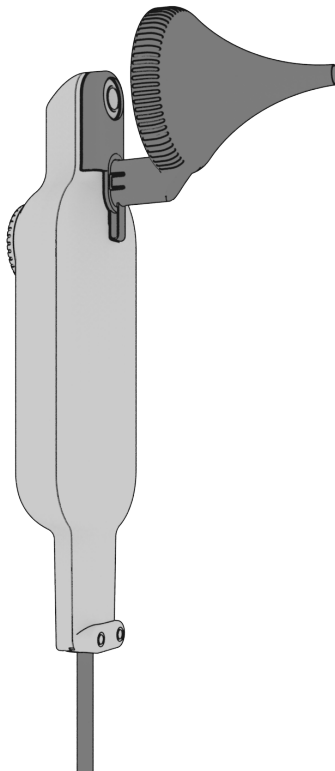


Audelation Ltd.



Instructions For Use (IFU)



Read instructions for use carefully before use.
Keep for future reference.



Table of Contents

Introduction	3
Intended Purpose	3
Intended Users and Patient Population	3
Intended Users	3
Patient Population	3
Indications	4
General Warnings and Cautions	4
Product Description and System Overview	6
Unpack	7
Unpacking the OWL	7
Assembly	8
Selecting a Speculum	9
Assembly of the Speculum to the Digital Otoscope	9
Removal of the Speculum from the Digital Otoscope	10
Set-up for Use and Operating Instructions	11
OWL Set-up	12
Operation of the OWL	16
Packing Away for Storage	19
Cleaning	19
Cleaning the OWL	19
Maintenance and Troubleshooting	20
Servicing	20
Ordering Devices, Consumables, Spare Parts and Accessories	20
Troubleshooting	20
Technical Data	22
Essential Performance	22
Symbols on the OWL and Documentation	23
Labelling on the OWL	24
Precautions for Electromagnetic Interference	24
Technical Specification	25
Disposal	26
Reporting Serious Incidents	26
Returns	26
Manufacturer Contact Details	26
Technical Support	26
EU Authorised Representative	26



Introduction

The OWL product is a portable digital camera system that maintains visualisation of the ear canal while simultaneously allowing instrumentation access for procedural work such as wax removal.

The OWL may be used to capture images and videos allowing users to share with their patient and to the patient record or with other clinicians for advice, communication, or training.

It is essential to read, understand, and strictly observe all warnings, precautions, contraindications, notes, and safety markings within this document and on the product. This product is for use by qualified and trained healthcare professionals familiar with currently known risks and benefits of digital otoscopy use.

Intended Purpose

The product shall be used by trained healthcare professionals, in a clinical setting, to visualise inside the ear canal during procedures of aural microsuction or instrumentation. Aural microsuction uses a suction probe (typically Zollner suction device) to remove wax by suction, instrumentation includes tools such as forceps and hooks.

Intended Users and Patient Population

Intended Users

The product shall be used by trained clinicians, including ENT (ear, nose & throat) doctors and nurses, otorhinolaryngologists, audiologists, healthcare assistants and primary care physicians.

Patient Population

Our product is aimed for persons >18 years of age for procedural work. Digital imagery (video/still shots) photography is unrestricted for age. Though not part of the equipment, it is good practice to obtain consent in the taking and storage of digital imagery by patients.

Regarding children – we recognise that adult size specula can fit older children and so otoscopy/procedural work maybe possible. However we advise consulting with local clinical guidelines.



Indications

The indications for using the product are for the outer ear examination (video otoscopy) and using the video system to perform aural microsuction or instrumentation to remove wax and debris from the outer ear canal (surgical tools not supplied).

General Warnings and Cautions



Serious injuries to a user or patient can occur if warnings are not followed.

