

SERVOX[®] digital XL



Servona Factory Authorized
Sales and Service

BRUCE
MEDICAL SUPPLY

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Foreword

Dear customer,

We would like to thank you for your trust and the purchase of our quality product.

The speech aid SERVOX® digital XL is characterised by its high quality, exceptional safety and easy operation.

In order to be able to use SERVOX® digital XL correctly and safely, please read the instructions in this manual carefully before using your speech aid for the first time!

Keep the instructions for future reference!

Note:

This manual does not replace comprehensive speech therapy under any circumstance.

Although the SERVOX® digital XL speech aid is comparatively easy to use, please contact a speech therapist to ensure maximum vocal rehabilitation.

We will be happy to help you.

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Package Contents

The package includes:

- **SERVOX® digital XL speech aid**
- **Oral tube with adapter**
- **Screw cap "soft tone"**
- **Carrying strap with replacement strap protection**
- **Belt pouch**
- **AAA rechargeable batteries**
- **Charger (commercially available)**
- **travel adapter**
- **2 battery holders**
- **Instruction manual**

Note:

A non-expert operator or non-expert organisation should contact the manufacturer or their representative:

- **for help with first use,**
- **for use or maintenance of the device**

to prevent unexpected operation or incidents.

Note:

The speech aid SERVOX® digital XL is a one-patient product.

Intended Use

The SERVOX® digital XL speech aid offers patients, who have lost their voice due to injury, illness or surgical removal of the larynx, the opportunity to quickly regain the ability to communicate.

The SERVOX® digital XL can also be used by patients who are temporarily voiceless due to a tracheotomy, who have to protect their vocal folds due to illness or who are connected to a respirator.

Even patients who are comfortable using the oesophageal voice can use the SERVOX® digital XL in a variety of scenarios, e.g. for making phone calls, at business meetings, when they are tired, sick or very stressed, in an emergency, or in settings where speaking in a loud voice is essential.

SERVOX® digital XL may only be used for the applications listed above. The manufacturer assumes no liability for all other applications and resulting damages of any kind.

Indication

For patients after laryngectomy. Under certain conditions, the use of the electronic speech aid is also possible in other patients (e.g. ventilated patients with preserved larynx).

Contraindication

Using the device is not recommended during the acute phase of radiotherapy (in the neck area) during the follow-up treatment of patients who underwent laryngectomy. For fresh surgical wounds at the "application point" of the patient the use of the device is also not recommended.

User Group

Patients who use the SERVOX® digital XL speech aid have lost their voice due to injury, illness or surgical removal of the larynx. Patients who are temporarily voiceless due to a tracheotomy, who have to protect their vocal folds due to illness or who are connected to a respirator can also use SERVOX® digital XL to communicate during the period of vocal impairment. The speech aid can also be used by patients who are able to use their oesophageal voice to amplify it.

Patients can be of all ages from 2.5 years (min. body weight 15 kg) and belong to any demographic groups. Independent use (without support from relatives or nursing staff) is possible from the age of about 12 years. If patients are between 2.5 and approx. 12 years old, it is recommended that the speech aid be used with the help of relatives or nurses. With this in mind, the minimum age of this patient group is raised to 12 years, strongly depending on the cognitive abilities of the child and the adult.

Other users of the device are medical specialists and third parties (e.g. relatives) who support the patient in the handling of the SERVOX® digital XL.

Separate instructions in the handling of the speech aid beyond the information in this manual are not necessary, but it is recommended to practice the application under the guidance of a speech therapist.

Usage Environment

SERVOX® digital XL can be used in everyday life. In this case, the speech aid should be protected from extreme temperatures and high humidity. For detailed information, please refer to the notes under “Operating Conditions” in the section on “Technical Specifications”.

The speech aid is protected against splashing water. The protection only works if the speech aid is firmly and completely assembled. The speech aid must never be submerged in water or other liquids. The same also applies to the charger.

Keep the device free of lint and dust. Clean the device regularly as described in the “Cleaning/Disinfection” Chapter of the Maintenance Section.

