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Meniett Pulse Generator

Indications for use

The Meniett Low-Pressure Pulse Generator is indicated for the symptomatic treatment of Ménière's Disease. The therapeutic effect of the Meniett device is achieved by application of low frequency, low amplitude pressure pulses to the middle ear whereby inner ear endolymphatic fluid is assumed to be evacuated from the inner ear and thus the patient is relieved of the symptoms associated with the disease.

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Patient information on insertion of tympanostomy tubes

The tympanostomy tube is usually inserted under either local or general anesthesia as determined by the physician. Your doctor should have informed you of possible complications and risks associated with tympanostomy tubes. Your doctor also should have informed you about precautions to take while the tympanostomy tube is in place.



About the device

The local pressure pulse treatment method is the result of years of research on how pressure affects the inner ear. Clinical studies have shown that local pressure treatment has a positive effect on the symptoms of Ménière's Disease, without causing side effects. The



treatment with the Meniett device means creating a series of pressure pulses that are delivered to the ear through the tubing. The pressure pulses proceed through a ventilation tube into the middle ear, where they influence the fluid

pressure balance in the inner ear and thereby ease the symptoms of the disease.

Since the pressure pulses are weak, they do not cause any discomfort. Natural pressure changes to the inner ear, caused by normal sneezing, for instance, are several times stronger.

The Meniett device may only be used according to your doctor's prescription.

This equipment must be used in accordance with the information provided in this guide.

Read the entire instructions carefully and follow all instructions given by your doctor in order to obtain an optimal result.

How to install the battery pack

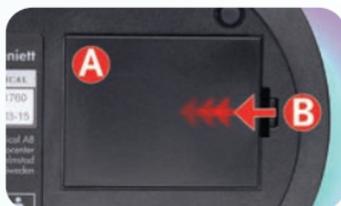
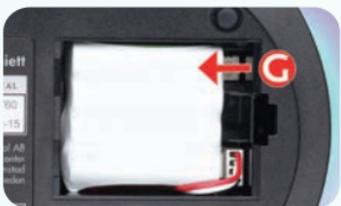
NOTE: The battery pack must be installed and fully charged prior to use.



EN Turn the Meniett device over and gently push the tab on the battery door towards the left, pulling outwards to remove the door.



Remove the battery pack from the Meniett package. Plug the white four pin connector on the battery pack into the mating connector in the Meniett device, pushing downwards until fully seated. NOTE: Make certain that the tabs and slots on the two connectors are aligned.



Place the battery pack in the Meniett device, being careful not to dislodge the connector. Replace the battery door. Follow the recharging instructions provided in the **Maintenance** section of this User Guide prior to use.

Labeling of parts

- | | |
|--------------------------------------|---------------------------------------|
| A. Door | E. Four-pin connector on battery pack |
| B. Door release | F. Tab on connector |
| C. Receptacles for tabs on connector | G. Battery pack |
| D. Four-pin connector in case | |

Preparation for treatment

Figure 1



Figure 2



- 1 Place the Meniett device on a stable surface so that it is level.
- 2 The device can be used either with the built-in battery or via a wall socket. You connect the Meniett device to a wall socket by using the power supply.
- 3 Open the Meniett case and unfold the tubing.
- 4 Place yourself in a comfortable position with your head in an upright position. Avoid lying down during treatment, as the treatment then may be less effective. (Figure 1)
- 5 **Warning: Ensure earplug is clean and free of substances.**
Warning: The Meniett device is not to be used to deliver any drug. Insert the tubing with the earplug into the ear canal. The earplug should feel comfortable in the ear canal and it should seal up against the ear canal wall. (Figure 2)

It is important that you keep the earplug in this position during the entire treatment.

Treatment

Softly press the Start/Stop button. 

The indicator  will flash green while the Meniett device warms up and performs a leakage test. This takes approximately 30 seconds. The earplug should be kept steady in the ear canal during the warm-up and leakage test.

If the indicator  is lit-up, the earplug is not properly seated in the ear canal and is leaking air. Adjust the position of the earplug so that the light goes out. You do not have to stop the device if you see the indicator light. Three attempts are allowed to get a tight fit before the device will automatically stop.