- The product is designed for appropriately trained healthcare workers.
- It is not designed for patients to use themselves or for non-professionals.
- Do not use the digital otoscope if damaged (e.g., if the casework is cracked).
- Do not use the speculum if damaged (e.g., if the plastic is cracked or has sharp edges at the tip).
- Do not use the cable if damaged.
- The speculum is single use only. Dispose of the speculum after each patient use.
- The digital otoscope and accessories such as the speculum are not supplied sterile, nor are they intended to be sterilised; ensure the digital otoscope is cleaned before use.
- Do not connect the digital otoscope cable to a PC, laptop or tablet until the speculum is assembled.
- Ensure cables are routed correctly and safely.
- The cable is fragile and should not be pulled or sharply bent in use.
- Use of accessories and cables other than those specified or provided by the manufacturer could result in improper operation.
- Use of accessories and cables, other than those provided by the manufacturer, may result in increased electromagnetic emissions, or decreased electromagnetic immunity. This may result in improper operation of this device or others nearby.
- The digital otoscope must be connected to an appropriate power source (i.e., a CE marked laptop or PC)
- The battery status of any laptop being used should be checked prior to use.
- Do not use the digital otoscope without the specified speculum by the manufacturer. Use of a third-party speculum may lead to injury.



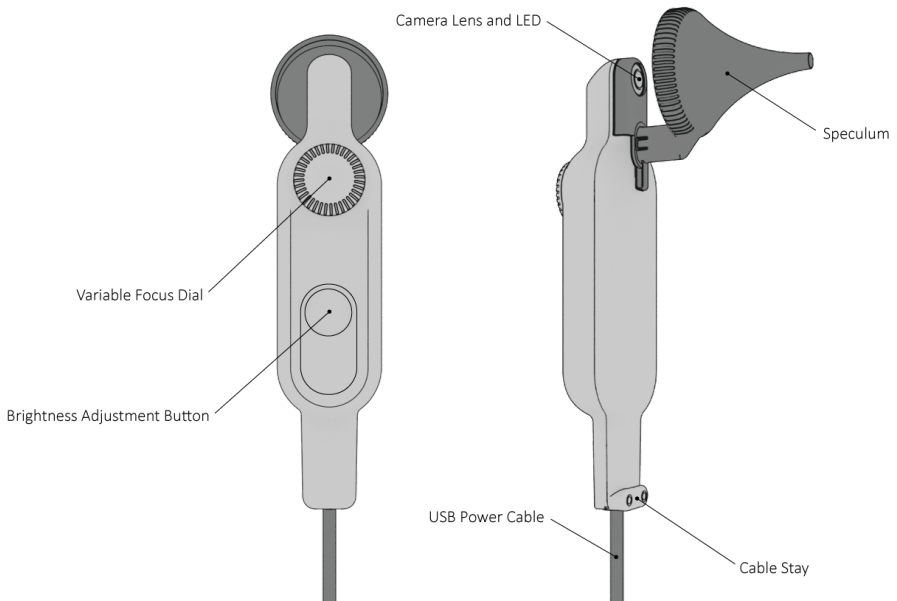
- Care should be employed while using the speculum and digital otoscope inside a patient's ear.
- Do not look at the LED light source on the digital otoscope or point the LED light source towards the patient's eyes.
- Do not use the digital otoscope if the device feels hot to handle.
- Do not attempt to clean the digital otoscope until it is unplugged from the power source.
- Do not attempt to deep clean the digital otoscope until it has cooled down sufficiently to be comfortable to the touch.
- No modification of this equipment is allowed.
- Care must be taken to ensure that additional equipment connected to the patient is electrically safe.



Product Description and System Overview

The OWL is a digital otoscope that allows high quality imaging of the outer ear canal and tympanic membrane and dual function capability of the insertion of instruments such as suction and surgical instruments to de-obstruct ears. The OWL allows digital capture of images and videos and is connected by wire to a laptop or PC.

The OWL uses a disposable bespoke engineered specula with a built-in gap that helps to protect the instrumentation and SpecGuard from contamination.





Unpack



Serious injuries to a user or patient can occur if warnings are not followed.

- Do not use the digital otoscope if damaged (e.g., if the casework is cracked).
- Do not use the speculum if damaged (e.g., if the plastic is cracked or has sharp edges at the tip).
- Do not use the cable if damaged.
- The digital otoscope and accessories such as the speculum are not supplied sterile, nor are they intended to be sterilised; ensure the digital otoscope is cleaned before use.

Unpacking the OWL

1. Remove all packaging materials from the device.
2. Check all parts are present. – Instructions for use (IFU) and a device with cable pre-assembled.
3. Unpack speculum from separate boxes and remove outer packaging.
4. Check the parts for any damage.

NOTE: Do not use parts if packaging is damaged.

