MiniMuffs® Neonatal Noise Attenuators
& Micro MiniMuffs® Neonatal Noise Attenuators

Instructions for Use

CHS USA Incorporated
200 Kelly Drive, Suite A
Peachtree City, GA 30269 USA
www.chsusainc.com

Canadian Hospital Specialties Ltd. (CHS Ltd.)
2060 Winston Park Drive, Unit 400
Oakville, Ontario, Canada, L6H 5R7

Products made in the USA.

Associated Product Part Numbers:

040341 MINIMUFFS ASSEMBLY, 36 PAIRS
040342 MICRO MINIMUFFS ASSEMBLY, 36 PAIRS

chsusainc.com

The MiniMuffs® eIFU version is available online in multiple languages at: https://www.chsusainc.com/minimuffs

You may scan this QR Code for easy online access.

English

Description:
MiniMuffs® and Micro MiniMuffs® Neonatal Noise Attenuators are single-use, soft foam earmuffs that fit around a neonate's ears to reduce the level of sound reaching the ear. The devices are sized and shaped to fit around the neonate's ear. Each pair of MiniMuffs is attached to a release liner and is removed from the liner one at a time for use on the neonates.

Indications for Use:
MiniMuffs® and Micro MiniMuffs® Noise Attenuators are indicated for short-term (less than 24 hours) hospital use with neonates in a supervised setting. MiniMuffs® and Micro MiniMuffs® Noise Attenuators are for single use only and are disposable.

Intended Use / Intended Purpose:
Noise attenuators reduce the sound level reaching the neonate's ears. Reducing noise can stabilize the heart rate, decrease adverse physiological states such as oxygen desaturation, can decrease behavior states such as crying and fussing, and can lead to an increase in length of sleep.

The device is used for the prevention of hearing damage in infants by decreasing adverse physiological states, and it does not have an active effect on sound reduction.

Intended Users and Patient Target Group:
This product is intended exclusively for professional use. The MiniMuffs® and Micro MiniMuffs® products are for use with neonates in a hospital setting or during clinical transport to reduce noise levels and result in longer periods of sleep time.

Clinical Benefits:
MiniMuffs® and Micro MiniMuffs® Noise Attenuators reduce noise levels, which results in longer periods of sleep time, optimal oxygenation, and improved physiological stability.

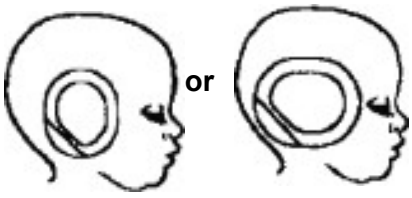
Noise Reduction Rating (NRR):
7 DECIBELS (When used as directed). The range of noise reduction ratings for existing hearing protectors is approximately 0 to 30 decibels (higher numbers denote greater effectiveness).
NRR was calculated in accordance with EPA 550/9-79-256.

Contraindications and Side Effects:
There are no known contraindications or side effects related to Canadian Hospital Specialties Ltd. MiniMuffs® and Micro MiniMuffs® Noise Attenuators.

Operating Instructions:

Important! Follow your facility's infection control and skin care management protocols for:
- Cleaning skin
- Using hydrogel adhesive on premature skin
- Determining the appropriate length of use
- Proper disposal.

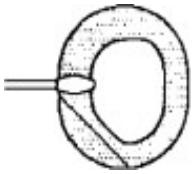
1. **Apply the Earmuffs**
   Remove MiniMuffs® and Micro MiniMuffs® earmuffs from the liner and place them on the infant one at a time. Position in either orientation shown.



2. **Ensure a Good Seal**
   Press the earmuff edges gently but firmly in place to ensure a good seal.
   - Avoid placing earmuffs on hair.
   - Do not press on the raised center of earmuffs.

   Important! Noise reduction is dependent on a good seal. Examine the earmuff seal when repositioning the infant.