The SERVOX® digital XL speech aid should be kept out of the reach of children and animals. It is not suitable for use in the areas with potentially explosive gases, for example at petrol stations and/or near anaesthesia machines. Always keep the device switched off near explosive gases.

Safety Instructions



Warning!

Risk of injury!

If the speech aid is used on a tracheostoma, restriction of breathing may occur. It can also damage the delicate tissue! Germs can enter cracks!

- Never apply the speech aid in the tracheostoma area! Always use your speech aid at the application points, see chapter “Application point”.



Caution!

Risk of infection!

If the speech aid is passed on, germs can infect other people!

- The speech aid SERVOX® digital XL is a one-patient product. Do not pass on the speech aid.



Caution!

Risk of injury!

The volume may lead to temporary, in the worst case even permanent, damage to your hearing, especially in children.

- Do not hold the speech aid directly to your ear! Always use your speech aid at the application points, see chapter “Application Point”.



Caution!

The skin can be pinched by sliding the titanium sleeve off or on.

- Never perform adjustments, maintenance or repairs while using the speech aid on the neck! Only perform adjustments, maintenance or repairs when you are not using the speech aid to speak.



Caution!

The device can become warm in continuous operation at full volume, which can lead to skin damage.

- Do not use the speech aid permanently at full volume! If your speech aid warms up while you are using it, take a break until it cools down. Use your speech aid only for speaking, according to the usage described in chapters “Intended Use” and “Application”.



Caution!

Primary batteries can explode during charging.

- Make sure that you insert rechargeable batteries, not standard batteries into the charger! Standard batteries cannot be recharged.



Caution!

The device includes small parts that could be swallowed.

The carrying strap can cause strangulation, especially in children.

- Keep the speech aid and the carrying strap out of reach of children or animals! Use your speech aid exclusively for intended use, according to the usage described in chapters “Intended Use”. Supervise children while using the speech aid. Always put down the speech aid and the carrying strap out of reach of children or animals!

Please also observe the following information in order to ensure the intended use of your speech aid throughout its service life.

Note:

- Do not drop the SERVVOX® digital XL speech aid. Otherwise, parts of the device can tear.
- Remove the rechargeable batteries from the device if you are not using the speech aid for a long time. Rechargeable batteries may leak and damage the device. If necessary, clean the device carefully. Dispose of defective rechargeable batteries appropriately.
- Do not use corroded, leaked or damaged rechargeable batteries. They can damage the speech aid and chargers, and in worst cases, they can ignite while charging.
- When inserting batteries, pay attention to the correct polarity.
- The charger is intended for use by children aged 8 years and over, as well as those with limited physical, sensory and mental capabilities, as long as the handling has been explained, and/or they are supervised and aware of the hazards involved.
- Do not let children play with the charger or the rechargeable batteries.
- Set up the charger so that it can be disconnected from the mains supply network at any time.
- Do not use a charger in humid or wet rooms. Metal parts can corrode inside.
- The speech aid and charger must never be submerged in water or other liquids. The speech aid is splash-proof (IP22), but not waterproof. Metal parts can corrode inside, and the device may potentially be damaged.
- Do not place chargers on the heater during charging or expose them to direct sunlight.
- Do not open rechargeable batteries, do not throw them into open fire, and do not short-circuit them. Do not use or store rechargeable batteries and chargers in environments with flammable materials.
- Do not dispose of rechargeable batteries in household waste. Use designated containers or collection points, as described in chapter “Disposal”.
- Use the speech aid and a charger only with approved accessories. Unauthorized accessories may affect the promised characteristics or damage the device.
- The environmental conditions specified in the chapter “Technical Specifications” must be observed. Use outside the specified environmental conditions may affect the promised characteristics or damage the device.
- Protect the speech aid and charger from extremely low or high temperatures. Use under extreme temperatures may affect the promised characteristics or damage the device.