5. Ensure the digital otoscope and speculum are clean before assembly.



Assembly



Serious injuries to a user or patient can occur if warnings are not followed.

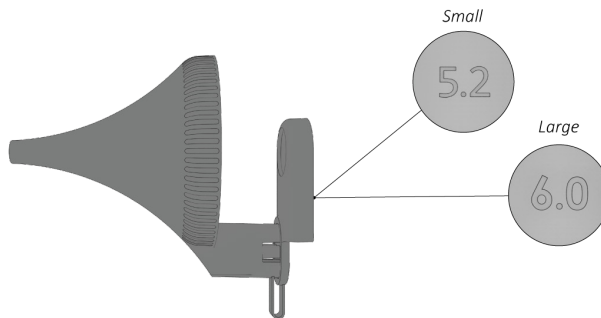
- Do not connect the digital otoscope cable to a PC until the speculum is assembled.
- Ensure cables are routed correctly and safely to prevent trip hazards.
- Use of accessories and cables other than those specified or provided by the manufacturer could result in improper operation.
- Use of accessories and cables, other than those provided by the manufacturer, may result in increased electromagnetic emissions, or decreased electromagnetic immunity. This may result in improper operation.
- The digital otoscope must be connected to an appropriate power source. The battery status of any laptop being used should be checked prior to use.
- Do not use the digital otoscope without the specified speculum by the manufacturer. Use of a third-party speculum may lead to injury.
- Care must be taken to ensure that additional equipment connected to the patient is electrically safe.



Selecting a Speculum

1. There are two sizes of disposable speculum available (5.2 mm and 6mm outer diameter). Unpack the appropriately sized speculum for the patient based on clinical need. Test the speculum size in the patients' ear. The 5.2 mm outer diameter speculum is approximately the same size as a 4.2 mm Welch Allyn speculum.

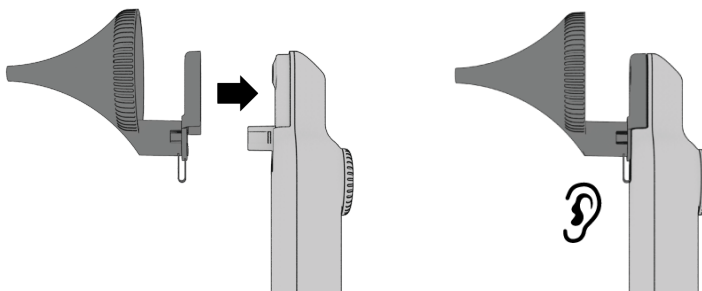
NOTE: We recommend that 5.2mm for general otoscopy alone and 6mm for ear instrumentation procedures.



CAUTION: Use only with the Audelation Speculum – Using a third-party speculum with the device could lead to injury.

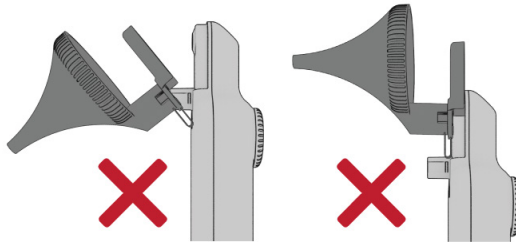
Assembly of the Speculum to the Digital Otoscope

1. Attach the selected speculum to the device. This can be done by a simple horizontal push fit, it will click into place when fitted correctly.





2. Avoid bending or angling the speculum post when fitting it to the OWL - this can cause undue stress on the speculum post causing it to potentially weaken and break.

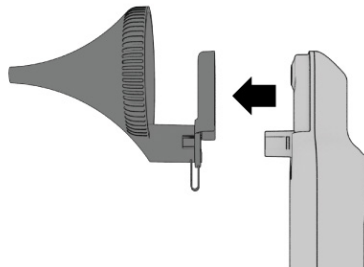


3. Ensure that the speculum sits well onto the lighting tower of the OWL.

NOTE: If you are having trouble with alignment – you can adjust the speculum with the camera so you can see the inner rim of the specula in its totality.

