attempting to set up and adjust the Rehadapter™ otherwise can cause severe damage to the Rehadapter™.

! Observe the mounting instructions in **Section 5.1**. Read the instructions carefully before setting up and using the Rehadapter™.

⚠ Stay within the following torque range:

Bolt	Torque Range
Kickstand fixation bolt (9)	Max. 4.5 Nm
Casing bolts (17)	Min. 1.1 Nm; max. 1.3 Nm

⚠ Only use hand tools and tools with torque limitation. Over-tightening the bolts can severely damage the threads.

Rehadapt Engineering GmbH & Co. KG offers a variety of training resources for the Rehadapter™ and the compatible mounts. These resources can be found at www.rehadapt.com

5.1 Setting up the Rehadapter™

5.1.1 Opening the Rehadapter™

Loosen the bolts (17) (12x) on the back casing and detach the back casing. Use the included 3 mm Allen wrench to loosen the bolts.

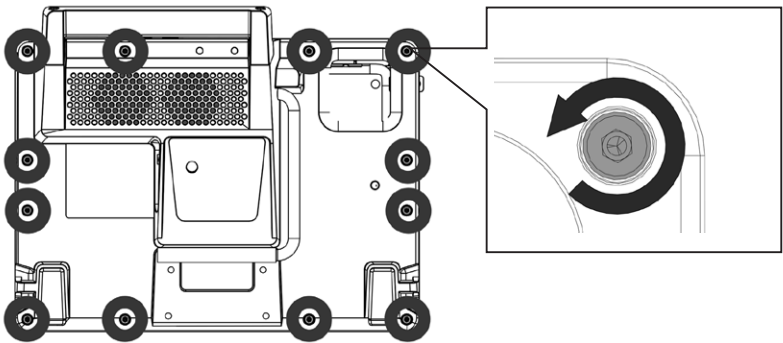


Figure 5.1 Loosening of the casing bolts (17) to open the Rehadapter™

5.1.2 Inserting the Tablet

The Rehadapter™ is compatible with a variety of tablets:

<i>Model</i>	<i>Version</i>	<i>Art. No.</i>	<i>Compatible tablets</i>
Rehadapter™ Mk-I	EU	10.0000	iPad® 10.2" (7th/8th/9th generation)
	INT	10.0001	
	US	10.0002	
Rehadapter™ Mk-II	EU	10.0004	iPad® 10.9" (10th generation)
	INT	10.0005	
	US	10.0006	
Rehadapter™ Pro Mk-I	EU	10.0100	iPad® Pro 11 (1st/2nd/3rd/4th generation) iPad® Air (4th/5th generation)
	INT	10.0101	
	US	10.0102	

Insert the tablet as shown in the illustration below. Mind the position of the on/off button and the camera cutout.

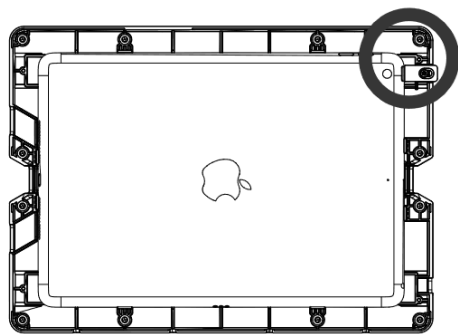


Figure 5.2 Corner of the tablet featuring the on/off button and the camera

5.1.3 Closing the Rehadapter™

Reattach the Rehadapter™ back casing. Make sure every part is correctly aligned. Tighten the bolts ⑰ (12x) on the back casing.

! Stay within the torque range of the casing bolts (from 1.1 Nm to 1.3 Nm).