Warranty and Product Liability

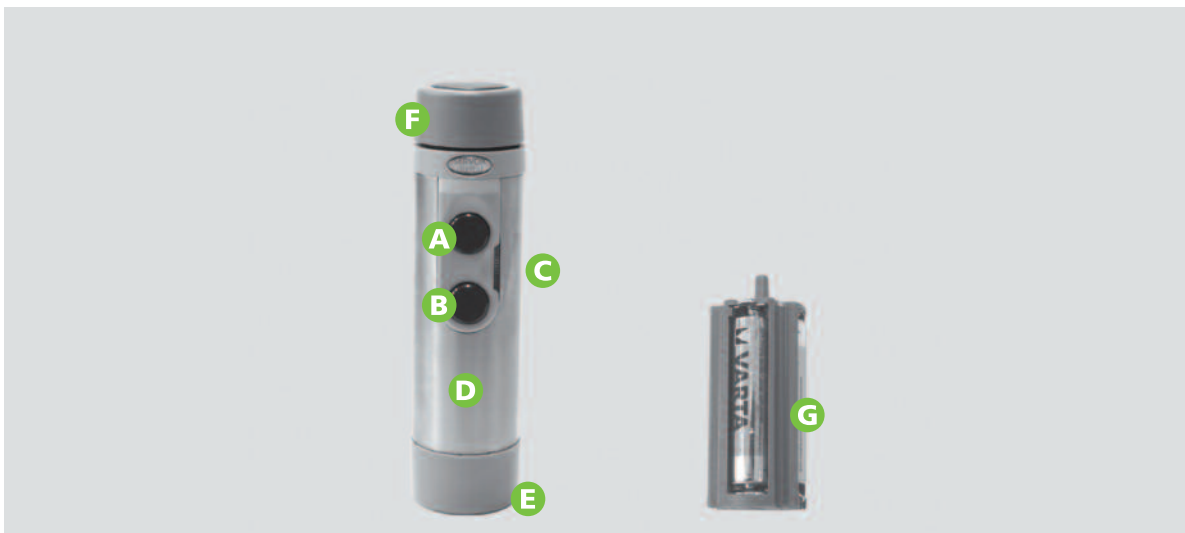
The warranty is 24 months for parts and material, 6 months for batteries. Shipping costs are the responsibility of the owner or warranty claimant. Only original spare parts and accessories may be used. Excluded are wear parts and consumables. The warranty period begins on the date of delivery.

Failure to observe these instructions, or repairs or changes to the SERVOX® digital XL speech aid and/or a charger or its components by unauthorized persons voids the warranty. In these cases, any product liability on the part of the manufacturer is excluded in advance.

The manufacturer excludes any liability for damages resulting from failure to observe the instruction manual or the safety instructions.

First use

Product overview



- A** Button A
- B** Button B
- C** Volume control / battery status display
- D** Titanium sleeve
- E** Bottom cover
- F** Screw cap with hard membrane
- G** Battery holder with 4 rechargeable batteries (AAA)

Inserting and replacing batteries

Fully charge the AAA rechargeable batteries in a charger before using them for the first time (see also general information to the charger). When inserting the batteries into a charger, observe the correct polarity (+ plus and - minus) of the battery and the charger.

⚠ Do not let children use the device unattended.

Insert the batteries into the battery holder. Also pay attention to the correct polarity here; see marking on the battery holder and the batteries.

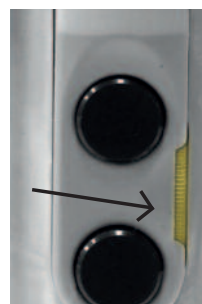


While inserting the battery holder into the speech aid, pay attention to the correct orientation of the holder. Align the side of the holder with the stylus in the direction of the casing.



Charge control

The SERVOX® digital XL ensures electronically that the volume does not decrease, but remains at the set value, even if the battery power decreases. When it becomes necessary to recharge the battery, a yellow LED flashes during use (see adjacent figure).



If the battery reaches such a low voltage that normal operation is not possible, the yellow LED lights up permanently when you press a button, but no sound is produced. The batteries must then be charged in a charger or replaced with already charged batteries.

