

Bone Anchored Hearing System

Oticon Medical Streamer Instructions for Use



oticon
MEDICAL

Introduction to this booklet

This booklet gives you guidance on how to use and maintain your Oticon Medical Streamer, hereafter referred to as Streamer. Please read the booklet carefully, including the Warning section. This will help you to obtain the full benefit from your Streamer.

If you have additional questions about the use of your Streamer, please contact your hearing care professional.

Intended use

Intended use	<p>Streamer is intended to be used by Oticon Medical sound processor users. The product is intended to be used together with the given hearing solution. Streamer is a communication interface between the sound processor and other devices such as mobile phones. Streamer can be connected to a range of external (additional) devices to enable the sound processor user to better hear a TV or to communicate through Bluetooth-enabled mobile phones, etc.</p> <p>Streamer can also be used as a remote control that enables you to adjust the sound processor volume and change programs in the sound processor.</p>
Indications for use	No indications for use.
Intended user	Adults and children older than 36 months.
User environment	Indoor/Outdoor.
Contraindications	Users of active implants must pay special attention when using the device. For more information, read the Warning section.
Clinical benefits	See clinical benefits of the sound processor.

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Package content

The package consists of the following elements:



Streamer



Neck loop – medium



Neck loop – long

This booklet (Instructions for Use)



Box 1



Charger

Power supply will vary from country to country.

Box 2

USB charger
cable



3.5 mm mini
jack stereo
cable for MP3 or
music

3.5 mm headset
splitter cable for
use with PCs



Box 3



Protective skin

Accessories and spare parts

Protective skins

Additional protective skins, dark or light grey, are available from your hearing care professional.



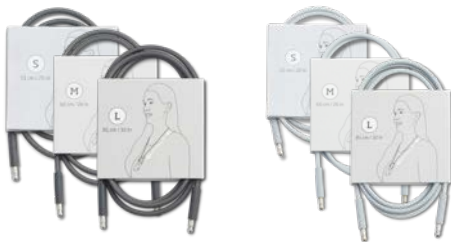
Protective skins – single button

Protective skins, dark or light grey, with one protruding button, which makes “blind” operation easier, are available from your hearing care professional.



Replacement neck loops

Replacement neck loops, black or white, are available in three sizes: short (51 cm), medium (66 cm) and long (81 cm), from your hearing care professional.



Belt clip

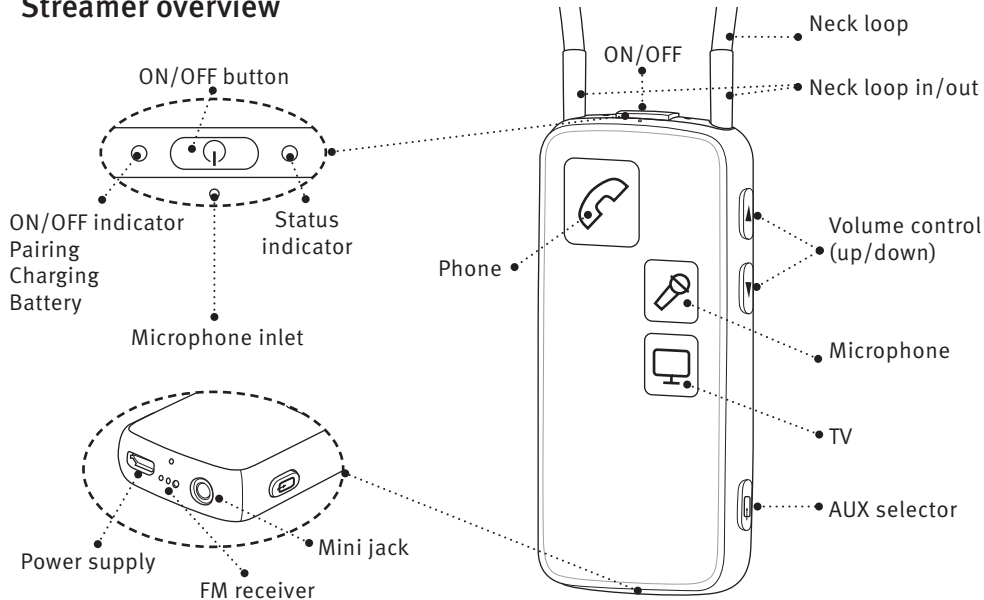
A belt clip, black or white, is available from your hearing care professional.



IMPORTANT NOTICE

Please refer to your sound processor Instructions for Use for details on the functionality of your specific sound processor solution.

Streamer overview



Use the Streamer with the neck loop

The neck loop is an integral part of the Streamer's electronic system. It is used as an antenna to transmit sound to your sound processor.

For the best possible sound and longest possible streaming time, the Streamer should always be worn with one of the included neck loops. The Streamer comes with two neck loops, a long and a medium.

