INSTRUCTIONS FOR USE

Fitting**LINK**

Introduction to this booklet

This booklet gives you guidance on how to use and maintain FittingLINK. Please read the booklet carefully including the **Warnings** section. This will help you get the most out of FittingLINK.

If you have additional questions about the use of FittingLINK, please contact your local distributor.

For your convenience, this booklet contains the below navigation bar to help you navigate easily through the different sections.

| **About** | Start-up | Handling | Warnings | More info |

Intended use

Intended use	FittingLINK is an accessory to the fitting software used when programming SBO wireless hearing aids. FittingLINK is intended for wireless transfer of fitting data between the hearing aids and the device running the fitting software. FittingLINK can be connected to the device running the fitting software through the provided Bluetooth adapter or USB cable.
Indications for use	No indications for use.
Intended user	Hearing care professionals and hearing aid users.
User environment	Hearing care professional's office.
Contraindications	Users of active implants must pay special attention when using the device. For more information, read the **warnings** section.
Clinical benefits	See clinical benefits of the hearing aid.

Table of contents

FittingLINK overview

Neck loop

ON/OFF

Top LED indicator

ON/OFF button

Front LED
indicator - red

Front LED
indicator - blue

Power supply
(and USB port)

Package content

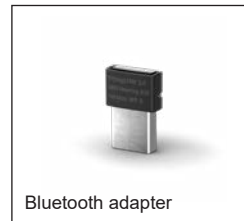The packaging box consists of the following elements:
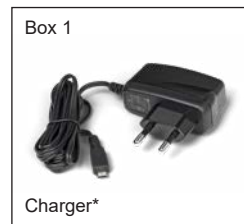

FittingLINK

This booklet (Instructions for Use)
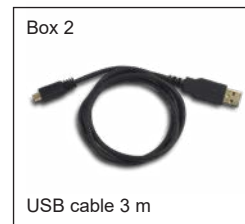

Bluetooth adapter

Clip

Box 1

Charger*

*Charger will vary from country to country.
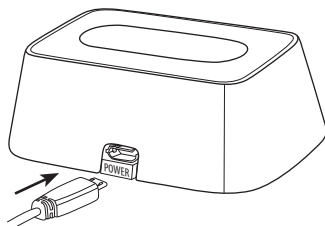
Box 2

USB cable 3 m

Box 3

Charging cradle

Basic functions - first-time use

Insert the USB cable in the bottom of the charging cradle and the charger is ready for use.

Turn FittingLINK ON/OFF

Power ON
Press the ON/OFF button on top of FittingLINK for about 2 seconds until you see a green steady light from the top LED and a short red and blue flash from the front LED indicators. The LED lights indicate that FittingLINK is powered on and you can release the ON/OFF button.

If FittingLINK cannot power on, make sure it is charged.

If the top LED shows a red light instead of the green light the battery is running low (steady red light) or very low (flashing red light) and FittingLINK should be charged. Please refer to "Charge FittingLINK".

Power OFF
Press and hold the ON/OFF button on top of FittingLINK for about 2 seconds until the top LED indicator turns off.

Charge FittingLINK

FittingLINK uses an internal rechargeable battery.

FittingLINK can be charged either by using the provided charger and charging cradle or by using the USB cable provided.

When charging FittingLINK for the first time, it should be left to charge for at least two hours even if the top LED indicator on the device shows that the battery is fully charged. We recommend that you turn off and store FittingLINK in the charging cradle whenever it is not in use, to ensure the best possible performance.

It is safe to leave FittingLINK in the charging cradle overnight – the battery cannot be overcharged.

Charging	
Top LED indicator	**Description**
🟢 ⊙	Device on and fully charged
🟢 ⊙	Device on and charging
🟢 ⊙	Device off and charging Once fully charged, the LED will be off

◯ Steady   🟢◖ Flash

IMPORTANT NOTICE

When charging FittingLINK, use the supplied original power supply 5.0V/1A, CE and safety marked.

IMPORTANT NOTICE

When charging, the charging indicators should be lit as described in this booklet.
If the charging indicators are not lit as described, disconnect the device from the charger and consult your local distributor.

