Aurical® Otocam 300

Aurical Otocam 300 and the Video Otoscopy Module

User Guide

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natus

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Technical support
Please contact your supplier.

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1 Introduction

Aurical Otocam 300 is a video otoscope (VO) for visually inspecting and capturing pictures of the ear canal, the tympanic membrane or other such applications. Aurical Otocam 300 is used in connection with the Otosuite Video Otoscopy module to capture and edit pictures.

2 Intended use

2.1 Aurical Otocam 300 and the Otosuite Video Otoscopy module

Users

Audiologists, hearing instrument dispensers, ENT doctors and other trained personnel. Please note that local regulations may define users for video otoscopy differently. Local regulations must be complied with at all times.

Use

To visually inspect the ear canal and the tympanic membrane, and to capture and store pictures of the ear canal and the tympanic membrane, or other such applications.

Intended patient population

The intended patient population is all patient groups from pediatric through adulthood.

2.2 Specula with cerumen management

Please note that the use of specula with cerumen management may require special training in order to authorize personnel to carry out cerumen removal. These requirements are locally defined. Local regulations must be complied with at all times.Natus Medical Denmark ApS cannot be held responsible for unauthorized use of specula.

3 Typographical conventions

The use of Warning, Caution and Note

To draw your attention to information regarding safe and appropriate use of the device or software, the manual uses precautionary statements as follows:

Warning • *Indicates that there is a risk of death or serious injury to the user or patient.*

Caution • *Indicates that there is a risk of injury to the user or patient or risk of damage to data or the device.*

Note • *Indicates that you should take special notice.*

4 Unpacking

1. Unpack the device carefully.
   When you unpack the device and accessories, it is a good idea to keep the packing material in which they were delivered. If you need to send the device in for service, the original packing material will protect against damage during transport, etc.
2. Visually inspect the equipment for possible damage.
   If damage has occurred, do not put the device into operation. Contact your local distributor for assistance.
3. Check with the packing list to make sure that you have received all necessary parts and accessories. If your package is incomplete, contact your local distributor.

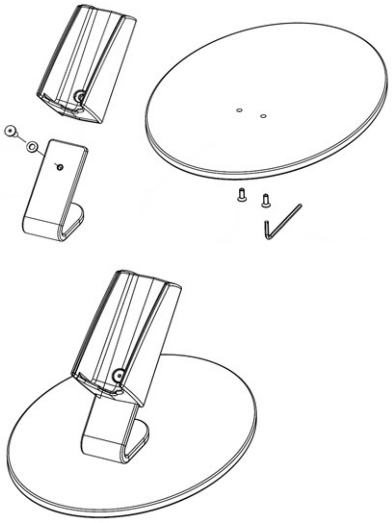
4.1 Storing

If you need to store Aurical Otocam 300 before you put it into operation, follow the guidelines below:

- Store Aurical Otocam 300 and accessories in the boxes provided to protect the equipment from damage.
- Store Aurical Otocam 300 and accessories in a dry environment.

5 Assembling

Only the cradle needs to be assembled. Use the supplied Allen key, screws and washer to assemble the cradle as shown.



5.1 Installing Otosuite

Install Otosuite on the PC before you connect to Aurical Otocam 300 from the PC.

For Otosuite installation instructions, see the Otosuite Installation Guide, on the Otosuite installation medium.

5.2 Connecting Aurical Otocam 300 to Otosuite

1. Connect the USB cable of Aurical Otocam 300 to one of the computer's USB ports.

   Aurical Otocam 300 is powered through the USB connection to the PC.

   If you are using Aurical Otocam 300 in connection with Aurical® Aud, you can alternatively connect Aurical Otocam 300 to one of the USB connections on the rear of Aurical® Aud.

2. Launch Otosuite and select the Otosuite Video Otoscopy module.

   Aurical Otocam 300 is automatically connected to the Otosuite Video Otoscopy module.

6 Switching Aurical Otocam 300 on and off

Switching on Aurical Otocam 300

1. Start up the computer.
2. Connect the USB cable of Aurical Otocam 300 to one of the computer's USB ports.
3. Launch Otosuite and select the **Video Otoscopy** module.
   - If Otocam 300 is not placed in its cradle, the light beam is switched on.
   - If Otocam 300 is placed in its cradle, the light beam is not switched on.

Note • *In order for the pre-heater to heat the camera tip to body temperature, Aurical Otocam 300 should remain in the cradle (connected to a PC which is powered on) for minimum 5 minutes before the camera is used. The time should be extended if Aurical Otocam 300 has been stored in a cold environment.*

Warning • *Do not stare into the light beam, or point the light beam in the direction of other people's eyes. It can damage the eyes.*

Switching off Aurical Otocam 300

To completely switch off Otocam 300, disconnect the USB cable from the computer.