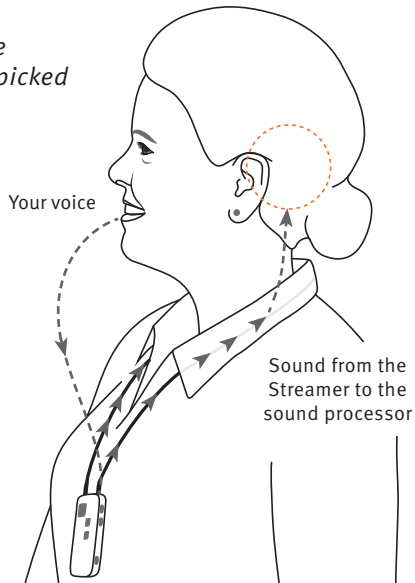
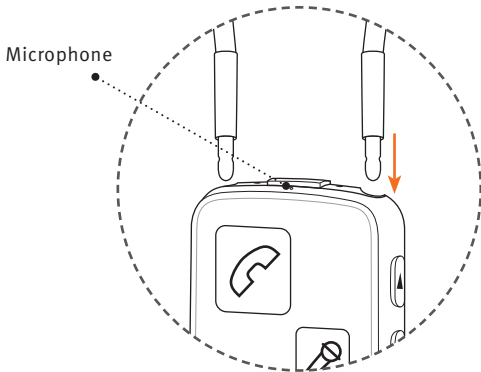
IMPORTANT NOTICE

Please use the neck loop carefully. To avoid strangulation the neck loop will automatically release if it gets caught in something. Do not shorten or modify the neck loop in any way, such as by tying a knot to shorten the length. If a neck loop breaks, it cannot be repaired and must be replaced immediately. Consult your hearing care professional for a replacement.

Insert the neck loop

The neck loop snaps into the holes on the top of the Streamer.

Note that when talking to somebody through the Streamer, it is important that your voice can be picked up by the built-in microphone on the top.



Use the Streamer without the neck loop

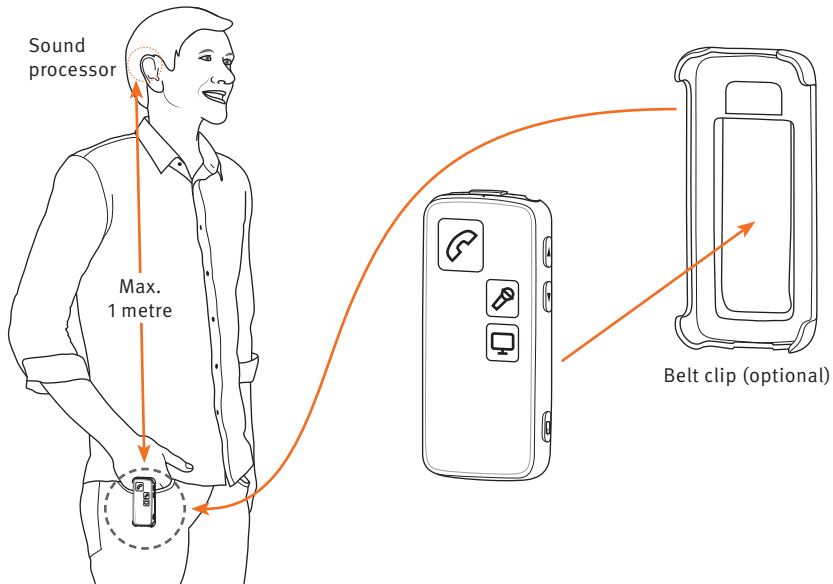
When using the Streamer without the neck loop, the distance to the sound processor should be less than one metre. You may experience drop-outs in sound, which is why we always recommend using the neck loop.

If you use the Streamer without the neck loop, it should be linked to get access to all Streamer functions. Your hearing care professional can link your Streamer.

When using the Streamer without the neck loop, more power will be used – consequently maximum streaming time is reduced to 5 hours on one full charge.

Functionality	Works in an open Streamer	Works in a linked Streamer
As a remote control	No	Yes
Hear the ring from an incoming call	Yes	Yes
Streaming of sound from e.g. TV or phone calls	No	Yes

If the Streamer is used with the neck loop, all functionalities are activated no matter whether the Streamer is open or linked.



IMPORTANT NOTICE

A defective neck loop should be replaced immediately.

Turn the Streamer ON and OFF

Power on

Press the ON/OFF button on the top of the Streamer for 2 seconds until all lights on the front and top flash to indicate it is powered on.

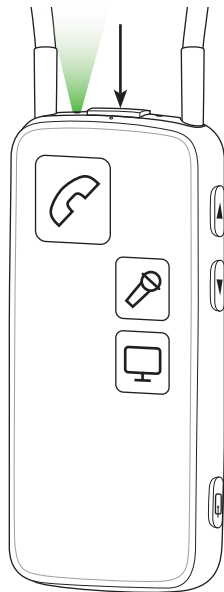
Release the ON/OFF button. The power indicator on the top of the Streamer should now fade to green.







If the Streamer does not turn on, make sure it is charged.

To see the status of the Streamer, press the ON/OFF button briefly.

Power off

Press and hold the ON/OFF button on the top of the Streamer for 2 seconds until the green power indicator is turned off.



Status	Front	Description
		<p>The Streamer is off.</p>
		<p>After pressing the ON/OFF button for 2 seconds, all lights will be on for a few seconds to indicate that the Streamer is now turned on.</p>
		<p>The Streamer is now turned on and ready for use.</p>

Remote control of the sound processor

Volume up/down

Briefly pressing on either volume up or down will regulate the volume in the sound processor accordingly. You will hear small confirmation “ticks” in the sound processor.