Charge FittingLINK with the charger and charging cradle

Place FittingLINK in the charging cradle when you want to charge FittingLINK with the provided charger and charging cradle. Remember to connect the charger to a power outlet. As soon as the power is switched on, FittingLINK will start charging.
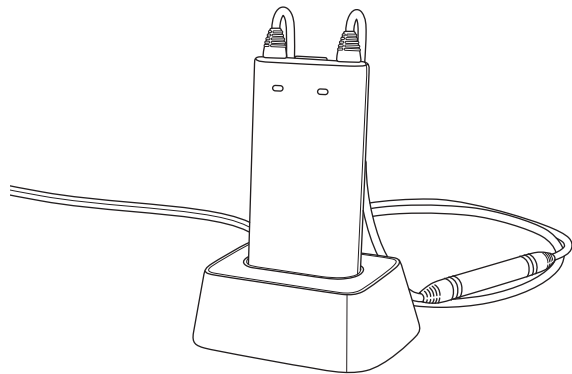
Charge FittingLINK with the charging cradle and USB cable

When charging FittingLINK with the provided charging cradle and the USB cable, place FittingLINK in the charging cradle and connect the USB cable to a USB port on your PC.

Please note that if you charge via a USB hub, some hubs do not deliver enough power to actually charge FittingLINK. In this case we recommend use of the provided charger instead.
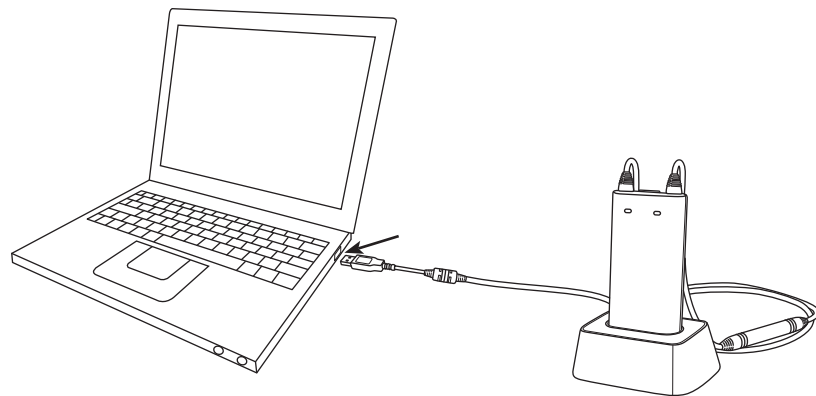
Only recharge FittingLINK using the provided charger or a stabilised USB hub/charger that provides 5VDC and ≥500 mA.

Note: When using the USB cable, always insert the USB cable into FittingLINK before connecting the cable to other equipment.

Charge FittingLINK without the charging cradle

If you prefer not to use the charging cradle when charging FittingLINK, you have the option to insert the USB cable directly into FittingtLINK instead of the charging cradle.

Low battery indicator

FittingLINK will indicate low battery (about 20 minutes programming capacity left) with a steady red light, and very low battery (about 5 minutes programming capacity left) with a flashing red light.

Low battery indicator	
Top LED indicator	**Description**
🔴 ⬜	Low battery – about 20 minutes capacity left
🔴 ⬜	Very low battery – about 5 minutes capacity left

🔴 Steady 🔴 Flash

To ensure the best possible performance, we recommend that you turn off and store FittingLINK in the charging cradle whenever it is not in use.

The battery should not be drained completely. Keeping the battery fully charged will prolong the capacity of the battery. The battery cannot be replaced by the user.

The battery capacity is up to 8 hours of typical daily use.

Battery charge time is 2 hours for complete charge, using the provided power supply.

Connect to a PC

You can connect FittingLINK to your PC either by using the provided Bluetooth adapter or the USB cable.

The Bluetooth adapter enables you to connect FittingLINK wirelessly to your computer.However, in some locations Bluetooth technology is not allowed. When this is the case, simply connect FittingLINK with the computer via the provided USB cable.

Before you start connecting FittingLINK to a PC for the first time, please make sure that you have the latest version of your fitting software installed on the PC. Please also make sure that FittingLINK is fully charged. See "Charge FittingLINK".

Please note that FittingLINK only connects to the Bluetooth adapter provided.