3. **Minimize Adhesion on Sensitive Skin**
   To reduce adhesion of hydrogel on sensitive skin, dab hydrogel on the surface with a clean cotton swab or gauze pad prior to placing the earmuff on the infant.



4. **Removing the Earmuffs**
   Use care when removing. Wet a cotton swab or gauze pad and gently work under the edge to loosen the hydrogel. Support the underlying skin while lifting the earmuff at the edge.

Understanding Warning Statements:

⚠ WARNING
Refers to a hazardous situation that could result in death or serious injury if not avoided.

Warnings:

⚠ WARNING
Be careful not to fold or bend the ear. Do not force large ears into earmuffs. Do not place over compromised skin.
Examine skin according to your facility's skin care management protocol. Discontinue use if irritation, abrasion, or edema is present.

Metal-Free Construction Statement:
MiniMuffs® and Micro MiniMuffs® are manufactured entirely from non-metallic materials and contain no ferromagnetic, conductive, or metallic components. MiniMuffs® and Micro MiniMuffs® are considered metal-free.

Compliance Standards
ISO 10993-1:2018 — Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Authorized Representatives:
EU Authorized Representative: Obelis s.a.
Bd. Général Wahis 53, B-1030 Brussels, Belgium
Phone: 32.2.732.59.54, E-mail: mail@obelis.net

UK Authorized Representative: Obelis UK Ltd.
Sandford Gate, Oxford, OX4 6LB, United Kingdom
Phone: +44.1491.378012, E-mail: info@obelis.co.uk

Instructions to Access the eIFU:

- A PDF version of the Instructions for Use is available at: www.chsusainc.com
- Search for "MiniMuffs Neonatal Noise Attenuators IFU" using the product part number.
- Select the correct version for your local language.
- Files can be printed, saved, or searched using Adobe Reader.
- Download Adobe Reader at www.adobe.com

Disposal Instructions:

- Dispose of MiniMuffs® and Micro MiniMuffs® Neonatal Noise Attenuators after a single use.

Disclaimer:

- Canadian Hospital Specialties is not responsible for injury, infection, or other damage resulting from the use of this product.
- Any serious incident that has occurred in relation to the device should be reported to Canadian Hospital Specialties and the competent authority of the Member State where the user and/or patient resides.

Contact Information:
For questions, product support, or to request additional information, please visit our website at www.chsusainc.com and navigate to the 'Contact Us' section to reach our customer support team.

Glossary of Symbols:

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	21 CFR Part 801.109(b)(1)	Labeling-Prescription devices	Prescription only	Indicates that the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1 Symbol 5.4.5 (Reference Annex B for the general prohibition symbol)	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Not made with natural rubber latex	Indicates that the medical device is not made with natural rubber latex.
	ISO 15223-1 Symbol 5.1.1	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Symbol 5.1.2	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	ISO 15223-1 Symbol 5.1.3	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Symbol 5.1.5	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Symbol 5.1.6	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Symbol 5.4.3 Annex A #A.16	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Consult instructions for use	Indicates an instruction to consult the electronic instructions for use (eIFU).
	IEC 60601-1 Table D.2 #2	Medical electrical equipment – Part 1: General requirements for basic safety and Essential performance	General warning sign	Indicates a hazard of potential personal injury to the patient or operator.
	MDR 2017/745	EU Medical Device Regulation	CE marking	Signifies European technical conformity.
	ISO 15223-1 Symbol 5.1.4	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Symbol 5.2.8	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Do not use if the package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Symbol 5.4.2	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Do not re-use	Indicates that the medical device is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Symbol 5.1.9	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Distributor	Indicates the entity distributing the medical device into the locale

Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	ISO 15223-1 Symbol 5.7.7	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Medical Device	Indicate that the item is a medical device
	ISO 15223-1 Symbol 5.7.10	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	UK Medical Device Regulations 2002	UK Medical Device Regulations 2002	UK Conformity Assessed	The UKCA marking (an abbreviation of UK Conformity Assessed) is a conformity mark that indicates conformity with the applicable requirements for products sold within Great Britain.