Changing programs in the sound processor

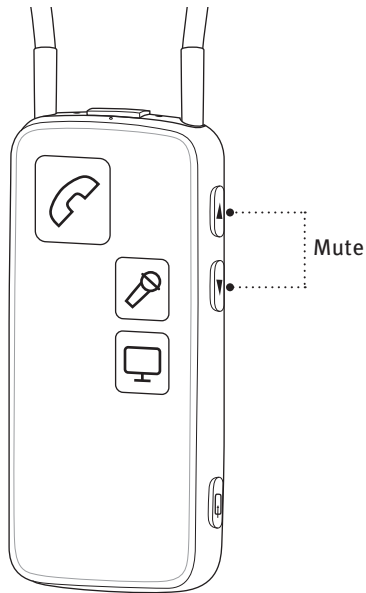
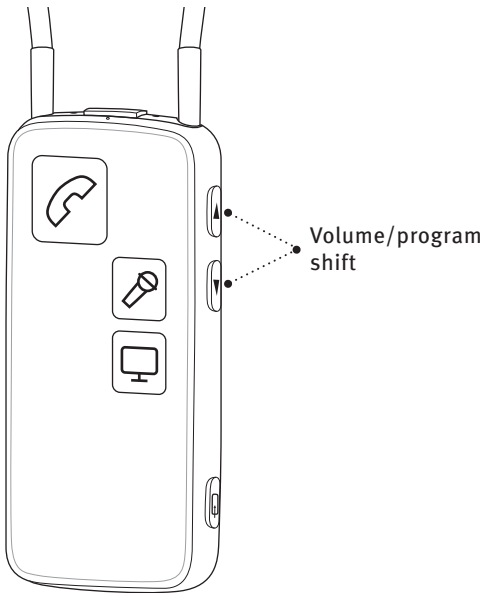
You can change programs up or down by holding the volume up or down for more than one second. Changing programmes is indicated by a sound in your sound processor.

Muting the sound processor

You can mute the sound processor by pressing the volume up AND down for 1 second simultaneously.

IMPORTANT NOTICE

Even if the Streamer is turned off, the remote functionality of the sound processor will still work.

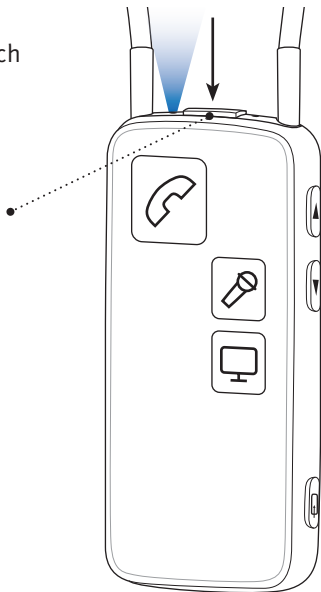


Pair the Streamer

Before the Streamer can be used with other devices – such as mobile phones – the two devices have to be paired.

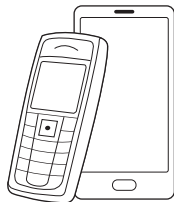
1. Set the Streamer in pairing mode.

Press and hold the ON/OFF button for about 5 seconds, until the indicator blinks blue.



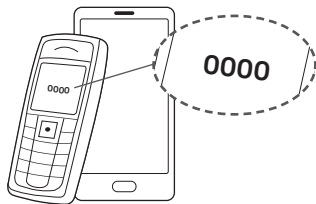
2. Set the other device (e.g. mobile) in pairing mode.

This is typically in a set-up menu on your phone.
We advise you to look in your mobile phone's
"Instructions for Use", e.g. under pairing.

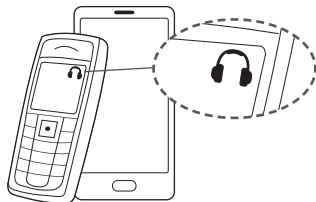


3. The other device (mobile phone) will often request a pin code.

The pin code for the Streamer is 0 0 0 0
(four zeros).



4. Once paired, the mobile phone will typically show a headset icon; at the same time the Streamer pairing indicator will be steady blue.



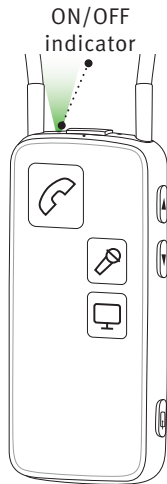
Charge the Streamer

The Streamer uses a rechargeable battery. We recommend that you charge the Streamer once a day for best possible performance.

Insert cable from the enclosed charger into the micro USB socket at the bottom of the Streamer **(A)**. Remember to connect the charger to a power outlet.

Charging, when turned on, is indicated by a blinking green indicator on the top. Once fully charged, the indicator will show steady green.



Charging, when turned off, is indicated by a blinking green indicator on the top. Once fully charged, the indicator will be off.



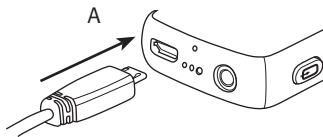
IMPORTANT NOTICE

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



Status	Front	Description
		Charging – when turned off – status indicator will blink green.
		Charging – when turned on (or in use) – the status indicator will shift between strong and soft green.

 Blink  Fade

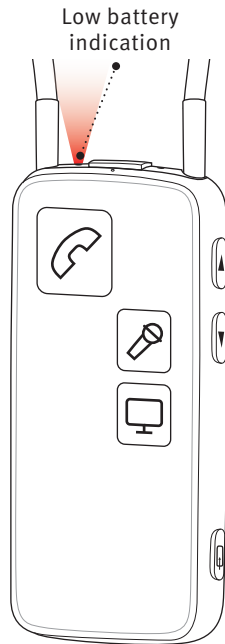




IMPORTANT NOTICE

When charging, the charging indicator should be lit as described in this booklet. If the charging indicator is not lit as described, disconnect the device from the charger and consult your hearing care professional.

Low battery indication

The Streamer will indicate low battery (about 20 minutes capacity left) with a steady red light, and very low battery (about 5 minutes capacity left) with a blinking red light.



Status	Front	Description
		Low battery– 20 minutes capacity left when streaming to sound processor.
		Very low battery – 5 minutes capacity left when streaming to sound processor.