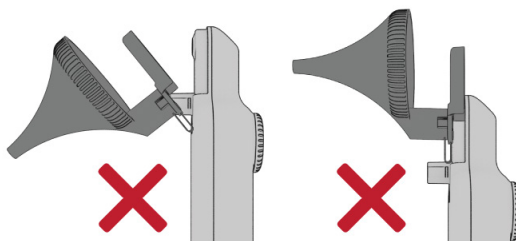
Removal of the Speculum from the Digital Otoscope

1. To remove the specula from the OWL – please pull the specula in a horizontal direction off the OWL.



NOTE: It may feel tight as the speculum is removed.

2. Avoid bending or angling the speculum post when removing it from the OWL - this can cause undue stress on the speculum post causing it to potentially weaken and break.





Set-up for Use and Operating Instructions



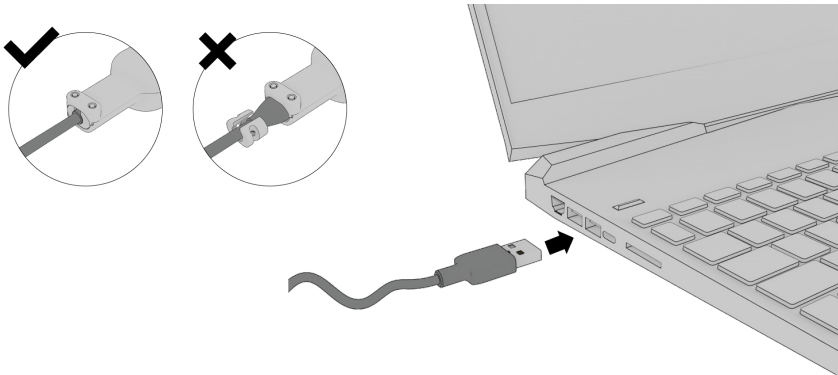
Serious injuries to a user or patient can occur if warnings are not followed.

- Do not use the digital otoscope if damaged (e.g., if the casework is cracked).
- Do not use the speculum if damaged (e.g., if the plastic is cracked or has sharp edges at the tip).
- The speculum is single use only. Dispose of the speculum after each patient use.
- Do not connect the digital otoscope cable to a PC until the speculum is assembled.
- Ensure cables are routed correctly and safely.
- Ensure the cable is not damaged before use.
- Ensure that an image is visible from the camera prior to use in patients.
- The cable is fragile and should not be pulled or sharply bent in use.
- Use of accessories and cables other than those specified or provided by the manufacturer could result in improper operation.
- Use of accessories and cables, other than those provided by the manufacturer, may result in increased electromagnetic emissions, or decreased electromagnetic immunity. This may result in improper operation.
- The digital otoscope must be connected to an appropriate power source. The battery status of any laptop being used should be checked prior to use.
- Do not use the digital otoscope without the specified speculum by the manufacturer. Use of a third-party speculum may lead to injury.
- Care should be employed while using the speculum and digital otoscope inside a patient's ear.
- Do not look at the LED light source on the digital otoscope or point the LED light source towards the patient's eyes.
- Do not use the digital otoscope if the device feels hot to handle.
- No modification of this equipment is allowed.
- Care must be taken to ensure that additional equipment connected to the patient is electrically safe.



OWL Set-up

1. Ensure that the USB-C cable is connected securely to the device which is then plugged into a PC or laptop. Check all wires are untangled and free to move without restriction.



CAUTION: Use only with the Audelation cable – Using a third-party cable with the device could lead to injury.

NOTE: The cable is fragile and should not be pulled or sharply bent.

NOTE: Ensure the connection is providing light.

2. When you connect to the computer – the LED's will turn on automatically.



CAUTION: Do not shine the bright light directly into eyes.

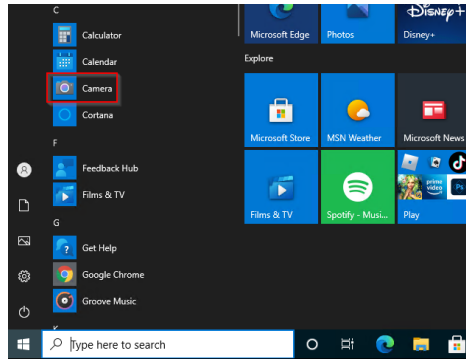
CAUTION: Equipment must be connected to an appropriate power source.

NOTE: Check the battery status is adequate the PC or laptop being used.

3. Ensure optimal clinician positional setup e.g., seating arrangement, screen in correct position to be easily visible (not obstructed by users' arms for example) and instruments in easy reach.



