Jazz Instruments

INSTRUCTIONS FOR USE

Keeler

– A world without vision loss –

CONTENTS

	Consult instructions for use		General warning sign
	Date of manufacture		Warning: Electricity
	Manufacturer's name and address		Warning: Floor level obstacle
GB	Country of manufacture		Warning: Non-ionizing radiation
	Waste Electrical and Electronic Equipment (WEEE) recycling		Warning: Optical radiation
	This way up		Warning: Hot surface
	Keep dry	CE	Conformité Européene
	Fragile		Type B applied part
	Do not use if package is damaged		Class II equipment
	Temperature limit		Atmospheric pressure limitation
EC REP	Authorised representative in the European Community	%	Humidity limitation
REF	Catalogue number	SN	Serial number
A → 文	Translation	MD	Medical device

The Keeler Jazz Instruments are designed and built in conformity with Directive 93/42/EEC, Regulation (EU) 2017/745 and ISO 13485 Medical Devices Quality Management Systems.

Classification: CE: Class I

FDA: Class II

The information contained within this manual must not be reproduced in whole or part without the manufacturer's prior written approval. As part of our policy for continued product development we the manufacturer reserve the right to make changes to specifications and other information contained in this document without prior notice.

This IFU is also available on the Keeler UK and Keeler USA websites.

1. INDICATIONS FOR USE

These devices are intended to be used only by suitably trained and authorised healthcare professionals.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician or practitioner.

Intended use / purpose of instrument

The Jazz Ophthalmoscope is indicated for examining the posterior segment of the eye referred to as the fundus, in order to aid in the screening and diagnosis of retinal pathology including, but not limited to, diseases such as cataracts, papilledema, glaucomatous disc cupping, diabetic retinopathy, hypertensive retinopathy and retinal detachments. When set to a high power and magnification, it can also be used to examine the anterior segment of the eye, which includes the eyelids, cornea, sclera, conjunctiva, iris, aqueous, crystalline lens and anterior vitreous.

The Jazz Otoscope is indicated for the examination of the health of the external auditory canal, the tympanic membrane and the middle ear. Otoscopy can aid in the detection of ear conditions, including but not limited to earache, ear infection, hearing loss, ringing in the ears, inflammation and foreign bodies.

2. SAFETY

2.1 PHOTOTOXICITY

CAUTION: The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 21 minutes.

While no acute optical radiation hazards have been identified for Diagnostic Instruments, we recommend keeping the intensity of the light reaching the patient's retina to the minimum possible for the respective diagnosis. Children, people with aphakia and people suffering from eye conditions are most at risk. An increased risk may also occur if the retina is exposed to the same or a similar device with a visible light source within 24 hours. This applies, in particular, if the retina has been photographed with a flashbulb in advance.

Keeler Ltd shall on request, provide the user with a graph showing the relative spectral output of the instrument.

2.2 WARNINGS AND CAUTIONS

Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Keeler Ltd. The use of other accessories may result in increased electromagnetic emissions or reduced electromagnetic immunity of the devic e and may lead to incorrect operation.

Observe the following precautions in order to ensure safe operation of the instruments.

WARNINGS

- Never use the instrument if visibly damaged and periodically inspect it for signs of damage or misuse.
- Check your Keeler product for signs of transport / storage damage prior to use.
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment.
- US Federal Law restricts this device to sale by or on the order of a physician or practitioner.
- This device is intended to be used only by suitably trained and authorised healthcare professionals.
- If the product emits a strange odour, heat, or smoke, stop use immediately. The continued use of a damaged product or part may cause injuries.
- This product should not be immersed in fluid.
- No modification to this equipment is allowed.
- Instrument may become hot if used for extended periods of time.
- Do not touch battery terminals and the patient simultaneously.

CAUTION

- Use only genuine Keeler approved parts and accessories or device safety and performance may be compromised.
- Batteries must be inserted as per instructions – see section 4 on page 7.
- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C.
- LEDs become hot during use; caution should be taken when replacing LEDs.
- Keep out of the reach of children.
- To prevent condensation from forming, allow instrument to come to room temperature before use.
- For indoor use only (protect from moisture).