 Steady  Fading

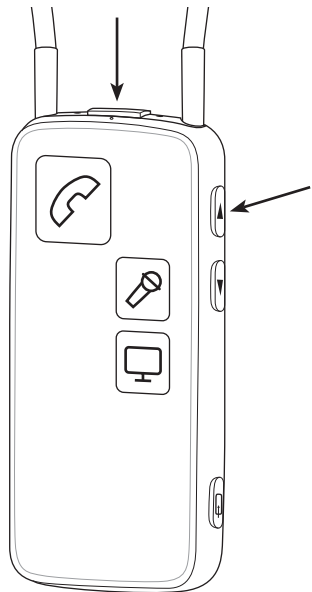
IMPORTANT NOTICE




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.

Battery capacity and charging time	
Battery capacity using neck loop	Up to 10 hours typical daily use: 2 hours phone, 6 hours TV and 2 hours standby.
Battery capacity not using neck loop	Up to 5 hours typical use: 1 hour phone, 3 hours TV and 1 hour standby.
Battery charge time	2 hours for complete charge, using enclosed power supply.
Remote control	If the Streamer is turned off, remote control of sound processor will work for up to 6 months on one full charge.
Battery life expectancy	The Streamer battery will last for more than 2 years if fully charged once a day.

Clear pairing

If you have problems with pairings, you can clear all pairings by pressing the ON/OFF button and the volume up button at the same time for 3 seconds.



Status	Front	Description
		Streamer in pairing mode.
		Pairing complete.
		Streamer on.

 Steady  Blinking

Static electricity

If the Streamer is exposed to electrostatic discharge, i.e. static electricity, it may stop streaming. The Streamer will by default restart and you can re-activate your streaming.

For detailed information on how to establish specific streaming connections, please refer to “Functions” in this Instructions for Use.

Cleaning and maintenance

The Streamer is a sealed device that requires minimum maintenance. Any dirt, moisture or grease should be cleaned off using a soft, dry cloth. It is recommended that you clean the Streamer on a regular basis. The microphone inlet and the connectors for audio input, neck loop and charging must be kept free of dirt or debris.

IMPORTANT NOTICE

Use a soft, dry cloth to clean the Streamer. The Streamer and the neck loop must never be washed or immersed in water or other liquids.

Primary functions

The Streamer user interface has been designed to give you the best possible daily use in the following situations:

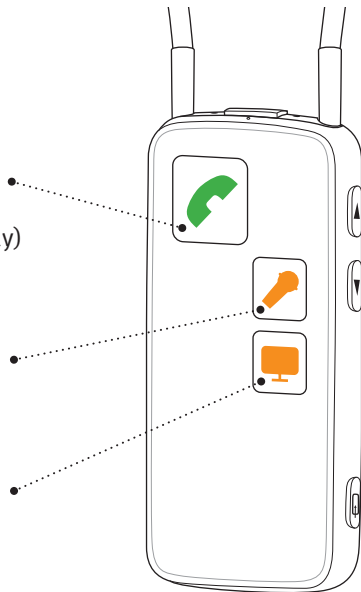
1. Use of a mobile phone through Bluetooth*.

Use of the ConnectLine phone solution (sold separately) with an analogue landline phone*.

2. Use of a ConnectLine partner microphone (sold separately), to improve your chances of hearing a chosen speaker at a distance, or in very noisy situations.

3. Use of ConnectLine TV solution (sold separately) to wirelessly transmit the TV sound to your sound processor*.

* In effect turning the Streamer and the sound processor into a wireless headset

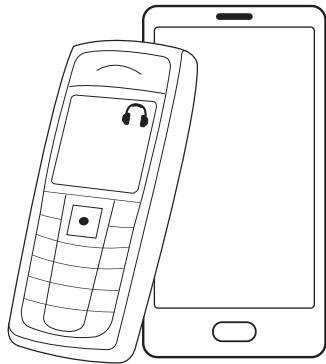


Mobile phone

To be able to receive or make calls while using the Streamer, make sure that the Streamer and mobile phone have been paired, are turned on and are within range (10 metres). Your mobile phone will often indicate that it is connected to the Streamer with a small headset icon.

For more information, please refer to:

www.oticonmedical.com/bone-conduction/solutions/accessories/streamer/connectline-app



How to answer a call

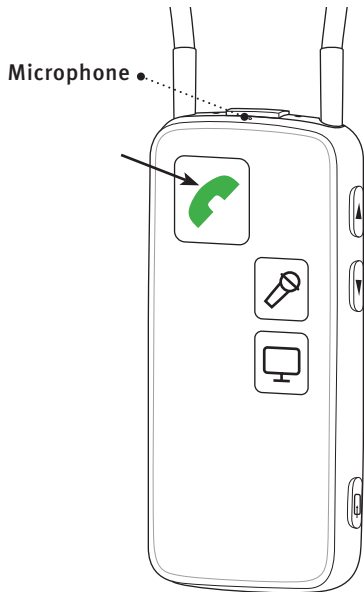
Make sure that you are able to speak into the Streamer's microphone.












When your mobile phone rings, you will hear an incoming call alert in your sound processor. At the same time the phone button on the Streamer and the status indicator will blink green.

Press the phone button on the Streamer briefly to answer the call. You will hear a small confirmation beep in your sound processor.

The phone button and status indicator will now be steady green.

To end the call, simply press the phone button on the Streamer briefly.



Status	Front	Description
  		Streamer on and ready.
  		Phone indicator and top status blinks green. You will hear an incoming call indicator in your sound processor.
  		When the call is connected, you will hear a beep acknowledging that the call is answered – you are now able to listen and talk to the other party.