Connect to a PC via the Bluetooth adapter

Make sure that FittingLINK is turned **OFF**.

To obtain wireless connection between FittingLINK and your PC, simply plug the provided Bluetooth adapter into a USB port on your PC and turn the PC **ON**.

FittingLINK has already been paired by the manufacturer with the Bluetooth adapter provided in the box set. However the first time you connect to a PC, a message may appear on the screen and inform you that the applicable driver is being installed. Allow the installation to run before you proceed.

Now turn **ON** FittingLINK. See "Turn FittingLINK ON/OFF". FittingLINK is now ready for programming compatible wireless hearing aids.
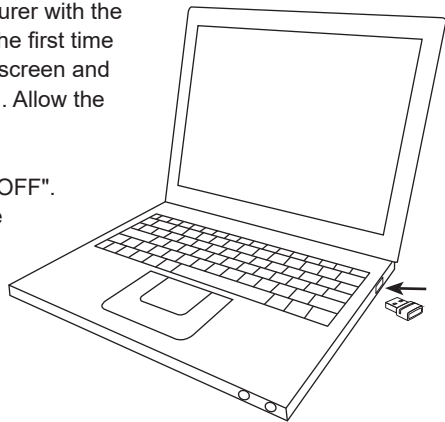
How to re-establish pairing between FittingLINK and the Bluetooth adapter

FittingLINK has been paired by the manufacturer with the adapter provided in the box set.

If for some reason the PC running your fitting software does not recognise FittingLINK, you may have to re-establish the pairing between FittingLINK and the Bluetooth adapter. In this case please close the fitting software before you continue.

1. Press and hold the pairing button on the Bluetooth adapter for five seconds until the LED lights up with a flashing blue light.
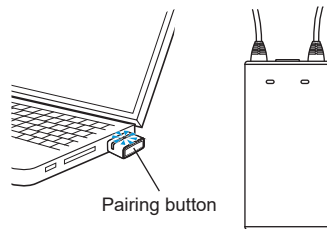
Pairing button

2. Press the ON/OFF button on FittingLINK for five seconds and the top LED will light up with a flashing blue light. The pairing will begin automatically. FittingLINK must be close to the Bluetooth adapter (about 10 cm) while the pairing takes place.

3. When the pairing is successfully completed the adapter LED will show steady blue (until the fitting software is turned on) while the top LED on FittingLINK shows steady blue for about 10 seconds.

Please note that FittingLINK can only be paired with a single Bluetooth adapter at a time and vice versa.

ON/OFF
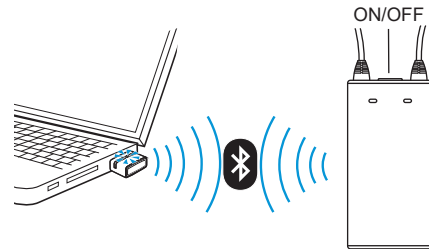
Pairing	
Top LED indicator	**Description**
◑ ⎯Ⓘ⎯	FittingLINK in pairing mode
● ⎯Ⓘ⎯	Pairing complete

◑ Flash ● Steady

When pairing is finished, open your fitting software, detect and select FittingLINK as your programming device. It is necessary to perform and complete this selection procedure only once.

FittingLINK is now ready for programming the hearing aids.

Connect to a PC via the USB cable

To connect FittingLINK to your PC with the USB cable, insert the USB cable in the USB port in the bottom of FittingLINK and then insert the other end of the cable in a USB port on your PC.

Turn **ON** your PC and then turn **ON** FittingLINK. Open your fitting software, detect and select FittingLINK as your programming device. It is only necessary to perform and complete this selection procedure the first time.

FittingLINK is now ready for programming wireless hearing aids.

Please note, you can leave the Bluetooth adapter in your PC while connecting via the USB cable.

Note: If you connect the USB cable to a non-powered USB hub, FittingLINK may not charge.
It is recommended to connect the USB cable directly to your PC.

FittingLINK and fitting software

When opening your fitting software the first time after FittingLINK has been installed on the PC, it will be detected as a programming device.

Depending on which fitting software you are using, FittingLINK is either automatically added as an option on the "Detect button" or needs to be manually detected and selected as programming device in the "Preferences" menu.