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The treatment starts when the indicator  is lit with a steady green light. The Meniett device performs three treatment cycles of 60 seconds each. The treatment cycles are separated by pauses of 40 seconds, during which the indicator will flash.

Please try to relax during the treatment, and keep your head in an upright position.

The Meniett device will not indicate that the tubing is blocked. If you cannot feel the pressure pulses, you should adjust the position of the earplug. If that does not help, make sure that the earplug or tubing is not blocked. If there still is no sensation of the pressure pulses, your hearing level may not be high enough to feel them. A common symptom of Meniere's disease is fluctuating hearing loss. Note: Some users may not experience the pulses. Check with your doctor for advice.

When the indicator  lights up, the treatment is completed. Remove the earplug from your ear and switch off the Meniett device.

Compliance

In general, doctors prescribe a minimum of three treatments per day. Failure to comply with the prescribed treatments per day may affect the efficacy of the Meniett device.

The expected service life of the Meniett is at least 5 years, assuming 15 minutes of treatment per day.



The meaning of the symbols



Start/Stop button. Button for manual switch on and off.

Normal Operation - Lighted indicators



Treatment in progress.



Treatment successfully completed.

Troubleshooting - Lighted indicators



Treatment has been stopped due to low battery power. Switch off and connect the device to a wall socket for further treatment. See the **Maintenance** section of this guide for instructions on recharging the battery.



Air leakage. Adjust the position of the earplug in the ear canal until the light goes out. If the indicator  is lit-up, the earplug is not properly seated in the ear canal and is leaking air. Adjust the position of the earplug so that the light goes out. In this case, start a new treatment and watch the leakage indicator. If this problem occurs frequently, please contact your supplier.

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Troubleshooting - Flashing indicators



The Meniett device is warming up or is in standby mode between two treatment phases.



The treatment has been interrupted due to:

- a) The surrounding temperature is too high or too low. The Meniett device should be kept at normal room temperature during the treatment.

SI Units (Operating temperature range)	American National Standard Units (Operating temperature range)
+15° to + 35°C	59° to + 95°F

- b) The Meniett device is not level. Please place the Meniett device on a stable surface and start a new treatment.
- c) The Battery is low.



Technical error. All indicators on the front panel are flashing. Contact your supplier for advice.

Other symbols

	Type BF Applied Part		Serial number
	Socket for power supply		Caution
	RF Transmitter (Interference may occur)		Date of Manufacture
	Recharging of the battery pack in progress		Operating temperature range
	Power supplied via the power cord – included in the set		Follow instructions for use
	ROHS - Environmental friendly use period - China (SJ/T11364-2006.)		Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	Manufacturer LiNA Medical ApS Formervangen 5, DK-2600 Glostrup, Denmark		
	Conformité européenne (European Conformity). This symbol means that the device fully complies with European Directive 93/42/EEC.		
	Ingress protection rated IP21: Protected against solid foreign objects of 12.5 mm diameter or greater, and protected against vertically falling water drops.		
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See meniett.com/recycling for instructions on proper disposal of this product.		

Maintenance

Power supply via a wall socket

Connect the power supply to the socket on the back of the Meniett device (Figure 3). Connect the plug to a wall socket. Make sure that the power supply indicator lights up.

Figure 3



Recharging of the battery pack

The Meniett device is equipped with a rechargeable battery pack. The battery pack is automatically recharged when the Meniett device is connected to a wall socket. When the battery pack is fully charged or during treatment, the recharging is interrupted. The recharging is indicated by the *Battery Recharging* indicator on the back of the Meniett case. It takes approximately 2 hours to fully recharge the battery pack. Try not to let the battery discharge completely, as it will become more difficult to recharge. When the *Battery Recharging* indicator light goes out, the battery is fully charged.

Note: You may hear a rattling sound in the Meniett device. The sound is due to a built-in position sensor.

The expected service life of the battery pack is at least 500 charge/discharge cycles.