 Steady  Blinking

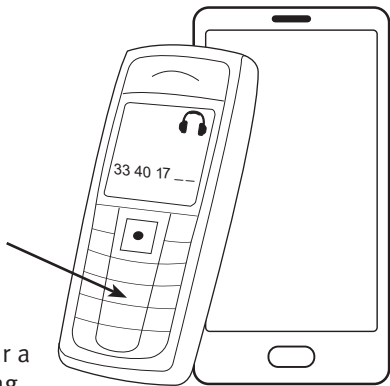
How to make a call




Make sure that you are able to speak into the Streamer's microphone.

To make a call, you only need to operate the mobile phone. You do not need to operate the Streamer. Simply dial the number as you normally do to make a call – the call is automatically connected to your Streamer.

The phone button on the Streamer and the status indicator on the top will turn green, and you will hear a confirmation beep in your sound processor indicating that the call is now connected through your Streamer and sound processor.

To end the call, simply press the “call end” button on the phone or the phone button on the Streamer briefly.



Status	Front	Description
		Streamer on and ready.
		When the call is connected, you will hear a beep acknowledging that the call is connected – you are now able to listen and talk to the other party.

 Steady
  Blinking

Personalisation of mobile phone features

The following mobile phone features can be enabled, or disabled, by your hearing care professional.

Reject call – default on

An incoming call can be rejected by briefly pressing the volume down button on the Streamer.

Voice dial – default on

Briefly pressing the phone button will enable voice dial (if supported by your mobile phone and you are not in range of a ConnectLine phone adapter).

Last number redial – default on

Pressing and holding the phone button will activate the last number redial (if supported by mobile phone).

Transfer call – default on

Pressing and holding the phone button will transfer a call back to the mobile phone.

All front buttons answer call – default on

If off, only the phone button on the Streamer will answer calls.

Enable incoming (A2DP) connections – default off

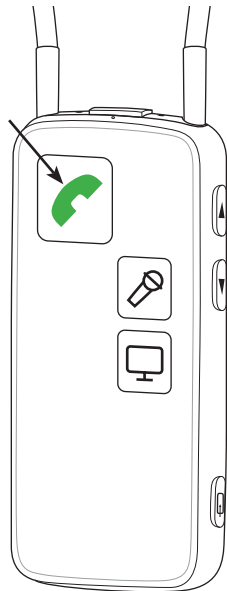
If enabled, other devices, e.g. iPods, computers and mobile phones can activate audio streaming, for example, incoming text alerts or music started from a paired and connected mobile phone.




ConnectLine phone solution

The Streamer can also be used with a traditional analogue landline phone by using a ConnectLine phone solution, which is available as a separate accessory.

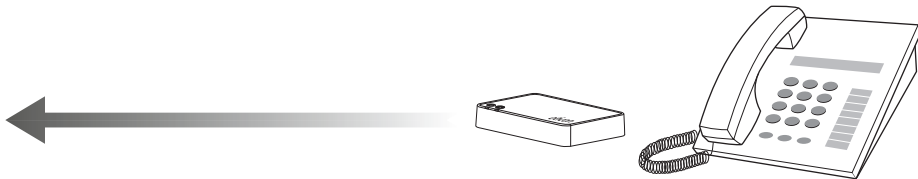
For details on how to use the ConnectLine phone solution, please refer to the Instructions for Use included with the ConnectLine phone solution or visit:

www.oticonmedical.com/connectlineapp



Status	Front	Description
		Streamer on and ready.
		Streamer connected – you are able to listen and talk to the other party.

 Steady

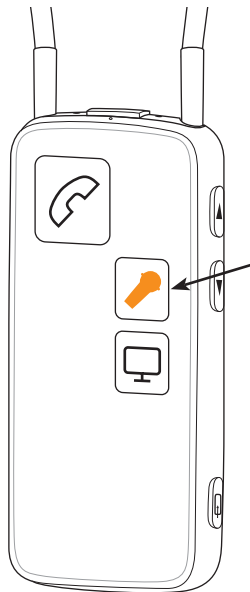





ConnectLine microphone

As a separate accessory, a ConnectLine microphone is available. Speech from the person wearing the microphone is transferred through the Streamer to the person wearing Oticon Medical sound processors.

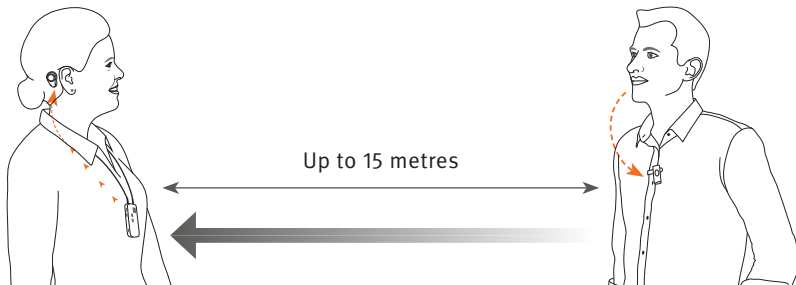
For details on how to use the ConnectLine microphone solution, please refer to the Instructions for Use included with the ConnectLine microphone solution or visit:

www.oticonmedical.com/connectlineapp



Status	Front	Description
		Streamer on and ready.
		When connected to the microphone – you will hear sound from the microphone in the sound processor.

  Steady

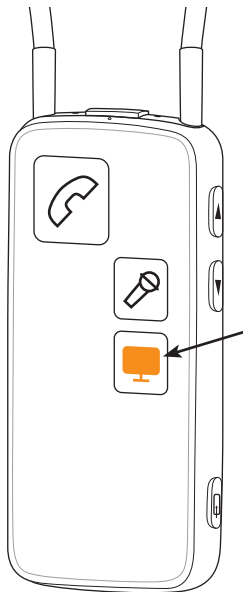







ConnectLine TV solution

As a separate accessory, a ConnectLine TV solution is available, which transmits the sound from a TV to your Oticon Medical sound processor through the Streamer.