For specific information about how to use FittingLINK with your fitting software, please refer to the documentation delivered with your fitting software (e.g. installation handbooks, help files or instructional videos).

How to use FittingLINK

FittingLINK has been designed to offer you the best possible daily use during programming sessions with and without your clients.

Programming without a client
When you want to program hearing aids without a client wearing them, turn **ON** FittingLINK.

Place FittingLINK with the neck loop flat on a table and the hearing aids on each side of the neck loop as shown in the drawing.

When you program hearing aids, the neck loop must always be closed as shown in the drawing.

5-10 cm/ 2-4 in.   5-10 cm/ 2-4 in.
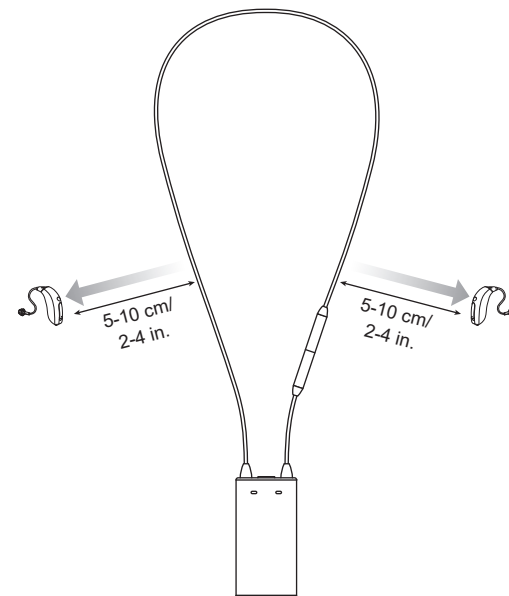
Make sure that the neck loop is not curled or touching any electrical wires or equipment and that the hearing aids are not touching the neck loop.

The optimal placement of the hearing aids is on the outside of the neck loop, between 5-10 cm. from the neck loop as shown in the drawing.

The distance between FittingLINK and the Bluetooth adapter in your PC can be no more than 10 metres (in direct line of sight).

Devices and installations such as power cables, TVs, PC monitors, LED light bulbs and other devices emitting magnetic noise might decrease the programming performance if placed too close to FittingLINK. Likewise a table made of or containing a lot of metal, may lead to decreased performance.

Please note that other active FittingLINK devices and wireless hearing aid accessories in proximity may create interference and should be turned OFF.

If you experience decreased performance, we recommend that you relocate FittingLINK or turn off possible sources of interference.

At the end of the session and before disconnecting or removing FittingLINK make sure that you have saved your programming to the hearing aids.

Please consult the fitting software for further guidance.

Programming with a client
When you want to program hearing aids while your client is wearing them, please make sure that FittingLINK is sufficiently charged.

For easy placement, the neck loop can be opened, as shown on the drawing below, while placing FittingLINK around the client's neck.
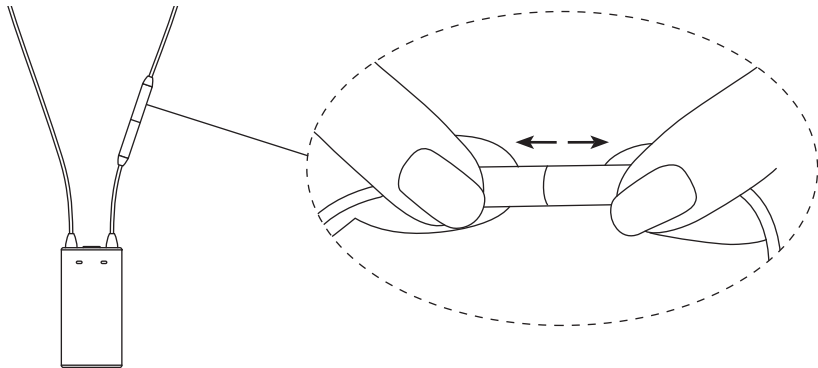
When opening the neck loop, pull the connectors apart. Do not pull the neck loop antenna.

When you program hearing aids, the neck loop must always be closed as shown in the drawing to the right.