- There are no user serviceable parts inside. Contact authorised service representative for further information.
- Follow guidance on cleaning / routine maintenance to prevent personal injury / damage to equipment.
- Failure to carry out recommended routine maintenance as per the instructions in this IFU may reduce the operational lifetime of the product.
- At product end of life dispose of in accordance with local environmental guidelines (WEEE).
- The product and the ear specula are supplied non-sterile. Do not use on injured tissue.
- Use new or sanitised specula to limit the risk of cross-contamination.
- The disposal of used ear specula must occur in accordance with current medical practices or local regulations regarding the disposal of infectious, biological medical waste.
- Should the unit not be used for an extended period of time or whilst travelling, remove batteries from the handles.
- Insert new batteries when light intensity of the unit is reduced, thus affecting examination.
- For maximum light yield it is recommended to always insert new high-quality batteries on replacement.
- Never immerse handles in fluid. Ensure that no fluid or condensation penetrates into the handle.
- Do not use a battery that is deformed, leaking, corroded or visually damaged. Handle a damaged or leaking battery with care. If you come into contact with electrolyte, wash exposed area with soap and water. If it contacts the eye, seek medical attention immediately.
- Ensure battery orientation is correct, or personal injury / damage to equipment may occur.
- Do not mix battery types.
- Dry cell batteries should be removed if your instrument is not to be used for long periods.
- Do not disassemble or modify the battery. There are no serviceable parts inside
- Do not dispose of battery in fire, puncture or short circuit.
- Dispose of batteries in line with local environmental regulations.
- Tape over battery contacts to avoid short circuiting during disposal.

- After removal of the battery do not touch the battery contacts and the patient simultaneously.

- Do not exceed maximum recommended exposure time.

- After removal of the LED do not touch the LED contacts and the patient simultaneously.

2.3 CONTRAINDICATION

There is no restriction to patient population this device can be used with other than those outlined in the contraindications stated below.

Due to high illumination levels, the Ophthalmoscope can cause some discomfort in photophobic patients.

Mydriatic agents when used in ophthalmoscopy can cause temporary symptoms of blurred vision and photophobia. Adverse reactions to mydriatic drops are rare.

There are very few risks associated with Otoscopy. Some patients may report a slight discomfort during the procedure, especially during the insertion of the speculum into a swollen and inflamed ear canal. If the plastic tip of the Otoscope is not replaced or cleaned properly, infection can spread from one ear to the other.

3. CLEANING AND DISINFECTION INSTRUCTIONS

Before any cleaning of the instrument ensure it is turned off.

Only manual non-immersion cleaning as described should be used for this instrument. Do not autoclave or immerse in cleaning fluids. Always disconnect power supply from source before cleaning.

1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with de-ionised water / detergent solution (2% detergent by volume) or water / isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.
2. Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution.
3. Surfaces must be carefully hand-dried using a clean non-shedding cloth.
4. Safely dispose of used cleaning materials.

3.1 STERILISATION

Plastic reusable Specula will degrade if exposed to ultra-violet light, dry heat, or gamma irradiation. These methods of sterilisation must not be used.

1. Re-useable specula should not be re-used if visibly contaminated with cerumen, ear drainage or blood. Dispose of safely.

The cleaning and sterilisation of reusable specula, can be accomplished as follows:

2. Manually clean all surfaces of the units using a suitable brush and de-ionized water/ detergent solution (2% detergent by volume). Ensure that hinged versions of Specula are cleaned in both open and closed positions. Ensure all crevices are accessed. Solution can be heated to no more than 35°C.
3. Carefully examine to ensure that all visible contamination has been removed.
4. Safely dispose of used cleaning materials.

5. Sterilise using a validated steam steriliser complying with BS 3970 or equivalent standard. Operating cycle conditions as below: 134-138°C sterilising temperature at 2.25 bar operating pressure for minimum of 3 minutes hold time.
6. Following cleaning and/or sterilisation processes inspect the device to ensure all visible soil has been removed and the device operates as intended and is suitable for its intended use. Do not use if damaged. Dispose of safely.
7. The useful life of the device is determined by the wear and damage during use.

Disposable Specula – use once only and dispose of safely.

4. BATTERY HANDLES AND START-UP

4.1 PURPOSE

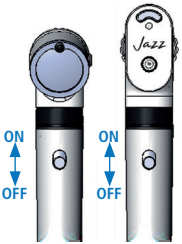
Keeler battery handles are fitted to the Keeler Jazz Ophthalmoscope and Jazz Otoscope.

4.2 START UP AND INSERTION AND REMOVAL OF BATTERIES

Unscrew the Jazz instrument head from the handle in an anti-clockwise direction. Insert two commercial type 'AA' alkaline battery of 1.5V (IEC standard reference LR6) into the case of the handle with the two plus pole towards the upper section of the handle.

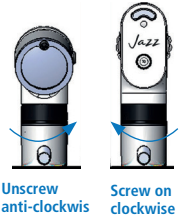
4.3 TURNING ON AND OFF

The handle is equipped with an On / Off switch. When in the up position, the unit is switched on, when in the down position, the unit is off.