Comment:

- If you do not use the speech aid for a long time, remove the batteries from the device. Batteries may leak and damage the device.
- Have pre-charged spare batteries ready to ensure the use of the speech aid without interruption.
- Ideally, the rechargeable batteries should be exchanged with each other from time to time.
- For better overview, you can number the batteries.
- If your batteries need to be replaced, choose Servona spare parts. Alternative (rechargeable) batteries must comply with the technical specifications. See chapters "Spare Parts" and "Technical Specifications".
- For problem-free and safe operation of the speech aid we recommend Servona spare parts.

Using SERVOX® digital XL

Your speech aid is ready for use when you have inserted charged batteries (or full standard batteries) in the speech aid, see chapter “Inserting and Replacing Batteries”.

The objective of using the speech aid is to make the air in the mouth and throat vibrate so that sounds or speech can be produced. When used as intended, SERVOX® digital XL is pressed against the body with the transducer so that the hard membrane in the screw cap transmits the vibrations to the tissue.

Application point

The best voice results are achieved by using you neck, a mouth arch or a cheek as an application point.

The SERVOX® digital XL speech aid may only be used on intact skin.

⚠ Never place the speech aid directly on the tracheostoma or on inflamed areas! See chapter “Safety Instructions”.

Application



To use your SERVOX® digital XL Speech Aid, press firmly on one of the above mentioned application points. Please also note the examples in the adjacent illustrations. Try out the speech aid in all of the above places until you find the optimal application point. This is the place that best reproduces the sound. In order to find the best location for yourself, you should first practice in front of a mirror or together with a family member or therapist, who can assist you in the handling and correct you if necessary. **⚠ Do not hold the speech aid to your ear.**



By pressing the button, the vibration can now be transmitted to the oropharyngeal cavity (mouth/throat). Modulation of the fundamental tone takes place in the oral cavity.

If you have problems with the use of your SERVOX® digital XL, it is recommended to practice the handling with a speech therapist.

Additional help can be found in "First Steps for Using SERVOX® digital XL". These are available separately upon request.

Individual adjustment of the volume and pitch of the speech is possible and is explained in the following chapter “Settings/Operation”.

⚠ Do not let children use the device unattended. Always clean the speech aid before and after use, see chapter “Cleaning/Disinfection”.

Settings/Operation

Using the buttons

Usually, the upper button (A) is used for the vocal base tone. Additional emphasis can be achieved with the lower button (B). You can also assign the buttons based on your own preference. Generally, every user of the SERVOX® digital XL Speech Aid should first practice speaking only with Button A. Button B should only be practised after the user is comfortable with the handling of Button A.



The two buttons are operated either with the index and middle finger (Figure 1) or by tilting the thumb (Figure 2 and 3).



- A** Button A
- B** Button B
- C** Volume control (Rocker)

Adjusting the volume

⚠ Make these settings only when you are not keeping the speech aid at the application point. ⚠ Do not hold the speech aid to your ear.

The volume can be adjusted using the volume control (rocker). The following modes can be used:

a) Assigning Buttons A and B with different volumes

To adjust the volume of a button separately, press the button (sound is audible) and at the same time slide the rocker upwards (the sound becomes louder) or downwards (the sound becomes quieter). When you release the button, the selected volume will be saved.

b) Simultaneously changing the volume of buttons A and B

No button is pressed (no sound is heard). By sliding the rocker up the sound becomes louder, or quieter by sliding it downwards. To control the set volume, press the corresponding button.

Adjusting the pitch

It is recommended to set the pitch similar to former voice. The pitch of the two buttons must be set individually for each button. ⚠ **Make these settings only when you are not holding the speech aid at the application point.** ⚠ **Do not hold the speech aid to your ear.**

To change the pitch, the following steps are necessary:



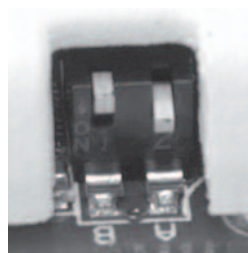
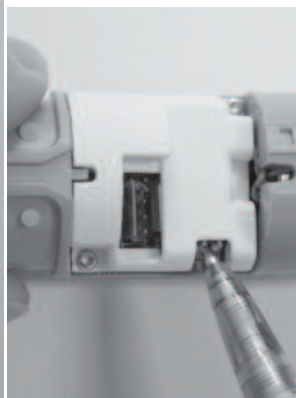
1.
Unscrew bottom cover and remove battery holder.