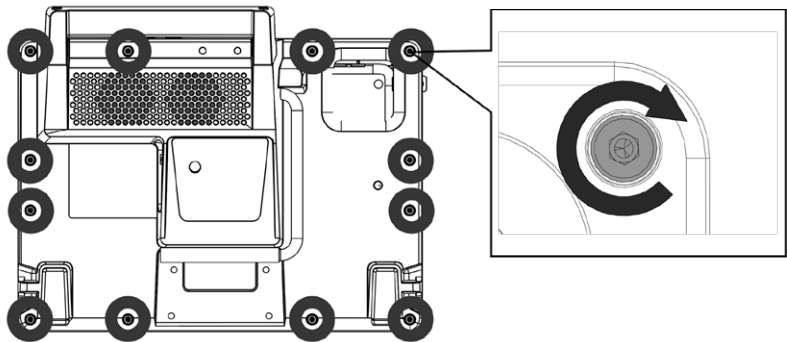





Figure 5.3 Tightening of the casing bolts ⑰ to close the Rehadapter™

5.2 Attaching the Keyguards

The keyguard blocks are inserted with the front casing detached. Choose the correct keyguard blocks depending on the use of the keyguards. You may need to replace the preassembled blocks with the respective choice.

Color		Hardness	Use
	white	soft	Keyguards are detached or replaced frequently
	grey	medium	Keyguards are detached or replaced occasionally (preassembled)
	black	hard	Keyguards are attached permanently

To attach the keyguard permanently, the keyguard must be inserted before the tablet is placed in the Rehadapter. Choose the hard keyguard blocks (black) for a permanent attachment of the keyguard.

To change the keyguard blocks follow these steps:

1. Open the Rehadapter. *(5.1.1 Opening the Rehadapter™)*
 2. Remove the tablet. *(5.1.2 Inserting the Tablet)*
 3. Remove the preassembled keyguard blocks ⑧ (4x) from the front casing ③.
 4. Choose the correct color *(see table above)* depending on the use of the keyguards.
 5. Attach the keyguard blocks (4x).
- 5.a. The white and grey keyguard blocks are self-adhesive on one side. When using the white or grey blocks, attach the keyguards from the front of the Rehadapter after it has been closed *(as shown in Section 4.6)*.

! For a correct positioning, the self-adhesive side of the white and grey keyguard blocks must face the casing and point towards the outer side of the front casing *(Fig. 5.4)*.

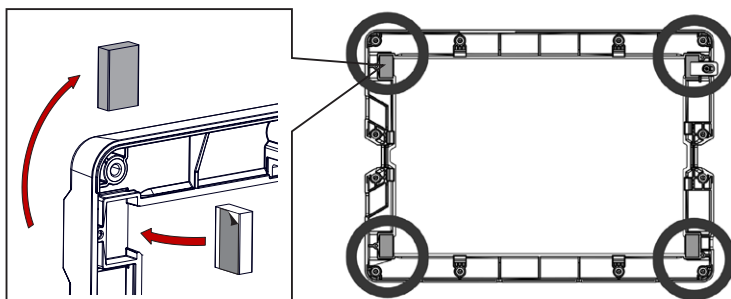


Figure 5.4 Positioning the white/grey blocks of the keyguard click system ⑧ in the front casing ③

- 5.b. When using the black keyguard blocks, insert the keyguards before closing the Rehadapter.

! For a correct insertion, the textured side of the black keyguard blocks must face the outer side of the front casing. Insert this side first and press on the two remaining corners until they click into place *(Fig. 5.5)*.

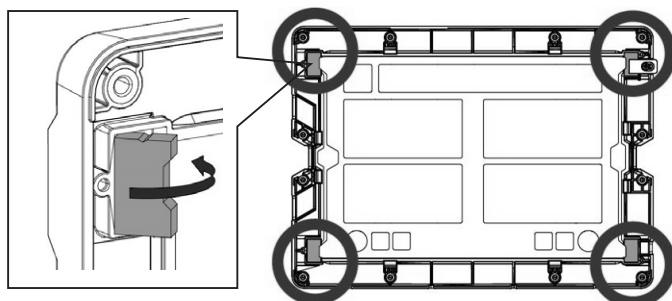


Figure 5.5 Positioning the black blocks of the keyguard click system ⑧ in the front casing ③

6. Insert the tablet. *(5.1.2 Inserting the Tablet)*

! Make sure the tablet is positioned correctly.