7 The Aurical Otocam 300 cradle

The cradle is a multi-functional holder for your Aurical Otocam 300 when it is not in use. It controls the light source and the camera tip heating.

When Aurical Otocam 300 is placed in the cradle, the light source is turned off and the camera tip heating is turned on.

Avoid condensation

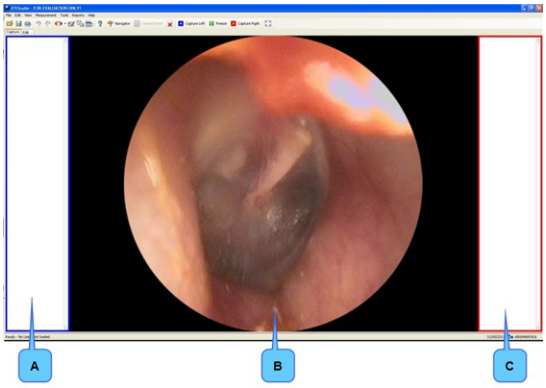
In Aurical Otocam 300 the built-in heater pre-heats the camera tip so that the temperature difference between the camera tip and the air inside the ear canal is minimal. The pre-heating function is activated when the Aurical Otocam 300 is plugged into the PC (which is powered on) and placed in its cradle. In order for the pre-heater to heat the camera tip to body temperature, Aurical Otocam 300 should remain in the cradle for approx. 5 minutes before the camera is used.

8 Capturing and editing pictures with Video Otoscopy

The **Video Otoscopy** screen is divided into three main sections.

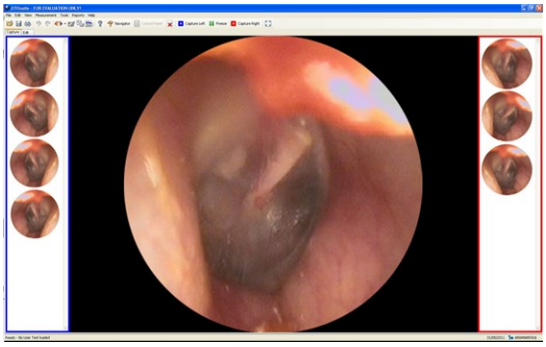
Before capturing pictures

If Aurical Otocam 300 is connected, the **Video Otoscopy** module opens up showing a live image.



A. Left Picture Panel
B. Main work area
C. Right Picture Panel

After capturing pictures



The left and right **Picture Panels** list the pictures you capture.

8.1 Capture mode

In **Capture** mode you can inspect the ear and capture pictures with Otocam 300.

The Capture toolbar

Delete All Pictures	
	Delete all pictures captured in this session.

Icon	Aurical Otocam 300	Shortcut	Capture
		**L**	Capture the picture as **Left Ear**.
		**R**	Capture the picture as **Right Ear**.

Freeze	
You can freeze a picture before capturing it as a picture.	
	1. To freeze the image, click the **Freeze** icon in the toolbar or press the **Spacebar**. 2. If needed, click the **Freeze** icon or press the **Spacebar** to unfreeze the image.

Full Screen mode	
	Displays a full screen view of the selected picture. Press **Esc** to return to regular viewing mode.

8.2 Capturing a picture

1. In Otosuite, click **Capture** in the **Video Otoscopy** section of the **Navigation Panel**. The **Video Otoscopy** module is launched and Aurical Otocam 300 is active.

> ***Warning*** • *Do not stare into the light beam, or point the light beam in the direction of other people's eyes. It can damage the eyes.*

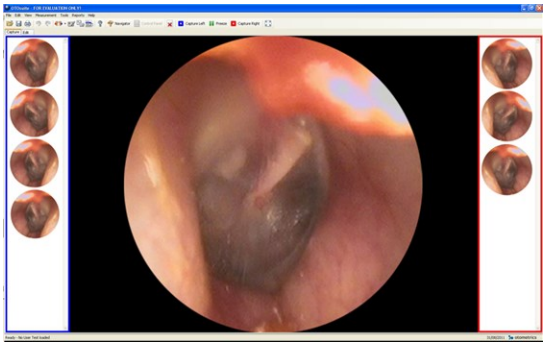
2. Press a speculum onto the tip of Aurical Otocam 300.

> ***Warning*** • *Be careful when you insert the speculum in the ear of the patient - there is a risk of damaging the wall of the ear canal and/or the tympanic membrane.*

The specula must be disposed of after single use.