Figure 4

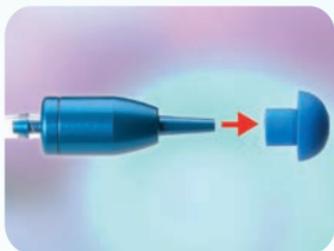


Figure 5

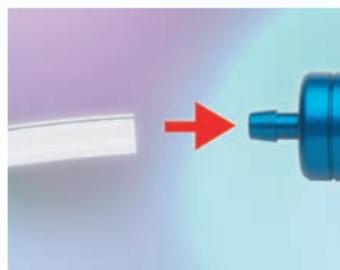


Figure 6



Do not allow liquid or cleaning detergents to enter tubing or equipment.

Changing and cleaning of the earplug and earplug connector

Carefully remove the earplug from the earplug connector (Figure 4). Then remove the earplug connector from the tubing (Figure 5). Use only mild soap and water when cleaning the earplug and earplug connector (Figure 6). As soon as both the earplug and the earplug connector are completely dry, they may be remounted to the tubing. Make sure that both parts are properly connected.

NOTE: Liquid or cleaning detergents must not enter the tubing.

Cleaning of the Meniett device

Clean the Meniett device carefully with a damp cloth. Water must not enter the equipment as this may cause electrical failure.

Environment

Keep the Meniett device in a normal indoor environment. Keep the Meniett device out of reach of unauthorized use. When in use, the Meniett device should be kept at normal room temperature. When not in use, the Meniett should be stored in its case within the environmental conditions stated in this guide.

Technical information for the Meniett device

Classification

The Meniett is an internally powered Class II electrical appliance for continuous operation conforming to IEC 60601-1 3rd Edition.

Data

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Characteristic	SI Units	American National Standard Units
Pressure pulse range	0 to 1.40 kPa	0 to 0.2 psi
Size (l x w x h)	154 x 115 x 51 mm	6 x 4.5 x 2 inches
Weight, including battery power supply	690 g	1.5 pounds
Operating conditions		
Temperature	+15°C to +35°C	+59°F to +95°F
Relative humidity (non-condensing)	15% to 93%	15% to 93%
Atmospheric pressure	700 hPa to 1060 hPa	10.15 PSI to 15.37 PSI
Storage conditions		
Lower temperature (no humidity control)	-20°C	-4°F
Upper temperature (up to 93% RH, non-condensing)	+70°C	+158°F

Content of Meniett device

The following components are delivered with the Meniett device:

- The Meniett Low-Pressure Pulse Generator
- Case
- Power supply
- Earplug connector
- User Guide
- Earplugs (6)
- Battery pack

Guidance and manufacturer's declaration – electromagnetic immunity – Part I

Guidance and manufacturer's declaration – electromagnetic immunity – Part I

The Meniett is intended for use in the electromagnetic environment specified below. The customer or the user of the Meniett should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-2	±8 kV air	±8 kV air	
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply lines	<5 % UT for 0.5 cycle	<5 % UT for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Meniett requires continuous operation during power mains interruptions, it is recommended that the Meniett be powered from an uninterruptible power supply or a battery.
	40 % UT for 5 cycles	40 % UT for 5 cycles	
	70 % UT for 25 cycles	70 % UT for 25 cycles	
IEC 61000-4-11	<5 % UT for 5 sec	<5 % UT for 5 sec	
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			

Note: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

The Meniett is intended for use in the electromagnetic environment specified below. The customer or the user of the Meniett should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Meniett uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Meniett is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the Meniett

Recommended separation distances between portable and mobile RF communications equipment and the Meniett

The Meniett is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Meniett can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Meniett as recommended below, according to the maximum output power of the communications equipment.

Rated maximum power of transmitter W	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration electromagnetic immunity - Part II

Guidance and manufacturer's declaration – electromagnetic immunity - Part II

The Meniett is intended for use in the electromagnetic environment specified below.
The customer or the user of the Meniett should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Meniett, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF	3 Vrms	3 Vrms	$d = 1.2 \sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	3 V/m	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Meniett is used exceeds the applicable RF compliance level above, the Meniett should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Meniett.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Precautions

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Use of accessories and cables other than those specified and sold by your supplier may result in increased emissions and decreased immunity of this unit.

The Meniett should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Meniett should be observed to verify normal operation in the configuration in which it will be used.