7. Close the Rehadapter. *(5.1.3 Closing the Rehadapter™)*

! Make sure the front ③ and back ②③ casing are correctly aligned!

5.3 Kickstand

5.3.1 Adjusting the Resistance

You may adjust the resistance of the kickstand ⑱ using the adjustable hinge on the inside of the casing.

1. Open the Rehadapter™ *(5.1.1 Opening the Rehadapter™)*.
2. Adjust the resistance by rotating the kickstand fixation bolt ⑨ clockwise (increase resistance) or counterclockwise (decrease resistance).

! Stay within the torque range of the kickstand fixation bolt (max. 4.5 Nm).

3. Insert the tablet and close the Rehadapter™ *(5.1.3 Closing the Rehadapter™)*.

5.3.2 Removing the Kickstand

If an accessory is attached to the BOTTOM accessory anchor point ⑳, removing the kickstand ⑱ is recommended *(Fig. 3.1 Rehadapter™ Overview)*.

1. Open the Rehadapter™ *(5.1.1 Opening the Rehadapter™)*.
2. Loosen the kickstand fixation bolt ⑨ counterclockwise by using the included 5 mm Allen wrench.
3. Slide the kickstand ⑱ off to the side.
Slightly refasten the kickstand fixation bolt ⑨ to make sure no parts detach accidentally. The kickstand can be reattached anytime.
4. Close the Rehadapter™ *(5.1.3 Closing the Rehadapter™)*.

! When the kickstand is removed, do not fasten the kickstand fixation bolt to the full torque of 4.5 Nm as this will damage the hinge.

6 Product Care

6.1 Temperature and Humidity

6.1.1 General Use

Use the Rehadapter™ in a dry environment and at room temperature. It is advised to stay within the following temperature and humidity range:

- Ambient temperature: 5 °C to 40 °C (41 °F to 104 °F)
- Relative humidity: 10% to 90% (no condensation on the device)
- Atmospheric pressure: 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)

! Do not submerge the Rehadapter™ in water or other liquids. Do not spill any liquids on the Rehadapter™, especially in the connector area (*Fig. 3.2*).

6.1.2 Charging the Rehadapter

When charging the Rehadapter™, it is advised to stay within the following temperature and humidity range:

- Temperature: 0 °C to 25 °C (32 °F to 77 °F)
- Relative humidity: 10% to 75 % (no condensation on the device)
- Atmospheric pressure: 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)

6.1.3 Transport and Storage

When transporting or storing the Rehadapter™, it is advised to stay within the following temperature and humidity range:

- Temperature: -10 °C to 35 °C (14 °F to 95 °F)
- Relative humidity: 10% to 75% (no condensation on the device)
- Atmospheric pressure: 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)

! Do not store the Rehadapter™ in overly humid environments or in damped or wet areas.

! Turn off the Rehadapter™ when it is not in use, before storage and transport.

6.2 Maintenance and Care

A damaged product or damaged components can injure the user and others. Only use the Rehadapter™ or its accessories if you can rule out any defect. Contact your distributor for any further questions.

! Only the Rehadapt Service Center is authorized to perform safety checks. Contact your distributor for this.

6.3 Cleaning

6.3.1 General Disclaimer

All Rehadapt products should be cleaned regularly, in order to ensure flawless hygiene and operation. Cleaning requirements depend on the type of use and usage environment of the product. The user or their caregivers bear sole responsibility for the cleaning of a product. Failure to carry out the necessary cleaning could result in loss of the product warranty as well as impairment of the clinical condition and safety of users and/or caregivers.

! All guidelines listed here are indicative only. More detailed “Cleaning and Disinfection Guidelines” can be found on our website (www.rehadapt.com) for each product. We recommend you wear gloves during cleaning. Make sure no moisture penetrates the device.