4. Connect to windows-based video software V10 or later (the camera app built into windows: accessed by typing 'camera' into the bottom left search bar).



5. Once this application is open, it will automatically use the laptop camera. To switch to the device, select the 'flip camera' icon that will appear in the top right corner and check that the screen image/video is live.



6. At the start of a clinical session, test the image projection by shining light on your hand to see if you can clearly see your skin. Also, test the variable function feature/mechanism and the gyroscope function.



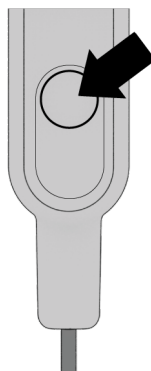
CAUTION: Do not shine the bright light directly in your eyes.



- The variable focus mechanism is a circular dial mechanism that rotates to get sharp focus from the tip of the speculum to approximately 20mm in front of it. It is designed to be single finger controlled in a rotation arc movement. The dial is designed that when the dial is at its starting position – the focus will be at the tip of the speculum and when rotated clockwise – the focus goes away from the tip of the speculum to a maximum of 20mm away from the tip of the speculum.



- The LED brightness adjustment is controlled by a button below the circular dial. Pressing it cycles through the 5 brightness options. The light by default switches on when connected to the computer. It will start on the lowest setting and cycle through the 5 options when pressed increasing in level of brightness. After the brightest setting – the light setting will cycle back to the lowest setting.



- Before you start, make sure you have selected the correct speculum by referring to pages 9 and 10.



10. Shine the light on an object e.g. back of your hand so you know that the image is working. Test functions such as variable focus for example start by rotating the wheel so the speculum tip is in focus and rotate around it so you can focus on a object such as skin on the back of your hand.
11. Check alignment before starting so that the majority, if not all, the specula end tip border is in view.
12. We recommend that when starting the variable focus is positioned so that the specula end point border is in focus.



Operation of the OWL

NOTE: The instructions are for using the OWL and not specifically about clinical technique performing otoscopy, ear instrumentation or wax procedures where only general guidance is given. Please refer to your own training and local guidance.

This device is intended for trained healthcare professionals only.

1. Before you start, make sure you have selected the correct speculum by referring to pages 9 and 10.
2. Insert speculum into patients' ear and adjust the brightness/focus as needed (using dominant hand). Hold the speculum at the circular grip with index and thumb of non-dominant hand and stabilise against patient's head in a bracing position.



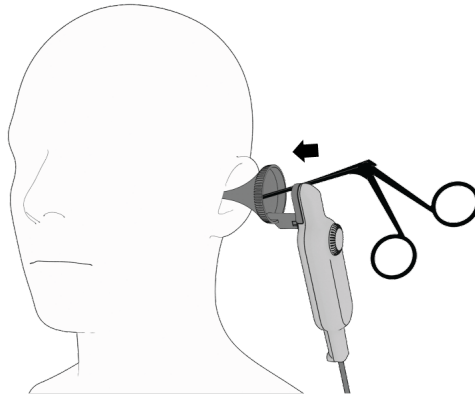
CAUTION: Take care when inserting into ear canal as poor use could cause damage to the ear canal.

NOTE: The braced position against the patient's head prevents insertion too deep into the ear canal.

3. Check the on-screen image and identify anatomical landmarks in the ear canal such as tympanic membrane/wax/ear canal then decide which tool is best suited based on the level of wax (e.g., suction/probe/forceps). You can use the variable focus feature to get clear views of the structures at varying distances while keeping the speculum steady and stable in the ear.



4. Manoeuvre tools and instruments for clinical procedures while viewing the on-screen live image (with dominant hand using instruments and non-dominant for safety brace against the patient's head and speculum control). Control the variable focus so the instruments/wax are in full focus throughout.