The distance between FittingLINK and the Bluetooth adapter in your PC can be no more than 10 metres (in direct line of sight).

Devices and installations such as power cables, TVs, PC monitors, LED light bulbs and other devices emitting magnetic noise might decrease the programming performance if placed too close to FittingLINK. Please note that other active FittingLINKs and wireless hearing aid accessories in proximity may create interference and should be turned off.

If you experience decreased performance, we recommend that you turn off possible sources of interference.

At the end of the session and before disconnecting or removing FittingLINK make sure that you have saved your programming to the hearing aids.

Please consult the fitting software for further guidance.

How to use FittingLINK on children

For children who are old enough to provide verbal feedback regarding their hearing aid, it will be possible to use FittingLINK for programming, real-ear verification or fine-tuning.

It is also possible to use FittingLINK with babies or small children. However, the programming process with infants and small children differs from adults since they are not able to provide verbal feedback on their hearing aids' sound quality. Therefore, it is recommended that the actual verification of the hearing aid be done using the coupler-based verification method. See below for instructions.

When working with children, it can be necessary to shorten the neck loop. Always use the provided clip to shorten the neck loop. Do not shorten or modify the neck loop in an unauthorised way. Please refer to the drawing on how to place the clip.
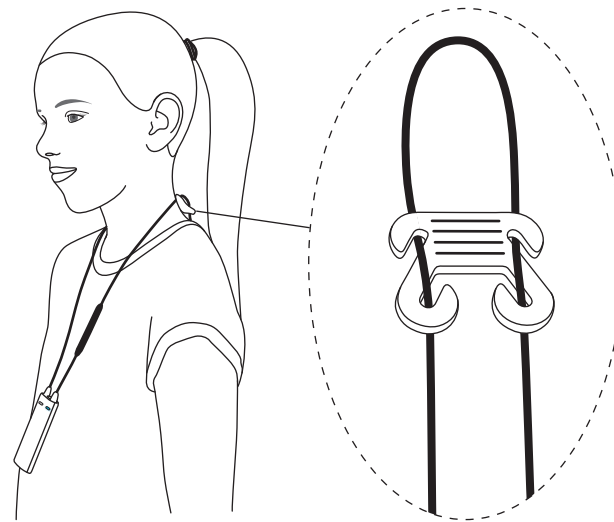
How to use FittingLINK for coupler-based verification using hearing aid analysers

Place FittingLINK in the test chamber. Connect the hearing aid to the 2cc coupler and place the hearing aid 5-10 cm away from the outside of the neck loop, as shown here.

Close the lid of the test chamber and proceed with the coupler-based verification.
Please note that FittingLINK will not work in some test chambers, due to the chambers being too small to ensure the 5-10 cm distance, or due to electromagnetic interference. If this is the case, programming must be done using the hearing aid programming cables and a non-wireless programming interface (e.g., EXPRESSlink).
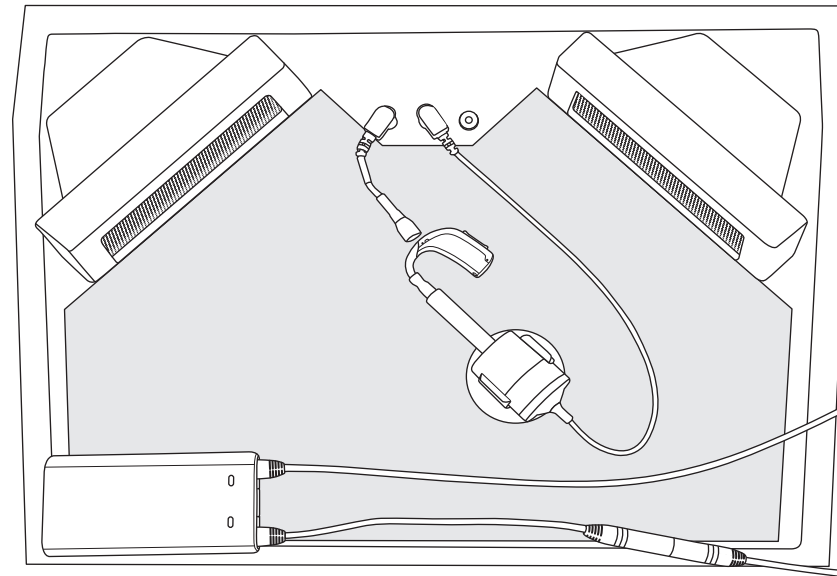
Overview of LED indicators

How to read the Bluetooth adapter LED indicator.