6.3.2 Cleaning the Rehadapter™

Before cleaning the Rehadapter™, turn off the Rehadapter™ and disconnect all cables. Use a slightly dampened, soft, lint-free cloth. Make sure no moisture enters the device openings and crevices. Do not use window cleaners, household cleaners, aerosol spray, solvents, rubbing alcohol, ammonia, or abrasives for cleaning the Rehadapter™.

It is necessary to perform regular wipe disinfection on the device in special environments, for example hospitals. For wipe disinfection, use any surface disinfectant suitable for polycarbonate and aluminum. Make sure no moisture enters the device openings and crevices. We recommend using 70% isopropanol or appropriate alcoholic wipes for wipe disinfection.

- !** Do not use steam sterilization or wet sterilization on any part of the Rehadapter™.

If the speaker openings are clogged, clean them carefully using a cotton swab to avoid damaging the speakers.

6.4 Redispatch and Return

Disconnect all cables, attachments and accessories from the Rehadapter™ before shipping. Turn off the Rehadapter™.

- !** We recommend keeping the original packaging of the Rehadapter™. If the device is returned to Rehadapt Engineering GmbH & Co. KG for a warranty claim or a repair, use the original packaging for shipping.

6.5 Disposal of the Rehadapter™

Do not dispose of the Rehadapter™ with household or office waste. Dispose of the Rehadapter™ according to the waste regulations of the country you are disposing it in.

6.6 Disposal of the Battery

Do not dispose of the battery with household or office waste. Dispose of the battery according to the waste regulations of the country you are disposing it in.

7 Troubleshooting

If problems occur, follow the steps described in the table below. If the issues are not resolved, please contact your distributor.

Failure	Possible cause	Rectification
Status indicator LED ④ is not lit	Rehadapter™ is not turned on	4.1 Turning the Rehadapter™ on/off
	Rehadapter™ is not charged	4.5 Charging the Rehadapter™
Rehadapter™ has no audio output ⑫	Tablet is not turned on	Turning the tablet on
	Rehadapter™ is not paired with the tablet	4.2 Pairing the Rehadapter™ with the tablet
Rehadapter™ is connected but has no audio output ⑫	The volume of the Rehadapter™ is too low	4.4 Volume Control
	Pairing process has been disrupted	4.2 Pairing the Rehadapter™ with the tablet
Rehadapter™ does not charge despite being connected with the charger	The power adapter used does not have the required output	Only use the supplied power adapter and charging cable
	Power adapter is not plugged in the power outlet	Plug the power adapter into a power outlet
	Magnetic charging plug has not audibly snapped into place ⑤	4.5 Charging the Rehadapter™
	Magnetic charging cable is connected with the port ⑤ at an angle	
	Magnetic charging connector is dirty	Clean the charging connector carefully
Tablet On/Off button ① does not work	Tablet is not correctly inserted	5.1.2 Inserting the Tablet
	The button ① is clogged with dirt	Open the Rehadapter and clean the button area (Fig. 5.2)
External switch ⑥ does not respond	Configuration in the tablet not set correctly	Check the settings in the tablet
The kickstand ⑩ moves with difficulty	Kickstand fixation bolt ⑨ is not adjusted correctly	5.3.1 Adjusting the Resistance
Keyguard ⑧ is difficult to insert	Too much resistance when inserting the keyguard	5.2 Attaching the Keyguards
Keyguard ⑧ is too easy to remove	Too little resistance when removing the keyguard	5.2 Attaching the Keyguards
Rehadapter™ turns off after a short time in pairing mode	After being turned on, the Rehadapter™ turns off automatically	4.2 Pairing the Rehadapter™ with the tablet
Status indicator LED ④ flashes red	The Rehadapter™ registered an internal error	Contact your distributor or the Rehadapt Service Center
Status indicator LED ④ lights up yellow	Battery empty after long-term use	4.5 Charging the Rehadapter™
Rehadapter™ does not automatically connect with the tablet	Tablet was turned off	Select the paired Rehadapter™ in the tablet Bluetooth® menu

8 Customer Support, Warranty, Training

8.1 Customer Support

For technical support contact your distributor or customercare@rehadapt.com.