3. Insert the speculum on Aurical Otocam 300 in the ear of the client.

4. When a satisfactory image is obtained, press the **Right Ear** or **Left Ear** button on Aurical Otocam 300.



8.3 Edit mode

In **Edit** mode you can add markers and comments to the individual pictures.

The Edit toolbar

Delete All Pictures	
	Delete all pictures captured in this session.

Markers

• Click on the desired marker in the **Edit** toolbar. • Position the cursor at the point where you wish to place the marker and click once.

Eraser tool	
	• Select the **Eraser** tool and click on the marker that you wish to remove.

Pointer tool	
	The **Pointer** tool is selected as default. • When you no longer want to use the **Eraser** tool or a **Marker** tool, click on the Pointer tool in the toolbar.

Right-click functions

You can right-click on a picture in one of the **Picture Panels**, and in **Edit** mode also on the central picture.

Delete	
	Delete the selected picture.

Edit	
	Select the picture for editing.

Copy to Clipboard	
	Copy the selected picture including markers to the clipboard. You can paste the picture into other software programs.

Swap Ear	
	Assign a picture to the other ear.

Right-click functions on the central picture

Remove All Markers	
	Right-click anywhere in the central picture and select **Remove All Markers**.

Remove Marker	
	Right-click on one marker in the central picture and select **Remove Marker**.

9 Service, cleaning and maintenance

Warning • *Under no circumstances disassemble Otocam 300. Contact your supplier. Parts inside Otocam 300 must only be checked or serviced by authorized personnel.*

9.1 Service and repair

For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.

***Note** • There are no user-serviceable parts inside the Otocam 300 housing.*

9.2 Cleaning

Never use sharp or pointed objects for cleaning!

***Warning** • Do not clean the otoscope in an ultrasonic bath and do not gas-sterilize or autoclave the otoscope!*

1. Disconnect Aurical Otocam 300 from the computer.
2. Use a soft, slightly damp cloth with a small amount of mild detergent on it to clean the housing, camera head, plugs and cable.

   ***Caution** • Do not allow any moisture inside the device!*

3. If the glass surface of the lens is very dirty, use a cotton pad with alcohol to clean it.
4. After cleaning, remove the cleaning agents thoroughly by wiping with a cloth dampened with pure, deionised water.
5. Finally, carefully dry all surfaces of Aurical Otocam 300 and the glass surface of the lens with a soft cloth.

Cleaning accessories

Specula

Specula are disposable and therefore should not be cleaned or re-used.

There are no special requirements for the disposal of specula.

9.3 Maintenance

Aurical Otocam 300 requires no preventive maintenance except for cleaning and regular inspection of cable and plastic housing of the device.

***Warning** • For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.*

10 Troubleshooting

Problem	Cause	Solution
The camera view area in the Video Otoscopy module is black.	Direct 3D is not rendered correctly by the graphics card.	Update the PC's graphics card driver.

11 Other references

After you install Otosuite, you can find Otosuite manuals and related documentation on your PC. In the **Start** menu, open **Otosuite Manuals**, which contains an overview with links to all manuals.

12 Technical Specifications

Type identification

Aurical Otocam 300 is type 1076 from Natus Medical Denmark ApS.

Video system

Sensor	0.3 inch CMOS Digital Image Sensor
Lens System	10 micro lenses with fixed focus with large depth of field
Sensor resolution	720 (H) x 720 (V) pixels
Frame rate	24 frames/second
Output signals	USB 2.0

Optical data

Minimum working distance	10 mm (0.4 inches)

Preheater

The preheater is active when the Aurical Otocam 300 is plugged into the PC and placed in its cradle.

Preheater activation	Activated by magnet in cradle.
Preheater power	Heats camera distal tip to approx +5°C (9°F) above ambient temperature after 5 minutes of activation

Buttons

Freeze frame	Right/left ear

Electrical data

Supply voltage through USB port	
Input power	USB 2.0, Max. 500 mA.
Light source	2 LEDs, fibre-optic light guide
USB plug	USB, type A (LED power supply/Camera/Pre-heating)

Switch activated by magnet contact used to switch between pre-heating and light.

Mechanical data

Cable length	2700 mm (8.86 feet)
Length without cable	170mm (6.7 inches)
Weight including cable	250 g (8.8 ounces)
Largest diameter	45 mm (1.8 inches)
Distal diameter	max. 3.4 mm (0.134 inches)
Total weight	1300 g

Service life

Expected Service life	5 years

Storage environment

Temperature	-20°C to +60°C (-4°F to +140°F)
Relative humidity	<90%, non-condensing
Air pressure	500 hPa to 1060 hPa

Operating environment

Temperature	+10°C to +30°C (+50°F to +86°F)
Air humidity	30% to 75%, non-condensing
Air pressure	600 hPa to 1060 hPa

Essential performance

Aurical Otocam 300 has no essential performance.

