

MINI VOICE AMP

TECHNICAL INFORMATION

09/09 Rev1


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EC DECLARATION OF CONFORMITY

Toby Churchill Limited; Norman Way, Over, Cambridge, CB24 5QE, declare under our own responsibility that:

- the **Mini Voice Amp** range of equipment and their associated medical device and accessories, as described within the technical documentation file referenced TF5, conform to the requirements of Council Directive 93/42/EEC concerning medical devices as amended by Directive 98/79/EC, Directive 2000/70/EC & Directive 2001/104/EC for Class I devices.
- is in conformity with the provisions of the Directives applicable to Class I equipment by conforming with Harmonized Standards as listed but not limited to the following:
 - EN16201; EN12182; EN301 511; EN 301 489; EN60601-1; EN 60601-1-1; EN 60601-1-2; EN 14971.
- the requirements of Annex I, Annex VII and Annex IX have been followed for Class I medical device and registration requirements of Article 14 have been notified to the UK Competent Authority.
- the Declaration covers equipment/devices manufactured from the period commencing February 2008 and until such time as a renewed conformity declaration is raised;
 - this declaration covers the equipment/device family range listed below and includes the software embedded within the hardware.
Mini Voice Amp
- the equipment is placed on the market and CE marked under Directive 1999/5/EC
- this declaration is signed on behalf of Toby Churchill Limited by:

Signed	
Name	David Mason
Authority	Director
Date	2009

Statement of Intended Use

- The Mini Voice Amp is intended to be used as an amplifier for people with low levels of natural speech. It is intended to be used as a portable unit..

GENERAL CONDITIONS OF USE

- The Mini Voice Amp, charger and accessories have been subjected to extensive quality control and test procedures to ensure compliance with the essential requirements of the Medical Devices Directive (MDA), and the National Health Service Purchasing and Supplies Agency specification for Electronic Assistive Technology. These tests include the simulation of fault conditions, in order to confirm the design and manufacturing process, and to ensure the safety of users of our equipment.
- Mini Voice Amps should not interfere with the correct operation of adjacent electronic equipment. Appropriate E.B.M.E. staff must confirm their safe use in critical areas such as Intensive Care Units.

General Description And Classification

CLASSIFICATION

The Toby Churchill Mini Voice Amp is considered to be a medical device because the intended purpose is to:

- compensate for low level of speech due to injury or handicap;
- to provide a means of communication for those where this would be difficult or impossible, due to injury, handicap or physical disability;

The devices are classified as a Class I device by virtue of Rule 1 and Rule 12 and that no other rules apply.

DESCRIPTION

The Mini Voice Amp augments loss of speech. See Point of Sale information for full details

Ingress of Fluids

- The Mini Voice Amp is splashproof but not waterproof. To prevent accidental damage to this electronic equipment, avoid fluids entering inside the case. If accidental spillage of fluid over the unit is likely to occur, it may be advisable to cover the unit with a flexible transparent membrane such as polythene or Clingfilm.
- When cleaning the unit please follow the instructions in the section of this document on Cleaning Procedure.
- The Mini Voice Amp operates at low voltage, and there is no risk of electric shock if the unit becomes wet.
- If the Mini Voice Amp becomes wet, it should be powered off and allowed to thoroughly dry before attempting to use again.

Safety Precautions

- If the Mini Voice Amp is used as a portable unit then the strap should be considered. If the strap is not used the Mini Voice Amp must be held securely so that it cannot fall. A fall may result in damage to the Mini Voice Amp or in personal injury.
- If the Mini Voice Amp is freestanding it may be supported on a suitable stand. Due consideration must be given to the stability of the unit. Care must be taken that any cables connected to the Mini Voice Amp or to an external power supply are secured or placed so that:
- They cannot be trapped in any way which could damage a cable.
- A cable cannot be accidentally pulled which could result in the Mini Voice Amp or the power-supply falling.
- Cables and connectors must not be put under strain by putting them under tension or by bending the cable sharply.

ACCESSORIES

- We recommend that TOBY CHURCHILL Limited accessories should be the first choice as they have been specifically designed to work with the Mini Voice Amp. However other accessories may be used providing they are compatible with the Mini Voice Amp. If other than genuine TOBY CHURCHILL Limited accessories are used, assessment of any associated risk is the responsibility of the installer.