Have your Rehadapter™ at hand for quick support. Have the serial number of your device ready. Find the serial number on the device identification label ⑩ of your device. Also, look for the invoice number or article number. You will find them on the delivery note.

Instructions for use of Rehadapt products are available for download at: www.rehadapt.com.

8.2 Warranty Policy

Service Life

The expected normal service life, depending on the intensity of use and number of reuses, is 3 years. For this purpose, the product must be used within its intended purpose and use, the specifications of the operating instructions must be followed, and all maintenance and service intervals must be adhered to. The product can be used beyond this period if it is in a safe condition. This usual, theoretical service life is not a guaranteed service life and is subject to a case-by-case examination by qualified personnel of the source of supply, as is the reusability. Use beyond the specified service life may result in an increase in residual risks and should only be undertaken after careful qualified consideration by the source of supply. The service life may also be shortened depending on the frequency of use, the operating environment and care. The usual service life does not refer to wearing parts such as cables or parts that are subject to material-specific aging and/or wear. Likewise, variations in battery performance may occur depending on use. This specified service life does not represent an additional warranty or guarantee.

Warranty

Rehadapt Engineering GmbH & Co. KG warrants that for a period of 3 years from the date of purchase, the Rehadapter will substantially conform with its specifications, be free from defects in material and workmanship, and will perform in accordance to its basic intended purpose.

However, depending on use, variations in battery performance may occur. In warranty cases, the date of purchase must be proven with the proof of purchase. We therefore recommend that you keep the proof of purchase.

Should you find a defect covered by the warranty provisions, Rehadapt Engineering GmbH & Co. KG will, within the 3-year warranty and at its own discretion, replace the complete product or defective parts with new or like-new components free of charge, or make repairs to the original product.

Should the Rehadapter™ be returned under warranty as well as for repair to Rehadapt Engineering GmbH & Co. KG, please contact your source of supply or the Rehadapt Service Center for a Return to Manufacturer Authorization number (RMA number for short). Visit our website www.rehadapt.com for more information.

It is requested to use the original packaging for shipping. Accordingly, we recommend that you keep the original Rehadapter™ packaging. Shipping costs will be covered by Rehadapt Engineering GmbH & Co. KG; however, on-site assembly services are excluded.

A warranty claim exists only if the device is used according to the instructions for use. Therefore, read these instructions for use carefully before use. Setup and adjustment of the Rehadapter™ must be performed by authorized distributors, otherwise all warranty claims will be voided. Be aware that the Rehadapter™ does not work for everyone and not under all environmental conditions. Rehadapt

Engineering GmbH & Co. KG does not guarantee that the Rehadapter™ will meet all user requirements, that the operation of the Rehadapter™ will be uninterrupted under all circumstances, or that the Rehadapter™ will always be free of errors and defects.

Compensation due to loss of use caused by defective Rehadapt products cannot be claimed. Rehadapt Engineering GmbH & Co. KG does not assume any liability for personal injuries as well as for damages to other objects indirectly caused by defects of Rehadapt products.

Excluded from the warranty are wearing parts such as cables, bolts, and all threads, as well as consequences of improper use. Furthermore, these warranty provisions do not apply to consumer goods such as rechargeable batteries, unless damage was caused by defects in material or workmanship. Rehadapt Engineering GmbH & Co. KG guarantees the essential performance of the battery according to the specification for one year from the date of purchase.

8.3 Training

Rehadapt Engineering GmbH & Co. KG offers a variety of training resources for the Rehadapter™, and its accessories. For more information about training, visit www.rehadapt.com

Appendix A Certification Information

CE The Rehadapter™ carries the CE marking, indicating the Rehadapter™ conforms with the applicable EU Directives and Regulations. Detailed information about the applicable regulatory requirements can be found in the Declaration of Conformity.