Bluetooth adapter	
LED indicator	**Description**
🔵	Bluetooth adapter active
◑	Bluetooth adapter searching for in-range FittingLINK
◓	Bluetooth adapter pairing
⚪	Bluetooth adapter inactive
◑	Self test error - contact your supplier

🔵 Steady ◑◑ Slow flash ◓ Fast flash ⚪ LED off

How to read FittingLINK LED indicators.

The top LED indicator is the battery status indicator.

Battery status	
Top LED indicator	**Description**
🟢 ⓘ	FittingLINK on and battery fully charged
🟢 ⓘ	Battery charging
🔴 ⓘ	Low battery
🔴 ⓘ	Very low battery

🟢🔴 Steady 🟢◑ Flash

The front LED indicators are programming status indicators.

Programming status	
Front LED indicator	**Description**
🔴	Connected to right hearing aid
◑	Communicating with right hearing aid
🔵	Connected to left hearing aid
◐	Communicating with left hearing aid
⚪	Not connected to the hearing aids

🔴🔵 Steady ◑◐ Flash ⚪ LED off

Front LED indicator - red

Front LED indicator - blue
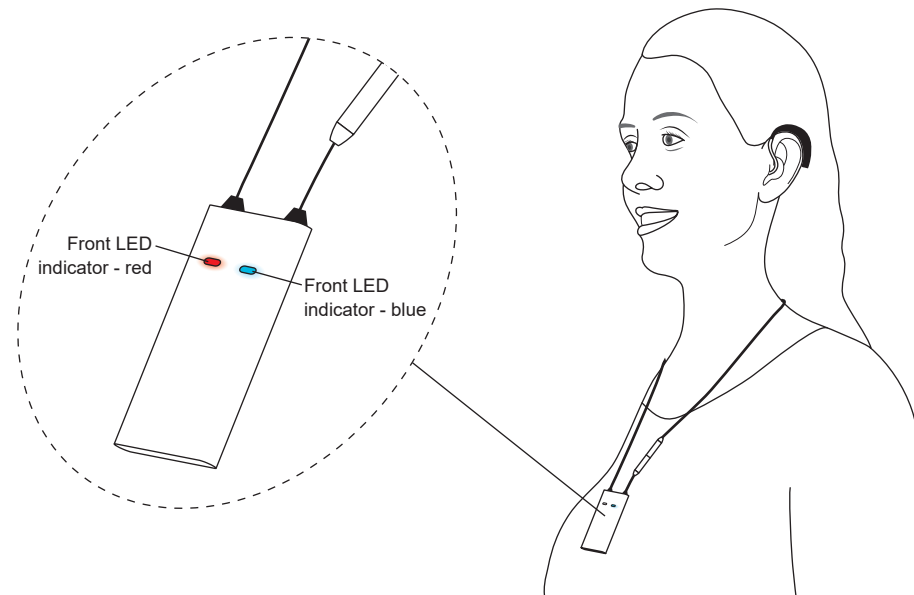
Caring for FittingLINK

FittingLINK is a sealed device that requires minimum maintenance.
To ensure high levels of hygiene always disinfect FittingLINK before a programming session begins.

To disinfect, wipe FittingLINK and the neck loop with a 70% alcohol / 30% water solution. FittingLINK and the neck loop must never be washed or immersed in water or other liquids.

The power supply, the charging cradle and the Bluetooth adapter must be kept free of dirt and debris. These parts are to be cleaned with a soft dry cloth only.

When FittingLINK is not in use, turn it OFF and store it in the charging cradle in order for it to be sufficiently charged and ready for the next fitting session.

⚠ Warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your FittingLINK. Contact your local distributor if you experience unexpected operations or serious incidents with your FittingLINK during use or because of its use. Serious incidents should also be reported to the national authorities.