CHARGER

- Our chargers are approved to EN60950. In addition we inspect and test them to ensure user-safety, in accordance with EN60601-1-1.
- Use of non-TCL chargers is not recommended, and may cause a hazard and/or damage the Mini Voice Amp. We have taken every precaution to avoid a fire-risk in this circumstance, but cannot accept responsibility should this occur. If you need to use any other supply, for example: an external battery, obtain approval for the use of the supply from TCL before using it.
- The charger lead should be safely positioned in order to avoid hazards.

PLUG-IN DEVICES

- All cable leads should be safely positioned in order to avoid hazards.

TRAVEL CARE WARNING

- Hard objects in front of passengers or loose in a vehicle could be dangerous in the event of emergency braking. Therefore, we recommend that if you remain in a wheelchair when travelling in a vehicle, stow the assembly securely so that it cannot easily become dislodged. See MDA document No. DB 2001 (03).

ENVIRONMENTAL CONDITIONS

- **Water and other liquids:** the Mini Voice Amp should not be exposed to heavy rain. Use in very light rain is possible. If there is ingress of water or other liquid into the Mini Voice Amp the system should be allowed to dry before use.
- **Humidity:** the Mini Voice Amp should not be exposed to conditions where condensation can occur inside the case. Usually when the system is operating it will not be affected by humidity but it should not be left for long in very humid conditions, for example in a bathroom or swimming pool. If condensation does occur when it is not operating it should be allowed to dry before switching it on.
- **Temperature:** the Mini Voice Amp can be operated in ambient temperatures in the range 0 C to 30 C. Note that the temperature may be outside this range if the Mini Voice Amp has been left in a vehicle exposed to the sun or to cold temperatures, in which case it should be allowed to reach a safe temperature before operation.
- The connection of non-approved accessories to the socket-strip may constitute a hazard to the patient under fault-conditions. A risk assessment is recommended in these circumstances.

EN60601

- Mini Voice Amps meet the essential requirements of EN60601.
 - **Earth Leakage**
All readings below 5 μ A
 - **Enclosure Leakage Current**
All readings below 2 μ A
 - **Patient Leakage Current**
All readings less than 45 μ A
 - **Patient Auxiliary Current**
All readings less than 40 μ A
- The Mini Voice Amp, together with accessories provided by TOBY CHURCHILL Ltd, are suitable for use within the PATIENT ENVIRONMENT; other accessories are not approved, and are to be used at the installer's risk.

FURTHER READING

- www.doh.gov.uk/ DOH (Dept of Health)
- www.nhs.uk/ NHS
- www.medical-devices.gov.uk/ MDA
- www.medical-devices.gov.uk/ > search for 'DB' > Device Bulletins 2001 > MDA document No. DB 2001 (03) "Guidance on the Safe Transportation of Wheelchairs"
- www.doh.gov.uk/scg/communityequipment.htm Community Equipment

Decontamination

The Mini Voice Amp and associated equipment may become dirty through a variety of means such as saliva, mucus, spilt food and drink, and from contact with dirty hands.

There may also be a need to decontaminate equipment to reduce the risk of infection transmission.

CLEANING PROCEDURE

- The recommended cleaning procedure is to wipe the affected external surfaces with a cloth moistened in hot water with some washing-up liquid, and use a nail brush for more stubborn dirt.
- The Mini Voice Amp is splashproof but not waterproof. Do not allow water to enter inside the Mini Voice Amp. It is recommended that you turn the Mini Voice Amp on end with the charger point lowest and to clean the Mini Voice Amp in this position, reducing the risk of any water entering inside the Mini Voice Amp.

DECONTAMINATION PROCEDURE

There may be a requirement to decontaminate a Mini Voice Amp and/or associated equipment after use to reduce the risk of infection transmission to other people. The Central Public Health Laboratory (a division of the Department of Health in the UK) has recommended the following decontamination procedure for this type of low-risk equipment:

- clean the external surfaces with a disposable paper wipe moistened with warm detergent solution. (see Cleaning Procedure)
- allow the surfaces to dry.
- wipe the surfaces with a commercially-available alcohol-impregnated disposable wipe.
- note that this equipment should not be sterilised, nor should disinfecting fluids be used as these may attack the plastic materials.
- **CAUTION:**
 - do not immerse equipment in water
 - do not use disinfecting fluids (such as surgical spirit, Hibitane (a brand name for chlorhexidene) or Cidex (a brand name for 2% alkaline-buffered glutaraldehyde)
 - do not autoclave equipment or expose to elevated temperature