A1 CE Statement

This device complies with the requirements for electromagnetic compatibility, the essential protection requirements of the Electromagnetic Compatibility (EMC) Directive 2014/30/EU regarding the approximation of the laws of the Member States about the Electromagnetic Compatibility, and the Radio Equipment Directive (RED) 2014/53/EU to meet the requirements for radio equipment and telecommunications terminal equipment.

A2 FCC Statement

The FCC ID of this device is 2AMWO-FSCBT1026. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

A Changes or modifications to this product not authorized by Rehadapt Engineering GmbH & Co. KG could void the user's authority to operate the product.

A2.1 Part 15 B 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 distance between the equipment and receiver.
- Connect the equipment to 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.

A2.2 Portable Devices

FCC Radio Frequency Radiation Exposure Statement:

1. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC radio frequency radiation exposure limits set forth for an uncontrolled environment. This equipment has been tested for typical handheld operation, with direct contact between the equipment and the human body on the sides and on the handle of the equipment. To comply with FCC requirements for exposure to radio frequency radiation, avoid direct contact with the transmitter antenna during transmission operation.

A3 Industry Canada Class B Compliance Statement

This Class B digital apparatus complies with Canadian ICES-003.

Contains transmitter module IC: 23872-FSCBT1026

This device can be operated with a minimum distance of 0 cm between the equipment and the user's body. As a precaution, keep 10 mm in the area of the kickstand/antenna.

Avis de conformité à la réglementation d'Industrie Canada

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

Contient le module émetteur IC: 23872-FSCBT1026

Ce dispositif peut être exploité en toute sécurité avec un 0 cm distance minimale entre le matériel et les corps de l'utilisateur. Par précaution, respectez une distance de 10 mm au niveau du support de pied/antenne.

A4 Regulations, Directives and Standards

The Rehadapter™ is a class I medical device and complies with the following regulations and directives:

- Medical Device Regulation (MDR) (EU) 2017/745
- Low Voltage Directive (LVD) 2014/35/EU
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- Radio Equipment Directive (RED) 2014/53/EU
- Restriction of Hazardous Substances 2 (RoHS 2) Directive 2011/65/EU, 2015/863/EU
- Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation 2006/121/EG, 1907/2006/EG Annex 17
- Battery Directive 2013/56/EU
- Federal Communications Commission (FCC), CFR Title 47, Part 15 Subpart B and C
- Industry Canada Equipment Standard, ICES-003, Issue 7, Class B

Among other, the following standards have been used:

- IEC 60601-1:2005 + AMD1:2012 (ed. 3.1)
- IEC 60601-1-11:2015
- EN ISO 13485:2016
- EN ISO 14971:2019
- IEC 62133-2:2017 + AMD1:2021
- UN 38.3 (ST/SG/AC.10/11/Rev.7)
- EN ISO 10993-5:2009
- IEC 60601-1-2:2014
- ETSI EN 301 489-1 V2.2.3
- ETSI EN 301 489-17 V3.2.4
- EN 55032:2015
- EN 55035:2017
- ETSI EN 300 328 V2.2.2

An extensive list of the standards used is included in the Declaration of Conformity for each intended market.