Explosives
The FittingLINK is safe to use under normal usage conditions. The FittingLINK has not been tested for compliance with international standards concerning explosive environments. Therefore, do not use your FittingLINK in environments with danger of explosions e.g. mines, oxygen rich environments or areas where flammable anaesthetics are handled.

Connection to external equipment
When using the USB cable always insert the cable into FittingLINK before connecting the cable to other equipment.

The safety of the use of FittingLINK when connected to external equipment with USB cable, is determined by the external signal source. When connected to external equipment plugged into a wall outlet, this equipment must comply with IEC 62368-1 or equivalent safety standards.

⚠ Warnings

Heat and chemicals
FittingLINK must never be exposed to extreme heat e.g. left inside a parked car in the sun. FittingLINK must not be dried in microwave ovens or other ovens. The chemicals in cosmetics, hairspray, perfume, aftershave lotion, suntan lotion and insect repellent can damage FittingLINK. Always remove FittingLINK before applying such products and allow time to dry before use.

Choking hazards
FittingLINK should be kept out of the reach of children and anyone else who might swallow parts or otherwise cause injury to themselves.

If a part is swallowed, see a doctor immediately.

Interference
FittingLINK has been thoroughly tested for interference according to the most stringent international standards. However, interference between FittingLINK and other devices (e.g. some mobile telephones, citizens band devices, and other wireless devices) may occur. If this occurs, increase the distance between FittingLINK and the interfering device.

Active Implants
FittingLINK has been thoroughly tested and characterised for human health according to international standards for human exposure (Specific Absorption Ratio - SAR), induced electromagnetic power and voltages into the human body. The exposure values are well below international accepted safety limits for SAR, induced electromagnetic power and voltages into the human body defined in the standards for human health and coexistence with active medical implants, such as pacemakers and heart defibrillators.

If your client has an active brain implant, please contact the manufacturer of your implantable device for information about the risk of disturbance. Immediately remove FittingLINK if interference is suspected and seek medical advice.

Interference can also be caused by power line disturbances, electromagnetic fields from other devices, radio signals and electrostatic discharges.

Please note that other active FittingLINK devices and wireless hearing aid accessories in proximity may create interference and should be turned off.

⚠ Warnings

Use of the neck loop
The neck loop is an antenna for the magnetic induction link to the hearing aids.

If the neck loop should accidentally get caught on something while the client is wearing it, the neck loop is constructed to release automatically. Therefore, never try to shorten or modify the neck loop in an unauthorised way.

Always use the provided clip to shorten the length of the neck loop.
If the neck loop breaks, it cannot be repaired and must be replaced immediately. Consult your local supplier for replacement.

Please refer to "How to use FittingLINK on children".

Rechargeable battery
Do not attempt to open FittingLINK, as it may damage the battery.

Never attempt to replace the battery. If battery replacement is needed, please return your device to the supplier. The service guarantee is void if there are signs of tampering.

The safety of recharging batteries using a USB connector is determined by the external signal source. When connected to external equipment plugged into a wall outlet, this equipment must comply with IEC 62368-1 or equivalent safety standards.

Charging
To prevent potential battery damage during storage please charge FittingLINK every 6 months.

Use of third party accessories
Only use accessories, transducers or cables supplied by the manufacturer. Incompatible accessories may result in reduced electromagnetic compatibility (EMC) of your device.

Possible side effects.
The otherwise non-allergenic materials used in your FittingLINK may in rare cases cause a skin irritation or other side effects. Please, seek consultation with a physician if these conditions occurs.

Conditions of use

Operating conditions	Temperature: +5°C to +40°C Humidity: 15% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Transportation and storage conditions	Temperature and humidity shall not exceed the below limits for extended periods during transportation and storage: Temperature: -25°C to +70°C Humidity: 15% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

Technical information FittingLINK

The device contains a radio transceiver using short-range magnetic induction technology, working at 3.84 MHz and a Bluetooth radio operating at 2.4 GHz.

The magnetic field strength of the transmitter is very weak and always below 15 nW (typically below -15 dBμA/m at 10 meter distance (-4.6 dBμA/ft) at 10 meter (33 feet) distance).

The device complies with international standards concerning radio transmitters, electromagnetic compatibility and human exposure.