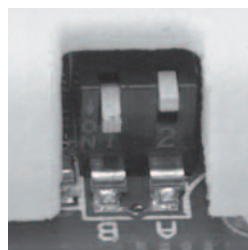
2.
Grasp the device at the top and pull off the titanium sleeve.



3.
Insert the battery holder back into the battery compartment and screw the bottom cover.



4.a
Setting Button A:
Slide DIP switch 1 to the ON position and DIP switch 2 to the OFF position.



4.b
Setting Button B:
Slide DIP switch 1 to the OFF position and DIP switch 2 to the ON position.



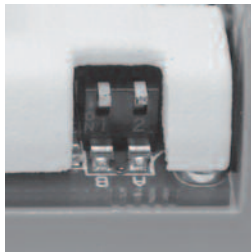
5.
Pressing Button A once increases the frequency by 1 Hz. Pressing button B once decreases the frequency by 1 Hz. To change the frequency by several steps, press the respective button several times. If you do not release the button, the currently set tone remains switched on for monitoring purposes. This is how you check if the changed pitch meets your expectations.

6.
After completing the settings, move both DIP switches to the OFF position (see the figure below).

After setting the desired pitch, wait 5 seconds until the setting is saved in the processor.

7.
You can adjust the sound by turning the screw cap (see chapter “Fine-tuning the Pitch”).

8.
Now unscrew the bottom cover and remove the battery holder. Then slide the titanium sleeve back on, insert the battery holder and tighten the bottom cover again.



Fine-tuning the pitch

If the sound is too indistinct, the bottom cover should be slightly tightened. Please make sure that the bottom cover is not tightened too much, because it may damage the bottom cover. To reach a clear sound at the maximum volume, the bottom cover should be slightly loosened.

Speech melody (optional)

The tone movement is not preset at the factory and is not active. If desired, it can be adjusted individually with the help of a PC transmission set (can be ordered separately for speech therapists). It is recommended to include the setting of the speech melody in the speech therapy.

Switching off the device

The device can be switched off by turning the bottom cover to the left (e.g. to avoid unwanted sound while carrying it).

Cleaning/Disinfection

Regular cleaning by the user is required. ⚠️ **Only clean the device when it is not at the application point.** For cleaning/disingfecting, wipe the exterior of SERVOX® digital XL with a cloth moistened in alcohol.

The charger must only be wiped dry. The charger should not be cleaned by children unless they are over 8 years old and supervised.

The battery contacts inside SERVOX® digital XL and the battery holder or the rechargeable batteries can be cleaned with an eraser pencil. Clean the contacts regularly. Dirty or oxidized contacts can cause sound interruptions. The cleaning can be done using mild household cleaning agents. Disinfection of the exterior of SERVOX® digital XL can be performed by wiping it with commercially available disinfectants. Excessive cleaning should be avoided, but daily cleaning before and after use is recommended. Excessive cleaning can result in too rapid wear. Never submerge the speech aid in water or other liquids. If the environment is too humid, parts inside the speech aid may corrode or rust.

Troubleshooting

Defect	Possible cause	Solution
The speech aid is not responding	No power supply due to loose battery cover	Check the position of the battery cover. It should be screwed straight and firmly on the speech aid.
	No power supply due to incorrectly inserted rechargeable battery in the battery holder	Check the batteries. Insert the batteries into the battery holder so that the polarity (+ and -) of the batteries matches the specifications of the battery holder.
	No power supply due to discharged or defective battery	Replace battery with charged battery
Speech aid generates vibrations that are too weak	Volume control on the speech aid set to minimum	Check the position of the volume control. It should be in the middle position.
	Screw cap on the speech aid is loose	Check the position of the screw cap. It should be screwed on straight and firmly.