Appendix B Technical Data

B1 Rehadapter™

Model	Rehadapter™ Mk-I	Rehadapter™ Mk-II	Rehadapter™ Pro Mk-I
Article No.	10.0000 (EU) 10.0001 (INT) 10.0002 (US)	10.0004 (EU) 10.0005 (INT) 10.0006 (US)	10.0100 (EU) 10.0101 (INT) 10.0102 (US)
Type	Communication aid for ● iPad® 10.2" (7th/8th/9th gen.)	Communication aid for ● iPad® 10.9" (10th gen.)	Communication aid for ● iPad® Air (4th/5th gen.) ● iPad® Pro 11" (1st/2nd/3rd/4th gen.)
Measurements (W x H x D)	293.2 x 237.3 x 62.1 mm 11.54 x 9.34 x 2.45 inch	293.2 x 237.2 x 61.6 mm 11.54 x 9.34 x 2.43 inch	293.2 x 237.2 x 60.6 mm 11.54 x 9.34 x 2.39 inch
Weight	897 g 1.98 lbs	899 g 1.98 lbs	899 g 1.98 lbs
Speaker	1x 5 W		
Connectors	1x Magnetic charging port 2x 3.5 mm switch connectors		
Buttons	1x Tablet On/Off button 1x Volume Down 1x Volume Up 1x Reset		
Bluetooth®	Bluetooth® 5.1 Dual Mode		
Estimated Service Life	3 years		
Average Battery Runtime	~10 hours in typical operation		
Battery Technology	Rechargeable lithium-ion-polymer battery		
Battery Capacity	12.58 Wh		
Battery Charging Time	~4 to 6 hours		
Input Voltage	5 VDC		
Power Consumption	12 W		
Input Current (max)	2.4 A		
Table Stand	Integrated		
Mounting Systems Supported	Rehadapt UDS		
Power Supply	Internal battery or charger		

B2.1 Medical Power Adapter EU

	Specification
Model	HNPM10-USB-WH
Article No.	01.0681
Input Voltage	100 to 240 VAC
Input Current (max.)	300 mA
Power	10 W
Input Frequency	50 to 60 Hz
Output Current	2 A
Rated Output Voltage	5 VDC
Plug type	EU

B2.2 Medical Power Adapter INT

	Specification
Model	EM1012AVRU
Article No.	01.0696
Input Voltage	100 to 240 VAC
Input Current (max.)	1 A
Power	12 W
Input Frequency	50 to 60 Hz
Output Current	2.4 A
Rated Output Voltage	5 VDC
Plug type	Interchangeable (US, UK, EU, AU)

B2.3 Medical Power Adapter US

	Specification
Model	YS10-0502000
Article No.	01.0693
Input Voltage	100 to 240 VAC
Input Current (max.)	400 mA
Power	10 W
Input Frequency	47 to 63 Hz
Output Current	2 A
Rated Output Voltage	5 VDC
Plug type	US

Appendix C Functions of the Buttons

Function	Input
Turn on	Press and hold (+) ⑪ button for 3 seconds
Turn off	Press and hold both (+) ⑪ and (-) ⑩ button for 5 seconds
Pair with the tablet	Press and hold (+) ⑪ or (-) ⑩ button while slowly pushing the other volume button 4 times (1 second each)
Volume up	(+) ⑪ button
Volume up (fast)	Press and hold (+) ⑪ button
Volume down	(-) ⑩ button
Volume down (fast)	Press and hold (-) ⑩ button
Reset	Press and hold the reset ⑦ button for 2 seconds using a blunt object (e.g. the reset pin)
Reset to factory settings	Press and hold (-) ⑩ button while pressing and holding the reset ⑦ button with a blunt tool (e.g. the reset pin) for 2 seconds. Let go of the reset ⑦ button and hold (-) ⑩ button until the status indicator LED ④ lights up.

Appendix D Accessories and Replacement Parts

D.1 Accessories

Accessories are not included and can be purchased separately.

Available accessories:

- 01.0700 Screen protector iPad® 7/8/9 (10 pcs)
- 01.0701 Screen protector iPad® Air 4 (10 pcs)
- 01.0702 Screen protector iPad® Pro 11 (10 pcs)
- 01.0706 Screen protector iPad® 10 (10 pcs)
- 02.0008 Rehadapter transportation bag
- 02.0009 Rehadapter protection sleeve
- 02.0010 Rehadapter shoulder strap
- 02.0011 Rehadapter transportation system
- 16.1250 Rehadapter GA Hiru
- 16.1248 Rehadapter GA HeadMouse Nano

- Keyguards for the Rehadapter™/Rehadapter™ Pro are available upon request.