Standards

Patient Safety	IEC 60601-1:2005+AMD1:2012 and EN 60601-1:2006+A1:2013
	CAN/CSA-C22.2 NO. 60601-1:14
	Class II; applied part Type BF; IPX0
	Endoscopic equipment: IEC 60601-2-18:2009 and EN 60601-2-18:1996 + A1:2000

EMC	IEC 60601-1-2:2007 and EN 60601-1-2:2007 IEC 60601-1-2:2014 and EN 60601-1-2:2015

12.1 Accessories

Accessory Name	Part Number
Desktop cradle	8-35-30800
Otosuite PC software	8-49-75800
Specula, normal (12 pcs)	8-62-42700
Specula, with cerumen management (12 pcs)	8-62-42710

12.2 Notes on EMC (Electromagnetic Compatibility)

Aurical Otocam 300 is part of a medical electrical system and is thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of Aurical Otocam 300.

IEC 60601-1-2:2014 and EN 60601-1-2:2015

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Aurical Otocam 300 is intended for use in the electromagnetic environment specified below. The user of Aurical Otocam 300 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	Aurical Otocam 300 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 CISPR11	Class B	Aurical Otocam 300 is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems
Aurical Otocam 300 is intended for use in the electromagnetic environment specified below. The user of Aurical Otocam 300 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 1 kV for input/output lines	+/- 1 kV for input/output lines	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	No relevant ports that could be affected	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems within Professional Healthcare use environment			
Aurical Otocam 300 is intended for use in the electromagnetic environment specified below. The user of Aurical Otocam 300 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V rms IISM Bands and Amateur	3 V rms 150 kHz to 80 MHz 6 V rms IISM Bands and Amateur	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Proximity fields from RF wireless communications IEC 61000-4-3	27 V/m 385 MHz 28 V/m 450 MHz, 9 V/m 710 MHz, 745 MHz, 780 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz, 28 V/m 1720 MHz, 1845 MHz, 1970 MHz 28 V/m 2450 MHz, 9 V/m 5240 MHz, 5500 MHz, 5785 MHz	27 V/m 385 MHz 28 V/m 450 MHz, 9 V/m 710 MHz, 745 MHz, 780 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz, 28 V/m 1720 MHz, 1845 MHz, 1970 MHz 28 V/m 2450 MHz, 9 V/m 5240 MHz, 5500 MHz, 5785 MHz	Separation distance between any electronic parts of Aurical Otocam 300 and any RF wireless communication equipment must be more than 30 cm (11.8 inches). **Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2:2007 and EN 60601-1-2:2007

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Aurical Otocam 300 is intended for use in the electromagnetic environment specified below. The user of Aurical Otocam 300 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	Aurical Otocam 300 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 CISPR11	Class B	Aurical Otocam 300 is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Aurical Otocam 300 is intended for use in the electromagnetic environment specified below. The user of Aurical Otocam 300 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 1 kV for input/output lines	+/- 1 kV for input/output lines	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
Aurical Otocam 300 is intended for use in the electromagnetic environment specified below. The user of Aurical Otocam 300 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of Aurical Otocam 300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 80 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 metres (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 this symbol: ((•))
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	
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.			
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 Aurical Otocam 300 is used exceeds the applicable RF compliance level above, the Aurical Otocam 300 should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Aurical Otocam 300. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and Aurical Otocam 300

The Aurical Otocam 300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aurical Otocam 300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aurical Otocam 300 as recommended below, according to the maximum output power of the communications equipment.

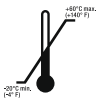
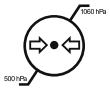
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

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.			

13 Definition of symbols

 ISO 15223-1 Symbol 5.1.1	Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
 ISO 15223-1 Symbol 5.1.3	Date of manufacture. Indicates the date when the medical device was manufactured.
 ISO 15223-1 Symbol 5.1.7	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.
 ISO 15223-1 Symbol 5.1.6	Catalog/product number Indicates the manufacturer's catalogue number so that the medical device can be identified.
 IEC 60601-1 Table D.1 #20	Type BF applied part Complies with Type BF requirements of IEC 60601-1.
 93/42/EEC	CE marking of conformity Certification mark that indicates conformity with applicable regulations and directives for the European Economic Area.