Accessories

Belt pouch

The velcro on the back allows the bag to be variably adjusted to different belt widths and fastened. A separate compartment allows you to carry spare batteries.



Oral tube with adapter

The SERVVOX® digital XL can be used together with the oral tube with an adapter immediately after the larynx removal and during the irradiation time, when the neck is still very sensitive or too swollen to be able to start the speech aid.

To do this, attach the oral tube to the adapter (see picture), and then place the adapter with the oral tube onto the screw cap of the speech aid.

Clean the oral tube and adapter immediately after use with a mild soap solution and store it in a clean place. The maximum period of use for an oral tube is intended for 30 days. Then it should be disposed of with the household waste and replaced by a new one.

Note: Please also read the separate leaflet for the oral tube



Screw cap “soft tone”

The screw cap with a soft tone offers a softer tone compared to the standard screw cap. The hard membrane of this screw cap is lighter for better distinction from the standard screw cap.



Carrying strap

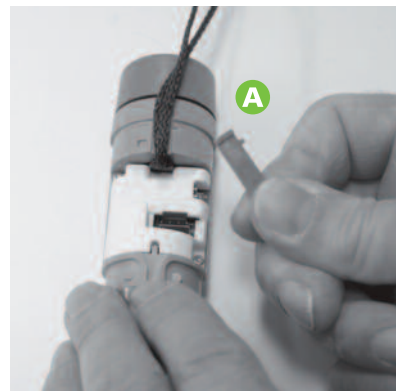
The device can be worn around the neck with the carrying strap. ⚠️ **Do not let children use the carrying strap unattended.** ⚠️ **Only put on the carrying strap if it is to be used on the device. Otherwise there is a risk of strangulation.** To attach or remove the strap, proceed as follows:



1.
Unscrew the bottom cover and remove the battery holder.



2.
Grasp the device by the top and pull off the titanium sleeve.



3.
Remove the strap **A** protection, push the clasp of the carrying strap vertically behind the electronics and insert the strap into a groove.



4.
Cover the carrying strap with the strap protection so that the U-end of the strap protection points towards the top of the device.

5.
Then slide the titanium sleeve back on again.

Note: The titanium sleeve must be easy to put on. If it is tough to put on or if it is jammed, then reverse the strap protection.








6.
Then insert the battery holder back into the battery compartment and screw in the bottom cover.

If no carrying strap is used, reverse the strap protection and insert it. In this case, insert the strap protection with the bevelled side towards the top of the device. Again, the titanium sleeve must be easy to put on. In this case, it serves as a cover of the opening and prevents the ingress of dirt into the casing interior.

Use of Charger, Charging of Batteries

Follow the safety instructions on page 5! And:

-  **Do not use corroded, leaked or damaged rechargeable batteries.**
-  **When inserting batteries, pay attention to the correct polarity.**
-  **Batteries may heat up during charging.**
-  **Set up the charger so that it can be disconnected from the mains supply network at any time.**
-  **Standard batteries cannot be charged, only rechargeable batteries.**

Check batteries used for the speech aid regularly to make sure they still work. Replace defective rechargeable batteries immediately.

Batteries inserted into a charger will discharge over time if the charger is not connected to the mains supply (socket).

The charging time depends on the remaining capacity of a battery and whether multiple batteries are charged at the same time.

Please also read the note regarding battery life in the technical specifications.

Charging the batteries

1. Check that the mains voltage matches the rating on the rating plate of the charger.
2. Place batteries to be charged in pairs inside the charger. Pay attention to the correct polarity! See chapter "Inserting and replacing batteries".
3. Connect the charger to the mains supply. The charger indicates that the batteries are being charged.
4. When the charging process is finished, the charger will indicate it accordingly. You can then remove the batteries.
5. Remove the charger from the mains supply.

Error during charging

If the charging process does not start immediately, check if the charger is correctly connected to the mains supply. Also check if the batteries in the loading compartment are inserted in the right direction. Check if you have inserted rechargeable batteries (and not standard batteries) in the charger.