This list is continuously updated. Find the latest information on accessories at www.rehadapt.com.

Read the respective instructions for use for using each accessory. Only authorized distributors may mount accessories.

D.2 Replacement Parts

Available replacement parts:

- 01.0681 Medical USB power adapter (10 W) EU
- 01.0696 Medical USB power adapter (12 W) INT
- 01.0693 Medical USB power adapter (10 W) US
- 10.9036 RD magnetic charging cable (1 m)
- 10.9000BS Set of RD soft keyguard blocks (white)
- 10.9001BS Set of RD medium keyguard blocks (grey)
- 10.9019BS Set of RD hard keyguard blocks (black)
- 01.0002 Allen wrench 3 mm
- 01.0014 Allen wrench 5 mm
- 01.0859 Reset pin

This list is continuously updated. Find the latest information on replacement parts at www.rehadapt.com.

Only authorized distributors may replace any parts.

Appendix E Guidelines and Manufacturer Declaration

The cable information below is provided for EMC reference

Cable	Max. cable length	Shielded/unshielded	Number	Cable classification
DC USB charging cable	100 cm	Shielded	1	DC power
Two switch button cables	150 cm	Unshielded	2	Signal

Important information regarding Electromagnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and be put into service according to the EMC information provided in the instructions for use. The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions.

This device has the following essential performances:

1. Playback of audio signals transmitted via Bluetooth®.
2. Transmitting input of two wired switches via Bluetooth®.

This device is intended for use in home healthcare and in professional healthcare. Nevertheless, special precautions need to be observed:

- **WARNING:** 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.
- **WARNING:** The 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.
- **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 Rehadapter™, including cables specified by the manufacturer. This could result in degradation of the performance of this equipment.
- **WARNING:** Should the location of use be near (e.g. less than 1.5 km from) AM, FM, or TV broadcast antennas, it is necessary to verify if the device is operating normally before use. This is to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected duration of use.

NOTE: For the purpose of its operation, the equipment has wireless communication function. It includes a RF transmitter and receiver (2.4 GHz, pulse modulation).

NOTE: The device is not compatible with high-frequency surgical equipment. Usage or being on standby in the immediate vicinity of high-frequency surgical devices is prohibited.

NOTE: In the case of electrostatic discharge (± 15 kV air) and surge voltages (± 1 kV), this device can switch off without causing damage to the device.

EMI Compliance Table – Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

EMS Compliance Table — Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Electrostatic Discharge	IEC 61000-4-2:	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3:	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3:	Refer to table
Rated power frequency magnetic fields	IEC 61000-4-8:	30 A/m 50 Hz or 60 Hz

EMS Compliance Table — Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Home healthcare environment
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ±5 kHz Deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810		
870	800-960	Pulse modulation 18 Hz, 28 V/m
930		
1720		
1845	1700-1990	Pulse modulation 217 Hz, 28 V/m
1970		
2450		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m

5240	5100-5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

EMS Compliance Table — Input AC power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Electrical fast transients/burst	EN 61000-4-4:	±2 kV 100 kHz repetition frequency
Surges Line-to-line	EN 61000-4-5:	±0,5 kV, ±1 kV
Conducted disturbances induced by RF fields	EN 61000-4-6:	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11:	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11:	0 % UT; 250/300 cycles

EMS Compliance Table — Signal input/output parts Port

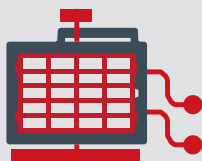
Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Conducted disturbances induced by RF fields	IEC 61000-4-6:	3V, 0.15 MHz - 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Your new AAC hub

equipped with all features needed



Ultimate
protective case



Support for all
access methods



Loud and clear
sound amplifier



Multiple options for
positioning



Maximum
portability



