

NEATCAP® DREAMIES® T-M CIRCUMAURAL HEARING PROTECTOR DEVICE - INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The NEATCAP® DREAMIES® T-M device is a single patient use medical device designed to provide hearing protection for infants during air or ground hospital transport, or magnetic resonance imaging (MRI). The device covers and makes a physical seal over and around the pinna (outside) of the ear. The NEATCAP DREAMIES T-M device contains noise attenuation material that reduces the level of sound reaching the ear. The device employs a soft neoprene/nylon headband to fix the ear cups in place. The device is provided in XS, S, M, LG and XL sizes to accommodate multiple sizes of infants.

NEATCAP DREAMIES T-M are biocompatible and are designed to be used for up to three (3) consecutive hours.

INDICATIONS FOR USE

NEATCAP DREAMIES T-M are intended for short-term use on infants during air or ground hospital transport, or an MRI examination to provide reduction of sound reaching the ears.

WARNINGS

- NEATCAP DREAMIES T-M have not been studied during extended use. DREAMIES T-M are intended for short-term use during air or ground hospital transport, or an MRI examination.
- Examine the skin according to clinical protocol.
- Do not use on broken skin.
- Discontinue use if irritation, abrasion or edema is present.

PRECAUTIONS

- DREAMIES T-M are designed for neonatal patients with occipitofrontal head circumference (OFC) between 23cm and 48cm. Patients with OFC smaller than 23cm or larger than 48cm should not wear DREAMIES T-M.
- Noise reduction is dependent on a good seal. The headband should be placed snugly on the head so that there are no gaps between the ear cups and skin. Examine the seal around the ear cup when repositioning the infant.
- If NEATCAP DREAMIES T-M become soiled, replace with a new device. If lightly soiled, DREAMIES may be wiped with isopropyl alcohol and thoroughly dried prior to re-use.
- Do not sterilize or reuse on multiple patients.
- Dispose of properly in accordance with hospital protocol after use.
- Device should be removed and skin integrity checked every 3 hours. Some erythema may be observed upon removal of the device. If erythema does not dissipate within 30 minutes, refer to your hospital's skin integrity protocol before re-application of the device.

HOW SUPPLIED

The NEATCAP DREAMIES T-M are provided non-sterile and for single patient use.

INSTRUCTIONS FOR USE:

Important: Follow hospital's infection control and skin integrity protocol(s) for cleaning skin, appropriate length of use, and proper disposal.

1. Measure the occipitofrontal circumference (OFC) of the infant's head according to hospital protocol. Based on the OFC, select the appropriate NEATCAP DREAMIES T-M Size based on the Sizing Reference Chart. If the OFC is within 0.5cm of the upper limit of the Size range, choose the next larger size. If the ear does not fit completely inside the plastic ear cup shell, the ear cup is too small, and the next larger size should be used.

DREAMIES T-M Sizing Reference Chart			
Catalog P/N	OFC	Headband	Ear Cups
NEAT005-01	23–27 cm	XS (23–27 cm)	XS (30mm)
NEAT005-02	27–31 cm	S (27–31 cm)	S (35mm)
NEAT005-03	31–35 cm	M (31–35 cm)	M (40mm)
NEAT005-04	35–41 cm	LG (35–41 cm)	LG (45mm)
NEAT005-05	41–48 cm	XL (41–48 cm)	XL (50mm)

MRI Safety Information



MR Safe – an item that poses no known hazards in all MR environments.

MRI testing demonstrated that the NEATCAP DREAMIES T-M is MR Safe. In addition, this statement is further substantiated by information related to the specific materials used to make this product, which are nonmetallic and non-conducting.

2. The headband and ear cups are marked with the letters **L** and **R** to designate the location of the ear cups to be placed over the infant’s Left and Right ears. On the outside surface of the device, the curved lines under the headband size and ear cup size markings should be “smiling” at you. The smile mark under the headband size indicates the inferior edge of the headband.

3. With the black side facing up, gently place the headband under the back of the infant’s head. The back of the head should be centered on the headband. The headband should straddle the base of the skull, and the top of each ear should be aligned with the top of each ear cup foam ring.

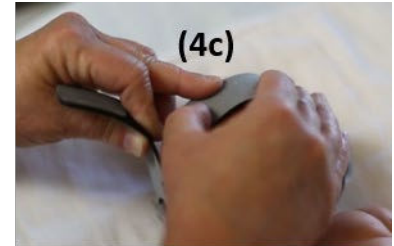


4. Secure the headband around the head, as follows:

- a. Grip the headband with the fingers of each hand in front of the ear cups, stretch the headband.
- b. Wrap the headband around the head so the ear cups cover over each ear.

NOTE: The ear cup size mark should be at the top of the ear; the **L** ear cup should be over the infant’s Left ear, and the **R** ear cup should be over the infant’s Right ear.

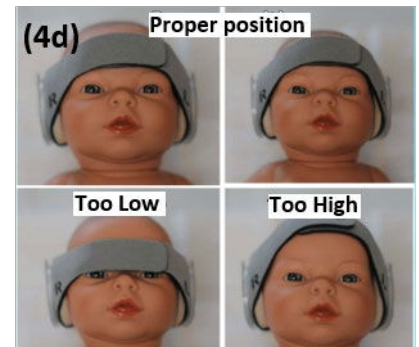
c. Wrap the gripper end (**L** side) of the headband across the infant’s forehead.



d. Overlap the Velcro fastener end (**R** side) straight across and over top of the **L** side, and close the headband by lightly pressing down on the Velcro patch end of the headband.

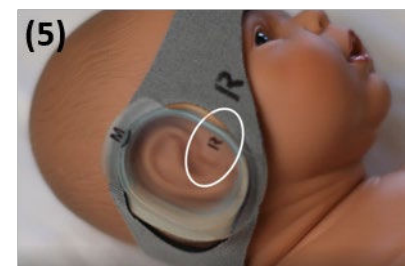
The frontal, bottom portion of the band should lay across the forehead, just above the brow line of the infant.

The **R** side marking on the headband should be visible in front of the infant’s right ear.



5. Adjust the angle and position of the ear cups, or the headband fit so that a uniform seal of the ear cups against the skin is achieved. The ear cup **R** and **L** markings should be aligned with the ear tragus (see photo).

6. If needed, re-seat the ear cups to form a seal with uniform foam ring compression by gently pulling on the ear cup retaining flanges and re-seating the foam ring against the skin.



7. Check headband tightness by sliding pinky finger under the band, in front of the ear cup. If pinky finger does not fit under the headband, it may be too tight; readjust headband closure and re-check.



Rx only

Manufactured by:
NEATCap Medical, LLC
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		DREAMIES T-M Sound Attenuation						
		Frequency (Hz)						
	Overall	125	250	500	1000	2000	4000	8000
Mean (dB)	27.3	17.4	18.9	19.2	27.9	37.7	35.2	36.5
SD	1.0	1.0	1.1	1.9	0.7	2.4	2.2	2.8