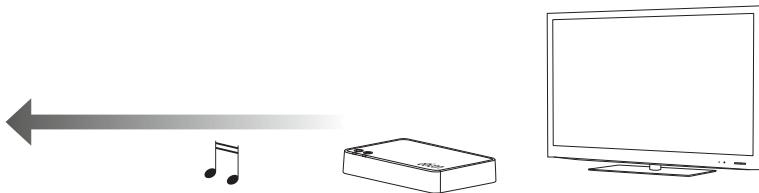
For details on how to use the ConnectLine TV solution, please refer to the Instructions for Use included with the ConnectLine TV solution or visit:

www.oticonmedical.com/connectlineapp



Status	Front	
		Streamer on and ready.
		Connecting to TV.
		Streamer connected – sound from TV in sound processor.

  Steady   Blinking



ConnectLine App

The app for iPhone®, iPad®, iPod touch® and Android™ devices offers an intuitive and discreet way to control the sound processor and the ConnectLine system. Also, it offers the possibility to customise the features of the ConnectLine system.

Available on App Store® and on Google Play™.



For information on compatibility, please visit:
www.oticonmedical.com/connectlineapp



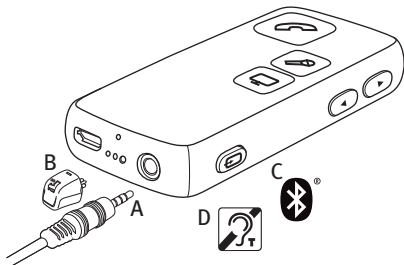
Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Apple, the Apple logo, iPhone, iPad, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc. Android, Google Play, and the Google Play logo are trademarks of Google LLC. Please note that use of this Accessory with iPod, iPhone, or iPad may affect wireless performance.

Secondary functions

The Streamer can be used with a wide range of standard peripherals, such as MP3 players, computers, etc.

The following priorities apply.

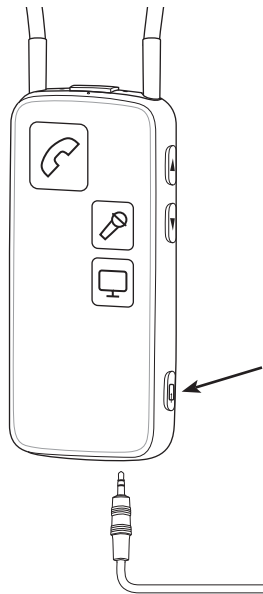




A	Priority 1	Mini jack in/out (if connected)	Briefly press AUX selector
B	Priority 2	FM (if connected)	Briefly press AUX selector
C	Priority 3	Wireless Bluetooth (built-in)	Briefly press AUX selector
D	Priority 4	Tele loop receiver (built-in)	Press and hold AUX selector for 2 seconds

Music or audio cable

Inserting and connecting the included mini jack cable enables you to listen to music/audio from a wide range of devices.

To listen to audio from your device, press the AUX selector briefly. When the cable is inserted, streaming will start automatically.



Status	Front	Description
		Streamer on and ready.
		You will hear a confirmation beep followed by the sound from the device.

  Steady

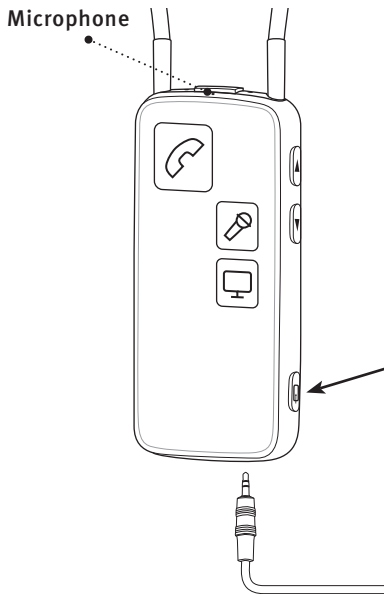




Headset cable

Make sure that you are able to speak into the Streamer's microphone.

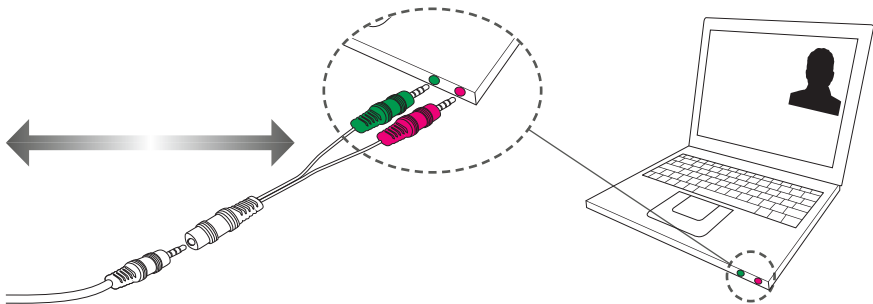
Inserting and connecting the included mini jack cable and the included headset splitter cable enables you to use the Streamer as a headset with your computer.

To use the headset function, simply press the AUX selector briefly.



Status	Front	Description
		Streamer on and ready.
		You will hear a confirmation beep – you are now able to listen and talk to the other party.