Possibly, a rechargeable battery is defective. Replace it with another or a new battery. Dispose of a defective battery correctly, see chapter "Disposal".

Maintenance, Repair

As a rule, regular maintenance of the speech aid is not required when it is used as intended. It must be cleaned before and after use and before long periods of non-use, see chapter "Cleaning/Disinfection". **⚠ Clean/disinfect only when you are not holding the speech aid at the application point.**

The lifetime of rechargeable batteries is usually about 6 months. Check your batteries regularly and replace defective batteries with the new ones in due time.

It is assumed that the device will have an expected service life of 10 years before wear and tear or failure will render it impossible to continue using it.

Do not carry out any repairs yourself! Repairs may only be carried out by trained and qualified personnel. **⚠ Improper repairs can cause irreversible damage to the speech aid.**

If repair becomes necessary, send SERVVOX® digital XL along with the charger and batteries in their original packaging to Bruce Medical Supply, 411 Waverley Oaks Rd., Ste.154, Waltham Massachusetts, 02452 USA. **Please also include an error description and a copy of the original receipt.**

If you have purchased the device directly from Servona, please send it to Servona GmbH. In order to ensure fast and smooth handling, we ask you to obtain a processing number from us before sending it in (telephone: + 49-2241-9322-206). Please write the processing number clearly visible from the outside on the package. **Please also include an error description and a copy of the original receipt.**

Spare parts

The speech aid may only be used with the accessories listed here. Spare parts are not included in the original package. If interested, these spare parts can be ordered.

Reference	Order no.
Standard screw cap, completely assembled	22774
Screw cap "soft tone", completely assembled	23285
Oral tube with adapter	18253
Strap set (carrying strap)	17093
Belt pouch	16555
Bottom cover	37505
O-ring	14831
Battery holder	37574
Rechargeable batteries (AAA)	37561
Charger	37469

Serial number

To read the serial number on the speech aid, unscrew the bottom cover and push the titanium sleeve off the casing. The serial number can be seen on the underlying plastic casing below the operating buttons.

For your own safety and to maintain the warranty, only original spare parts may be used. For questions about spare parts and accessories, please contact:

Bruce Medical Supply

411 Waverley Oaks Rd., Ste. 154

Waltham, MA 02452 USA

1-800-225-8446

www.BruceMedical.com



Serial number

Disposal

This product is subject to EU Directive 2002/96/EC (WEEE) and must not be disposed of with normal household waste. For disposal, collection points have been set up at the public waste disposal authorities (municipalities). Old household appliances from private households are accepted there free of charge. The packaging can be thrown away with the normal household waste. The device and accessories must be decontaminated before disposal, as pathogen-containing substances can lead to a hazard.



Do not dispose of rechargeable or standard batteries in household waste. Dispose of old batteries at locations designated for used battery disposal.

Technical specifications

Dimensions

Speech aid: L 128 x Ø 35 mm

Charger: L 115 x B 77 x H 57 mm

Rechargeable battery: Ø 10,5 x L 44,5 mm

Weight

Speech aid: Approx. 110 g without rechargeable battery

Charger: 138 g without rechargeable battery

Rechargeable battery: Approx. 13 g

Electrical specifications of (rechargeable) battery

Voltage: 1.2V / 1.5V

Type: AAA (HR03)

Type capacity: 750 mAh to 900 mAh

Type lifespan: 1,000 cycles

The talk time depends on the selected battery capacity.

Note that batteries have a limited life, which is about 3 years shorter than the lifetime of your speech aid. Replace old rechargeable batteries with new ones in good time. It is also possible to use standard batteries with appropriate specification.

The supplied batteries meet the safety requirements of IEC 62133. All replacement batteries must meet this standard.

Electrical specifications of charger

Commercially available charger, suitable for charging batteries type AAA (HR03)

Other notes

The speech aid and charger are not suitable for use in potentially explosive atmospheres

Application parts

Application parts are the speech aids themselves, as well as the exchangeable transducers.

Operating conditions













Environmental conditions during operation, as well as during storage and transport between applications.