5. Control the lighting to prevent any “white-out” of the tissues in the area of interest.

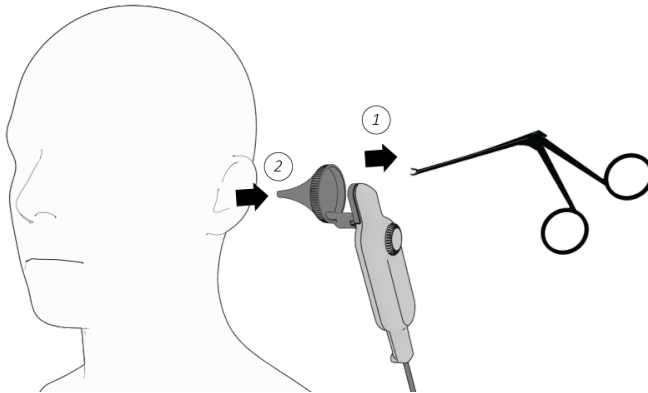
NOTE: The tympanic membrane is the furthest structure down the outer ear canal, when using a brighter setting to view, the tissues near the tip of the specula (e.g. eardrum wall) will be white due to being nearer the brighter illumination. Turn down the brightness to view the closer structures in better detail.

NOTE: If you need better access for instruments, you can consider rotating the OWL with your fingers. A typical use case is having the OWL in an 8 or 9 o'clock position when being held in the left hand or 3 or 4'clock position when held in the right hand. **If performing general otoscopy (without instruments) – this does not apply.**

6. You can also record video and capture images using the controls on the laptop/tablet software and you can assign through Windows separate keys for photography and video function.
7. A foot pedal is also available, which is connected by USB to the laptop. You may need to use a USB multi-port splitter (to buy separately) if your computer doesn't have enough USB ports. You can assign the foot pedal as a “key” to take photography or video within Windows.



8. When you finish procedure; remove any instruments from the ear canal before retracting the speculum and device (while directly looking at screen to ensure constant vision and avoid tissue injury).



9. Refer to pages 9 and 10 for correct specula removal and disassembly.



Packing Away for Storage

1. Disconnect the Audelation OWL cable from the laptop or tablet. Make sure to close down the windows camera application before unplugging the device.
2. Clean the device with anti-infection wipes and store away when not in use.
3. Please keep the OWL in a secure carry case - a padded/foamed hard case to prevent damage during transport.

Cleaning



- Only use recommended cleaning agents.
- Certain cleaning products may cause discolouration of the OWL.
- Some wipes can leave a residue - please consult wipe manufacturer.
- The Audelation OWL (camera unit and cable) is supplied clean but not sterile.
- The speculum is supplied clean but not sterile.
- The speculum is single use only and should be disposed of after each patient use.

Cleaning the OWL

1. Wipe down the Audelation OWL after each patient use with standard anti-infection wipes (such as Clinell Wipes).
2. The speculum can then be removed from the device and disposed of into clinical waste, along with any other instruments/swabs/gloves/wax debris, in line with your local protocols.



CAUTION: The speculum is single use and should be changed between patients.

NOTE: Remove the speculum straight off the device without twisting or pulling to the side – this could cause damage to the mounting point.



Maintenance and Troubleshooting

Servicing

The cable of the OWL is designed to be replaced. To change the cable – please use a blunt head Phillips head screw to release the screws and loosen the case. Once the case is loosened – you can gently pull it apart and then disconnect the wire from the OWL device.



CAUTION: When the case is pulled apart – this will expose the electronics so please do this in a clean environment with minimal dust and water vapour.

Ordering Devices, Consumables, Spare Parts and Accessories

Specula are sold in 2 sizes: 6 mm and 5.2 mm outer diameter end tip specula. The 5.2 mm outer diameter specula is of very similar size to a Welch Allyn 4.2 mm diameter specula.

The OWL is packaged with a 2 metre cable however longer cables are available on request and at additional cost.

Please contact info@audelation for availability, pricing and order size.

Troubleshooting

Fault	Solution
OWL device casework becomes hot	Mildly warm during prolonged use is expected from use. However, in the event the OWL becomes too uncomfortable to hold due to heat; do not use and if in warranty, contact info@audelation.com
Loss of video stream	Ensure USB cable is connected to the laptop/tablet. Ensure the laptop/tablet is connected to mains power or has adequate battery levels. Check that the USB cable is connected to the OWL. To request new cable, contact info@audelation.com
No visualisation	After checking that the video stream is running, please check speculum alignment.
LEDs come on but there is no video stream on the camera application	Unplug the device and plug in again after 10 seconds. Please contact info@audelation.com
Poor alignment	Adjust the specula to get a full view of the specula ring on the video.