  Steady



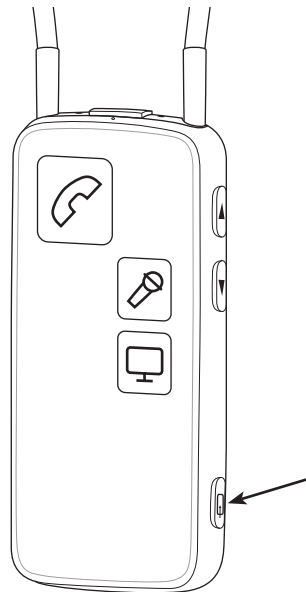
Music or audio wireless




To hear music or sound wirelessly, e.g. from an MP3 player or a computer with built-in Bluetooth, make sure that the device has been paired to your Streamer, that both are turned on, and within range (<10 metres).




To listen to music, e.g. from a mobile phone, press the AUX selector before starting the music player.

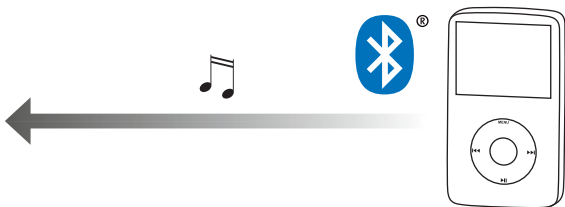
Enable automatic connections – default off

If enabled by your hearing care professional, iPods, computers and mobile phones can automatically activate audio streaming. For example, incoming text alerts or music started from a paired and connected mobile phone.



Status	Front	Description
		Streamer on and ready.
		Streamer connecting to music or audio device.
		When connected, you will hear a confirmation beep followed by the sound from the device.

  Steady  Blink






Headset – wireless




Make sure you are able to speak into the Streamer's microphone inlet.

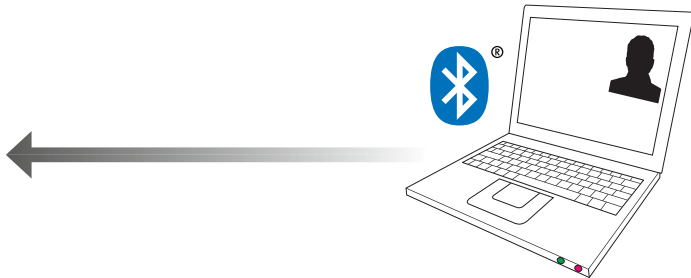
When pairing to a computer, make sure the Streamer is paired as a headset device.

To use the headset function, call control is done from the computer.



Status	Front	Description
		Streamer on and ready.
		Streamer connecting to music or audio device.
		When connected, you will hear a confirmation beep followed by the sound from the device.

  Steady  Blink

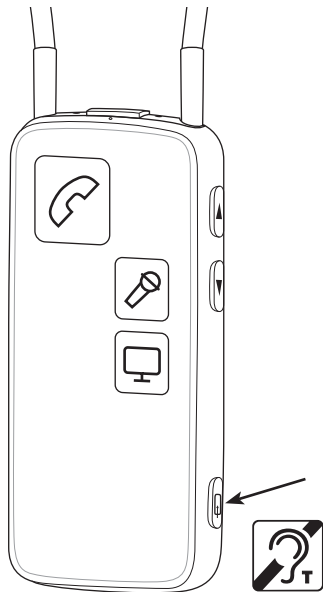




T-coil (built-in)

The Streamer has a built-in teleloop receiver (T-coil).

To receive sound from the teleloop receiver, press and hold the AUX selector for 2 seconds.

Please note: if desired, the operation can be changed so the T-coil can be activated by a brief press.



Status	Front	Description
		Streamer on and ready.
		When connected, you will hear a confirmation beep followed by the sound from the teleloop system.

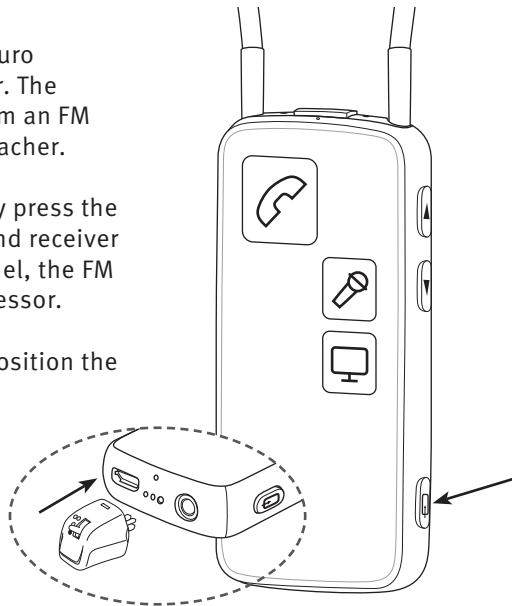
  Steady



FM receiver (optional)

An FM receiver can be plugged into the Euro pin socket, at the bottom of the Streamer. The receiver is used to receive FM signals from an FM transmitter, typically worn by a school teacher.

Simply plug in the FM receiver and briefly press the AUX selector. When the FM transmitter and receiver are synchronised and on the same channel, the FM signal will be received in the sound processor.

If your FM receiver has a toggle switch, position the switch onto the OO position.



Status	Front	Description
		Streamer on and ready. FM receiver powered on and ready for channel synchronisation.
		When connected, you will hear a confirmation beep followed by the sound from the device.

  Steady

IMPORTANT NOTICE

Please ensure the Streamer is turned on, but not streaming sound to the sound processor, when FM channel sync is required.

Warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your Streamer. Consult your hearing care professional if you experience unexpected operations or serious incidents with your Streamer during use or because of its use. Your hearing care professional will support you with issue handling and, if relevant, reporting to the manufacturer and/or the national authorities.

Connection to external equipment

The safety when using the Streamer, while it is connected to external equipment with an auxiliary input cable or with a USB cable directly, 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.