Warnings

- No modification to this equipment is allowed.
- It can be unsafe to:
 - use accessories, detachable parts or materials not described in this guide.
 - connect the Meniett to any other equipment not described in this guide.
- Consult your physician regarding any medication being used before beginning treatment with the Meniett device.
- The Meniett is not a toy. Keep out of the reach of children and pets.
- This device contains small parts, cables and tubing that may pose a strangulation or choking hazard.
- If there are noticeable changes in the performance of the Meniett, or adverse effect during treatment, immediately discontinue use and consult your physician.

Service

For service or repair please contact your supplier.

Limited warranty

- A. This LIMITED WARRANTY provides assurance for the customer who purchases a Meniett Low-Pressure Pulse Generator (hereinafter the “Product”) that should the Product fail to function to the published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), your supplier will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from an authorized distributor or representative.
- B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
- (1) The Product must be used on or before its “Use By” or “Use Before” date, if applicable.
 - (2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
 - (3) your supplier must be notified in writing within thirty (30) days following discovery of a defect.
 - (4) The Product must be returned to your supplier within thirty (30) days of your supplier receiving notice as provided for in (3) above.
 - (5) Upon examination of the Product by your supplier,

it shall have been determined that: (i) the Product was not repaired or altered by anyone other than the manufacturer or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

- C. This LIMITED WARRANTY is limited to its express terms. **THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** In no event shall your supplier be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.
- D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

Caution

Applicable law may restrict the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.

Returns and/or Repairs

EN Contact your supplier to obtain a Return Goods Authorization number (RGA#) prior to shipping the Product to your supplier. Please have the original invoice number or purchase order number available to assist in verifying warranty information. The RGA# should be prominently displayed on the box and included on all paperwork enclosed with the return and/or repair. All Product returned to your supplier should be safely packed in protective wrapping.

Customer must supply the Purchase Order number; the correct shipping and billing address; and either a completed Repair Order Form or a statement of the problem or reason for return.

In no event shall your supplier or the manufacturer and its affiliates be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

Customer responsibility

This product and its components will perform reliably only when operated and maintained in accordance with your doctor's instructions, the instructions contained in this manual, accompanying labels, and/or product inserts. A defective product should not be used. Parts which may be broken or missing or are plainly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from your supplier. The responsibility of your supplier for a defective product is limited by the warranty set forth in this manual. Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from the supplier prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the unit is functioning properly and ready for use. The owner of this product has sole responsibility for any malfunction resulting from improper use or maintenance, or by repair by anyone other than the manufacturer or its affiliates and from any malfunction caused by parts that are damaged or modified by anyone other than the manufacturer or its affiliates.

Assistance

Please contact your supplier for assistance in setting up, or maintaining the Meniett, or to report unexpected operation or events.

Accessories for your Meniett device

Please contact your supplier to order accessories for your Meniett device.

Reference the part numbers listed below for the items you'd like to order.

Part number	Description
MT-GEN	Meniett Pulse Generator
MT-BATT	Meniett Battery Pack, 9.6 VDC, 1/each
MT-EP-CON	Meniett Earplug Connector, 1/each
MT-POW	Meniett Power Supply, 1/each
MT-CASE	Meniett Carrying Case, 1/each
MT-IFU-EU	Meniett User Guide, Continental Europe, 1/each
MT-CAB-EU	Meniett Power Cord, Continental Europe, 1/each
MT-CAB-UK	Meniett Power Cord, U.K. & Ireland, 1/each
MT-CAB-US	Meniett Power Cord, North America, 1/each
MT-CAB-AUS	Meniett Power Cord, Australia & New Zealand, 1/each
MT-EP-11	Earplug, Grey, 11mm, 12/bag
MT-EP-12-5	Earplug, Red, 12.5mm, 12/bag
MT-EP-14	Earplug, Green, 14mm, 12/bag
MT-EP-16	Earplug, Blue, 16mm, 12/bag
MT-EP-18	Earplug, Grey, 18mm, 12/bag
MT-EP-19	Earplug, Clear, 19mm, 12/bag

Please contact your doctor or health care practitioner if you have questions concerning your treatment with the Meniett Low-Pressure Pulse Generator.