Due to the limited space available on the device relevant approval markings can be found in this booklet.

Additional information can be found in the Product information document.

For body-worn operation, this device meets FCC and IC RF exposure limits and has been tested while in contact with the human body.

The transmitter must not be co-located or used in conjunction with any other antenna or transmitter.

USA and Canada

This device is certified under:

FCC ID: 2ACAHWLP021
IC: 11936A-WLP021

Notice:

The device complies with Part 15 of the FCC Rules and with Industry Canada's licence-exempt RSSs standards.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Technical information Bluetooth adapter

The Bluetooth adapter contains a radio transceiver using Bluetooth Low Energy and Bluetooth at 2.4 GHz. The radio transmitter is weak and always below 10mW equal to 10 dBm in total radiated power.

USA and Canada

This device contains a radio module with the following certification ID numbers:

FCC ID: DMOCBBSKE
IC: 2099D-BTD800

Notice:

The device complies with Part 15 of the FCC Rules and with Industry Canada's licence-exempt RSSs standards.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

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

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

Notice: 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 the receiver.
• Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
• Consult your manufacturer for help.

Radiofrequency Radiation Exposure Information
This equipment complies with FCC and IC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of 20 cm between the radiator and your body.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

Technical information

FittingLINK model	WP-2
Bluetooth adapter model	BTD 800 USB
Bluetooth adapter version	WP-3
Bluetooth adapter GTIN number	05714464006717

International warranty

Your device is covered by an international limited warranty issued by the manufacturer for a period of 12 months from the date of delivery. This limited warranty covers manufacturing and material defects in the device itself, but not in accessories such as e.g. batteries, cables, power supplies, etc. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorised party, exposure to corrosive conditions, damage due to foreign objects entering the device or incorrect adjustments are NOT covered by the limited warranty and may void it. The above warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods.

If you need service
Please contact your supplier's support function, who may be able to assist in sorting out minor problems and adjustments immediately.

The manufacturer declares that FittingLINK (WP-2 and BTD 800 USB) is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. Declarations of Conformity are available from the manufacturer. This medical device complies with Medical Device Regulation (EU) 2017/745.

SBO Hearing A/S
Kongebakken 9
DK-2765 Smørum

Waste from electronic equipment must be handled according to local regulations.

Complies with
IMDA Standards
DA103820

Bluetooth®

Description of symbols and abbreviation used in this booklet	
⚠	**Warnings** Text marked with a marking symbol must be read before using the product.
🏭	**Manufacturer** The product is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Regulations 2017/745 and 2017/746.
CE	**CE mark** The device complies with all required EU regulations and directives.
🗑	**Electronic waste (WEEE)** Recycle your hearing aids, accessories or batteries according to local regulations. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).
◈	**Regulatory Compliance Mark (RCM)** The product complies with electrical safety, EMC and radio spectrum requirements for products supplied to the Australian or New Zealand market.
❀ Bluetooth®	**Bluetooth logo** Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.
GTIN	**Global Trade Item Number** A globally unique 14-digit number used to identify medical device products including medical device software. GTIN in this booklet is related to medical device firmware. GTIN on regulatory packaging label is related to medical device hardware.

Description of additional symbols used on labels	
🌂	**Keep dry** Indicates a medical device that needs to be protected from moisture.
⚠	**Caution symbol** Consult instructions for use for warnings and cautions.
REF	**Catalogue number** Indicates the manufacturer's catalogue number so that the medical device can be identified.
SN	**Serial number** Indicates the manufacturer's serial number so that a specific medical device can be identified.
MD	**Medical Device** The device is a medical device.
♻ Li-ion	**Battery recycling symbol** Li-Ion Battery recycling symbol.
5.0V ⎓ 200mA	**Power supply outlet** Indicates the rate at which power is sent from the outlet to your electrical device.
⊜ ℝ	**Japan TELEC symbol** Indicates mark for certified radio equipment.
Complies with IMDA Standards DA103820	**Singapore IMDA label** Indicates that the device complies with the standards and specification published by Info-Communications Media Development Authority (IMDA) and is compatible with the public telecommunication networks in Singapore and does not cause radio frequency interference to other authorized radio-communication networks.