MD	Medical device
LOT ISO 15223-1 Symbol 5.1.5	Use-by date Indicates the date after which the medical device is not to be used.
 ISO 15223-1 Symbol 5.4.2	Do not reuse. Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
℞ ONLY 21 CFR Part 801. §801.109(b)(1)	Device is cleared for the US market as requiring a prescriptionUSA Code of Federal Regulations. 21 CFR Part 801. § 801.109(b)(1)
 ISO 15223-1 Symbol 5.4.3 and IEC 60601-1 Table D.1 #11	Consult instructions for use Indicates the need for the user to consult the instructions for use.
 IEC 60601-1 Table D.2 #10	Follow instructions for use
	Complies with Class II requirements of the safety standard IEC 60601-1:2005+AMD1:2012 and EN 60601-1:2006+A1:2013.
	MEDICAL - General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1:2005 + A1:2012, C1:2009/(R)2012 and A2:2010 (R)2012, CAN/CSA-C22.2 NO. 60601-1:14 , IEC 60601-1:2005+A1:2012.
 ISO 15223-1 Symbol 5.3.8	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.

 ISO 15223-1 Symbol 5.3.7	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
 ISO 15223-1 Symbol 5.3.9	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
Made in China	Made in China Indicates that the device is manufactured in China.
Made in Thailand	Made in Thailand Indicates that the device is manufactured in Thailand. (Accessories only.)
 2012/19/EU	Electronic equipment covered by the Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Natus Medical Denmark ApS, or to any Natus Medical Denmark ApS supplier. You can also contact your local authorities for advice on disposal. See the full Natus Medical Denmark ApS WEEE statement below.

WEEE Statement

Natus is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Regulations 2014. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus may pass along the obligation for take back and recycling to the end user, unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at www.natus.com

Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the crossed-out wheeled bin is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.

14 Warning notes

This manual contains information and warnings, which must be followed to ensure the safe performance of the devices and software covered by this manual. Local government rules and regulations, if applicable, should also be followed at all times.

When the Video Otoscopy module is used in conjunction with a device (including devices other than those produced by Otometrics), make sure that all information and warnings in the documentation of the device are followed.

- Do not stare into the light beam, or point the light beam in the direction of other people's eyes. It can damage the eyes.
- For continued protection against fire hazard, replace fuses with the same type and rating only.
- Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.
- No parts may be eaten, burnt, or in any way used for purposes other than the applications defined in the Intended Use section of this manual.
- For safety reasons and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
- This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
- Unwanted noise may occur if the device is exposed to a strong radio field. Such noise may interfere with the performance of the device. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of Aurical Otocam 300 be restricted.
- RF emissions from Aurical Otocam 300 are very low and are not likely to cause any interference in nearby electronic equipment. However, local devices placed in close vicinity of Aurical Otocam 300 may experience a negative effect or loss of functionality..
- It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.
- We recommend that the device should not be stacked with other equipment or placed in a poorly ventilated space as this may affect the performance of the device. If it is stacked or placed adjacent to other equipment, make sure that the operation of the device is not affected.
- Before use, ensure that live video is provided on the screen.
- Before each use of Otocam 300, make sure there are no rough surfaces, sharp edges or protrusions.
- The distal tip may be warm.
- To prevent cross-infection or re-infection, do not use the device without a speculum mounted on the distal tip.
- To prevent cross-infection or re-infection, the speculum must be disposed of after single use.
- Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.
- Aurical Otocam 300 is intended for use by audiologists and other trained health care professionals in visually inspecting the ear canal and tympanic membrane.
- Do not use the device for uses other than those described in the Intended Use section. For example, do not use the device for examination of nasal cavities, eyes or larynx.
- Do not store or operate Aurical Otocam 300 at temperatures and humidity exceeding those stated in Technical Specifications. Noncompliance can have negative effects on performance and/or cause degradation of device components.

- Be careful when you insert the speculum in the ear of the patient - there is a risk of damaging the wall of the ear canal and/or the tympanic membrane. Do not apply excessive force to the outer ear with the speculum.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the country or the EU Member State in which the user and/or patient is established

When you connect other electrical equipment to Aurical Otocam 300, remember that equipment that does not comply with the same safety standards as Aurical Otocam 300 can lead to a general reduction in the system's safety level. The equipment must comply with IEC 60950.

When selecting accessories connected to the Aurical Otocam 300, the following points must be considered:

- Use of connected equipment in a patient environment
- Proof that connected equipment has been tested in accordance with IEC60601-1 and/or IEC60601-1-1

Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.

15 Manufacturer

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15.1 Responsibility of the manufacturer

The manufacturer is to be considered responsible for effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.