USB driver incompatibility	Please update your Windows software and drivers with the latest patches and security updates. If there are further issues – contact info@audelation.com .
Can't find your images/videos	Please check the path on your computer system on where images/videos are saved.
Image is blurry	Check connections. Please check the cleanliness of the glass covering with the LED component is clear and free from obstruction.
LED failure	Please contact info@audelation.com
Faulty variable focus	Please contact info@audelation.com



Technical Data

The Audelation OWL has been classified as a Class I medical device under UK Statutory Instrument 2002 618 (European Medical Device Directive 93/42/EEC).

This device is approved for Electrical Safety according to the standards EN 60601-1-1:2012 (Edition 3.1) and for electromagnetic compatibility (EMC) EN 60601-1-2:2015.

Essential Performance

The Audelation OWL digital otoscope is a digital imaging system that can view, record and take photography of the outer ear canal.

The Audelation OWL is intended for use by healthcare professionals.















The Audelation OWL has been developed and tested to meet the following regulatory standards applicable to medical device regulation as applicable to the United Kingdom.

<u>Standard</u>	<u>Standard Title</u>
EN 60601-1:2006+A12:2014	Medical electrical equipment. General requirements for basic safety and essential performance.
EN 60601-1-2:2015+A1:2021	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests.



[Symbols on the OWL and Documentation](#)


The symbols and labels on the device have the following meanings:


Symbol	Description
	Name and address of the manufacturer Date of manufacture
	Model number
	Serial number
	Reference number
	Lot number
	UK Conformity Assessed marking
	Optical radiation warning
	Follow instructions for use
	Disposal in accordance with European Directive 2012/19/EU (WEEE)
	General warning
	Keep dry
	Non-sterile
	Single use part
	Do not use if packaging is damaged




Labelling on the OWL

CKM-0782-PI-vD

 Audelation Ltd,
Suite 63,
61 Praed St,
London,
W2 1NS, UK

 OWL



 DD/MM/YYYY



Otoscope, Model OWL

SN 00000000000000

EC **REP** **MD**

CEPartner4U
Esdoornlaan 13,
3951 DB Maarn,
Netherlands

CE **UK** **CA**  



Precautions for Electromagnetic Interference

The OWL product is approved for electrical safety according to the standards for EMC compatibility EN 60601-1-2:2015



Technical Specification

Product Name	Audelation OWL
Model Number	OWL001
User Control Settings	
Focus Control Dial	Manual focus adjustment - on video stream
Brightness Control Button	1-5 compensation steps to cycle - on video stream
Operating Environment	
Temperature	18°C to 25°C
Humidity	10-90% - RH non-condensing
Storage Conditions	
Temperature	0°C to 40°C
Humidity	10 to 90% - RH non-condensing
OWL Device Specifications	
Size	<152mm x 38mm x 38mm
Weight	<60g
Warranty Period	2 years
Manufactured Date	See device label
Speculum Specifications	
Product Life	Single use only - non-sterile
Sizes	5.2mm and 6mm
Manufactured Date	See device label
System Performance	
Power	From laptop or tablet via USB 3 or higher
Connection	USB-C to USB-C or USB-C to USB-A
Image Resolution	640×400 pixels
Image Orientation	Correct orientation <60 in Z direction
Field of View	6mm in diameter
Variable Focal Length	20mm beyond speculum tip
Image Circle Radius	0.76mm
Image Sensor Pixel Size	1.4µm x 1.4 µm



Disposal

Please dispose of the Speculum as hazardous medical waste in accordance with your local institution's standard procedures. If you have any queries, please refer to the local authorities responsible for waste disposal.

The unit contains electronics and should be disposed of via electronic recycling programmes.

Please dispose of Audelation OWL in accordance with the Waste Electrical and Electronic Equipment (WEEE) directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012. If you have any queries, please refer to the local authorities responsible for waste disposal.

Reporting Serious Incidents

Any serious incidents – please email info@audelation.com with the nature of the incident, any user or patient harm and what corrective measure you've taken.

Returns

Email info@audelation.com for more information regarding the return address.

Manufacturer Contact Details

Audelation Ltd,
Suite 63,
61 Praed Street,
London,
United Kingdom,
W2 1NS

www.audelation.com
info@audelation.com

Technical Support

info@audelation.com

UK Declaration of Conformity

TBC