4.4 CHANGING THE COLOUR CODED RINGS

Unscrew the Jazz instrument head from the handle in an anti-clockwise direction.



Remove the existing ring and replace with a new ring in the colour of your choice. Screw the instrument heads back on in a clockwise direction.

5. OTOSCOPE AND ACCESSORIES

5.1 INSERTION AND REMOVAL OF EAR SPECULUM

Position the selected speculum on the chromium plated metal cone of the otoscope. Turn speculum to the right until resistance is felt. The size of the speculum is marked on the outer surface.

5.2 INTRODUCTION OF EXTERNAL INSTRUMENTS INTO THE EAR

When intending to introduce external instruments into the ear (such as forceps), turn magnifying lens (approx.2.5 x magnification) on the Otoscope head in anti-clockwise direction. Replace cover lens in reverse direction.

5.3 REPLACEMENT OF LED – OTOSCOPE

Remove instrument head from battery handle. The LED is in the bottom section of the instrument head. Remove LED from instrument head by using your thumb and forefinger or a suitable tool. Firmly insert new LED.

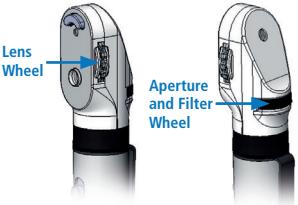
Caution:
- **LED may be hot**
- **Speculum are Applied Parts**

6. OPHTHALMOSCOPE AND ACCESSORIES

6.1 LENS WHEEL AND CORRECTING LENSES

The correcting lenses may be adjusted on the Lens Wheel.

The following correcting lenses are available: diopters 0 to +20 and 0 to -20. Readings will be displayed on a lit panel. Plus values are displayed in black digits and minus values in red digits.



6.2 APERTURES AND FILTERS

The following apertures and/or filters may be selected by the Aperture and Filter Wheel:

Small Circle

Designed specifically for examination of the macular region of the fundus where a larger beam would create excessive papillary reaction or patient comfort.

Semi-circle

For reduction of reflexes of small pupils.

Large Circle

For standard fundus examination.

Fixation Star

For definition of central and eccentric fixation.

Red-free filter

To increase contrast for assessment of changes in fine vessels, i.e. retinal haemorrhages.

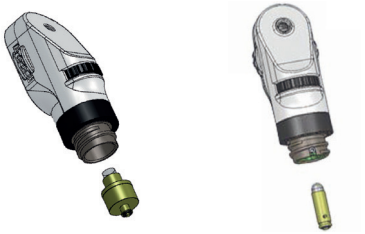
Cobalt Blue filter

Used with fluorescein dye for the detection and examination of corneal scars and abrasions.

6.3 REPLACEMENT OF LED – OPHTHALMOSCOPE

Remove instrument head from battery handle. The LED is located in the bottom section of the instrument head. Remove LED from the instrument head by using your thumb and forefinger. Insert a new LED with the pin on the LED fitted in the recess / slot provided on the base of the instrument.

Caution: LED may be hot.



7. MAINTENANCE

Jazz instruments and their accessories do not require any specific maintenance. Should an instrument have to be examined for any reason, please return it to your supplier or an authorised dealer in your area. Addresses can be supplied on request or visit www.keeler.co.uk.

8. WARRANTY

No user serviceable parts – all preventative maintenance and servicing must only be performed by authorised Keeler representatives.

Your Keeler product is guaranteed for 3 years and will be replaced, or repaired free of charge subject to the following:

- Any fault due to faulty manufacture.
- The instrument and accessories have been used in compliance with these instructions.
- Proof of purchase accompanies any claim.

Please note:

- LEDs are guaranteed for 1 year from date of purchase.

The manufacturer declines any and all responsibility and warranty coverage should the instrument be tampered with in any manner or should routine maintenance be omitted or performed in manners not in accordance with these manufacturer's instructions.

There are no user serviceable parts in this instrument. Any servicing or repairs should only be carried out by Keeler Ltd. or by suitably trained and authorised distributors. Service manuals will be available to authorised Keeler service centres and Keeler trained service personnel.

9. SPECIFICATIONS AND ELECTRICAL RATINGS

The Keeler Jazz Otoscope and Ophthalmoscope and associated power systems are medical electrical instruments. These instruments require special care concerning electromagnetic compatibility (EMC). This section describes the suitability in terms of electromagnetic compatibility of these instruments. When installing or using these instruments, please read carefully and observe what is described here.

Portable or mobile-type radio frequency communication units may have an adverse effect on these instruments, resulting in malfunctioning.