Rechargeable battery

Do not attempt to open the Streamer, 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 power source. When connected to external equipment plugged into a wall outlet, this equipment must comply with IEC 62368-1 or equivalent safety standards.

Choking hazards and risk of swallowing batteries or other small parts

The Streamer, its parts and batteries should be kept out of reach of children and anyone who might swallow these items or otherwise cause injury to themselves.

If a battery, sound processor or small part is swallowed, see a doctor immediately.

Cross control

Your Streamer should be kept out of the reach of children or anyone who might take control of the functionality, to ensure your personal safety and avoid incorrect use.

Use of the Streamer with neck loop

If by accident the neck loop is caught on something while wearing it, the neck loop is constructed to break automatically. Therefore, never try to shorten or modify the neck loop in an unauthorised way. The neck loop should not be used for children who weigh less than 11 kg.

Heat and chemicals

The Streamer must never be exposed to extreme heat e.g. left inside a parked car in the sun. The Streamer 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 the Streamer. Always remove your Streamer before applying such products and allow time to dry before use.

X-ray/CT/MR/PET scanning, electrotherapy and surgery

Remove your Streamer before X-ray/CT/MR/PET scannings, electrotherapy, surgery, etc. as your Streamer may be damaged when exposed to strong electromagnetic fields.

Active implants

Streamer 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.

Warnings

Possible side effects

The otherwise non-allergenic materials used in your Streamer may in rare cases cause a skin irritation or other side effects.

Please seek consultation with a physician if these conditions occur.

Use in traffic

Using the Streamer can distract you. Be aware of your surroundings while using the Streamer.

Please refer to national traffic laws regarding the use of communication devices while in traffic.

Use on aircraft

Your Streamer contains Bluetooth. Your Streamer should not be used on board an aircraft, unless specifically permitted by the flight personnel.

Explosives

The Streamer is safe to use under normal usage conditions. The Streamer has not been tested for compliance with international standards concerning explosive environments.

Therefore, do not use the Streamer in environments with danger of explosions e.g. mines, oxygen rich environments or areas where flammable anaesthetics are handled.

Interference

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

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.

Charging

To prevent potential battery damage during storage please charge the Streamer every 6 months.

Mobile phone compatibility

Please refer to www.oticon.global/compatibility for a list of mobile phones that have been tested comprehensively by Oticon, and have been found to fulfil the minimum requirements for ConnectLine compatibility at the time of testing. However, Oticon takes no responsibility for such compatibility in general. Specifically, Oticon shall not be responsible for incompatibility resulting from future updates of the mobile phones, nor from events of incompatibility not covered by and/or found in these tests. Oticon takes no financial responsibility in terms of reimbursements of mobile phones that do not work as expected. Before purchasing a new mobile phone, you are advised to consult the list mentioned above.

Conditions of use

Operational environment conditions	Temperature: +10°C to 45°C Humidity: <85% 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: -20°C to +60°C Humidity: <85% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

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 to you. 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. Under this warranty, the manufacturer will choose, at its sole discretion, whether to repair the device, or replace it with an equivalent model. The above warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods. Your hearing care professional may have issued a warranty that goes beyond

the clauses of this limited warranty. Please consult your hearing care professional for further information.

If you need service

Take your Streamer to your hearing care professional, who may be able to sort out minor problems and adjustments immediately. Your hearing care professional can assist you to obtain warranty service from the manufacturer. Your hearing care professional may charge a fee for their services.

Warranty

Certificate

Name of owner: _____

Hearing care professional: _____

Hearing care professional's address: _____

Hearing care professional's phone: _____

Purchase date: _____

Warranty period: _____ Month: _____

Serial no.: _____

Technical information

Model	GTIN
Oticon Medical Streamer, black	5707131293978
Oticon Medical Streamer, white	5707131293985
Oticon Medical Streamer Demo, black	5707131293961

The Streamer contains a radio transceiver using short range magnetic induction technology working at 3.84 MHz. The magnetic field strength of the transmitter is very weak and always below 15 nW (typically below -15 dBuA/m at 10 metre distance).

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

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

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

Additional information can be found in the Technical Data Sheets (TD) on www.oticon.global

USA and Canada

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

FCC ID: U28CL2STRM

IC: 1350B-CL2STRM

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, and
2. this device must accept any interference received, including interference that may cause undesired operation.

Note

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

The manufacturer declares that this device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

This medical device complies with Medical Device Regulation (EU) 2017/745.

Declaration of conformity is available at the manufacturer.



Oticon A/S
Kongebakken 9
DK-2765 Smørum
Denmark
www.oticon.global



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



Complies with
IMDA Standards
DA103820

Description of symbols and abbreviations used in this booklet



Warnings

Text marked with a warning symbol must be read before using the device.



Manufacturer

The device 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 mark

The device complies with all required EU regulations and directives.



Electronic waste (WEEE)

Recycle sound processor, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).



Regulatory Compliance Mark (RCM)

The device complies with electrical safety, EMC and radio spectrum requirements for devices supplied to the Australian or New Zealand market.



Indoor use

For indoor use only.



Double insulation

The power supply is double insulated. This means a very low risk of single fault failures.



Made for Apple badges

The device is compatible with iPhone, iPad and iPod touch.

Description of symbols and abbreviations used in this booklet



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.

Complies with
IMDA Standards
DA103820

Singapore IMDA label

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 authorised radio-communication networks.

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.
	Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Battery recycling symbol Li-Ion Battery recycling symbol.
	Power supply inlet Indicates the rate at which power is sent from the power supply to your device.
	Medical device The device is a medical device.
	Japan TELEC label Mark for certified radio equipment.
	South Africa ICASA label The device is licensed to be sold in South Africa.



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