Description	Storage/transport	Operation
Temperature in °C	+0 °C – 40 °C	+5 °C – 40 °C
Relative humidity	Up to 93% without condensation	15% - 93% without condensation
Air pressure	700 hPa – 1060 hPa	700 hPa – 1060 hPa

Technical specifications subject to change!

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Explanation of symbols

	Device of protection class II
	Observe the safety instructions!
	Risk of infection!
	Only for indoor use
	Protect from moisture.
	The medical device complies with the relevant provisions of EU Directive 93/42/EEC for medical devices.
	The product complies with the applicable safety requirements set out in the Technical Codes of the Eurasian Economic Union.
	This product must not be disposed of with normal household waste. The crossed-out waste bin symbol indicates the need for separate collection.
IP22	The product is protected against the ingress of solid foreign bodies $\geq 12.5 \text{ mm } \varnothing$, as well as against vertically falling drops of water with an inclined casing of up to 15° . The protection class is only achieved when the casing is properly closed.
	Application part of the type BF.
	Please follow the instructions
	Manufacturing year
	Manufacturer: Servona GmbH - Biberweg 24-25 - 53842 Troisdorf

Information on electromagnetic compatibility (EMC)

Medical electrical equipment is subject to special precautions regarding EMC and must be installed in accordance with the EMC instructions below. Portable and mobile RF communication devices may affect medical electrical equipment. The use of accessories, transformers, and power supplies other than those specified in this manual may result in increased signal emissions or reduced interference resistance of the equipment or system.

Guidelines and manufacturer's declaration - electromagnetic emissions

The speech aid is intended for use in an environment as specified below. The customer or the user of the speech aid should ensure that it is operated in such an environment.

Interference emissions test	Conformity	Electromagnetic environment – guidelines
RF emissions according to CISPR 11	Class B	The speech aids are suitable for use in all settings, including in residential areas and those directly connected to a public supply grid that also supplies buildings used for residential purposes.
Transmission of harmonics according to IEC 61000-3-2	Not applicable	
Transmission of voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	

Recommended safety distances between portable and mobile RF telecommunication devices and the SERVOX speech aids

The speech aids are intended for use in an electromagnetic environment in which the RF disturbance variables are controlled. The user of the speech aids can thereby help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the speech aids, depending on the output power of the communication device, as indicated below.

Nominal power of the transmitter (W)	Safety distance depends on the transmission frequency (m)		
	150 kHz to 80 MHz	80 MHz bis 800 MHz $d = \sqrt{\frac{P}{6 \cdot 10^3}}$	800 MHz bis 2.5 GHz $d = \sqrt{\frac{P}{6 \cdot 10^6}}$
0,01	0,06	0,06	0,06
0,1	0,19	0,19	0,19
1	0,6	0,6	0,6
10	1,90	1,90	1,90
100	6,00	6,00	6,00

For transmitters whose maximum rated power is not listed above, the recommended safety distance can be determined using the equation in the corresponding column. P is the maximum nominal power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications.

Guidelines and manufacturer's declaration - electromagnetic immunity

The speech aid is intended for use in an environment as specified below. The customer or the user of the speech aid should ensure that it is operated in such an environment.

Immunity testing	IEC 60601 - test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 1000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Magnetic fields at the supply frequency (50/60 Hz) according to IEC 31000-4-8	30 A/m	30 A/m	Grid frequency magnetic fields should be the same as those typically found in the business and hospital environment.

Guidelines and manufacturer's declaration - electromagnetic immunity

The speech aid is intended for use in an environment as specified below. The customer or the user of the speech aid should ensure that it is operated in such an environment.

Immunity testing	IEC 60601 - test level	Compliance level	Electromagnetic environment – guidelines
Radiated RF disturbance variables according to IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	Recommended safety distance: $d = \sqrt{6/10} \sqrt{P}$ $d = \sqrt{6/10} \sqrt{P}$ for 80 MHz to 800 MHz $d = \sqrt{6/10} \sqrt{P}$ for 800 MHz to 2.5 GHz P is the nominal power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications, and d is the recommended safety distance in meters (m).

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