9.1 ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions

Keeler Jazz Otoscope / Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Jazz Otoscope / Ophthalmoscope 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.
	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	The Jazz Otoscope / Ophthalmoscope 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 used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

9.2 ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The Jazz Otoscope / Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of the Jazz Otoscope / Ophthalmoscope should assure 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 ± 15 kV air	± 8 kV contact ± 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	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not Applicable	Mains power quality should be that of a typical professional healthcare facility environment.
Surge. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical professional healthcare facility environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	U_T = 0% 0.5 cycle (0, 45, 90, 135, 180, 225, 270, 315°) U_T = 0%; 1 cycle U_T = 70%; 25/30 cycles (@ 0°) U_T = 0%; 250/300 cycle	Not Applicable	Mains power quality should be that of a typical professional healthcare facility environment.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical professional healthcare facility environment.

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

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 Jazz Otoscope / Ophthalmoscope, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	6 Vrms 150kHz to 80MHz	Not Applicable	**Recommended separation distance** $d = 1.2 \sqrt{p}$
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m	$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.7GHz
			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[1], should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with this symbol.

Note 1: At 80MHz and 800MHz, 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.
1 Field strength 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 Jazz Otoscope / Ophthalmoscope is used exceeds the applicable RF compliance level above, the Jazz Otoscope / Ophthalmoscope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Jazz Otoscope / Ophthalmoscope.

2 Over the frequency range 150kHz to 80 MHz, field strengths should be less than 10 V/m.

9.3 RECOMMENDED SAFE DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and Keeler Diagnostic Instruments.

The Jazz Otoscope / Ophthalmoscope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Jazz Otoscope / Ophthalmoscope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Jazz Otoscope / Ophthalmoscope 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 80MHz $d = 1.2\sqrt{p}$	80MHz to 800MHz $d = 1.2\sqrt{p}$	800MHz to 2.7GHz $d = 2.3\sqrt{p}$
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	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be determined 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 80MHz and 800MHz, 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.

10. TECHNICAL SPECIFICATIONS

Dimensions	Otoscope - 18cm x 3cm x 7.5cm (H x D x W) (including handle and speculum) Ophthalmoscope - 18cm x 3cm x 3cm (H x D x W) (including handle)
Weight	Otoscope - 96gm (including handle without batteries) Ophthalmoscope - 87gm (including handle without batteries)
Apertures	Small Circle, Semi-circle, Large Circle, Fixation Star, Red-free filter, Cobalt Blue filter (see page 9)
Diopters:	0 to +20 and 0 to -20 (see page 9)
Complies with	Electrical Safety (Medical) BS EN 60601-1 Electromagnetic Compatibility EN 60601-1-2 Ophthalmic Instruments - Fundamental Requirements and Test Methods ISO 15004-1 Optical Radiation Hazard ISO 15004-2

Environmental Conditions:

USE		
	10°C – 35°C 30% – 90% 800 hPa – 1060 hPa	
	Shock (without packing)	10 g, duration 6 ms
STORAGE CONDITIONS		
	-10°C – 55°C 10% – 95% 700 hPa – 1060 hPa	
TRANSPORT CONDITIONS		
	-40°C – 70°C 10% – 95% 500 hPa – 1060 hPa	
	Vibration, sinusoidal	10 Hz to 500 Hz: 0.5g
	Shock	30 g, duration 6 ms
	Bump	10 g, duration 6 ms

11. ACCESSORIES AND SPARES

Item	Part Number
Specula – Jazz	
Jazz 2mm Reusable Specula (Pack of 10)	1514-P-7036
Jazz 2.5mm Reusable Specula (Pack of 10)	1514-P-7044
Jazz 3mm Reusable Specula (Pack of 10)	1514-P-7052
Jazz 4mm Reusable Specula (Pack of 10)	1514-P-7060
Jazz 5mm Reusable Specula (Pack of 10)	1514-P-7079
Jazz 2mm Specula (Pack of 100)	1514-P-7087
Jazz 2.5mm Specula (Pack of 100)	1514-P-7095
Jazz 3mm Specula (Pack of 100)	1514-P-7108
Jazz 4mm Specula (Pack of 100)	1514-P-7116
Jazz 5mm Specula (Pack of 100)	1514-P-7124

12. PACKAGING AND DISPOSAL INFORMATION

Disposal of old electrical and electronic equipment

This symbol on the product or on its packaging and instructions indicates that this product shall not be treated as household waste.

To reduce the environmental impact of WEEE (Waste Electrical Electronic Equipment) and minimise the volume of WEEE entering landfills we encourage at product end of life that this equipment is recycled and reused.

If you need more information on the collection reuse and recycling then please contact B2B Compliance on 01691 676124 (+44 1691 676124). (UK only).

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of your Member State.

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