Jazz Instruments

Instructions for use

Keeler

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1. Introduction

Thank you for purchasing your Keeler Jazz Instruments. Manufactured in compliance with Directive 93/42/EEC for medical products.

Please read and follow these instructions carefully.

2. Symbols

Read user instructions for Warnings, Cautions and additional information

The CE mark on this product indicates it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive

Consult instructions for use

Manufacturers name and address

Keep dry

Type B protections against shock

3. Safety

3.1 Device Classification

CE Regulation 93/42 EEC: Class 1

3.2 Warnings and cautions

Warning

- **Please read these instructions carefully prior to use and keep in a safe place.** Should you have any queries, please contact your supplier or your Keeler Agent who will be pleased to assist you. For addresses please see the back page of these instructions. The address of your authorised Keeler Agent can be supplied on request.
- Please note that any instruments described in these instructions are only suited for application by trained operators.
- Correct and safe operation of instruments will only be guaranteed when Keeler instruments and accessories are used throughout.
- Do not use if the product is visibly damaged and periodically inspect for signs of damage.
- Do not use in the presence of flammable gases or an oxygen rich environment
- This product should not be immersed in fluids.
- Batteries must be inserted as per instructions - see section 5.2
- No modification to this equipment is allowed.
- Do not touch battery terminals and patient simultaneously.
- Instrument may become hot if used for extended periods of time.

Caution

- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C.
- Keep out of the reach of children.
- To prevent condensation from forming, allow instrument to come to room temperature before use.
- Bulbs/LEDs become hot during use, caution should be taken when replacing bulbs/LEDs.
- 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 30 minutes.

4. Cleaning instructions

Only manual non-immersion cleaning as described should be used for this instrument. Do not autoclave or immerse in cleaning fluids.

a Wipe the external surface with a clean absorbent, non-shedding cloth dampened with a water / detergent solution (2% detergent by volume) or water / isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.

b Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution.

c Surfaces must be carefully hand-dried using a clean non-shedding cloth.

d Safely dispose of used cleaning materials.

4.1 Sterilisation

Keeler recommend that ear speculum are used once. However, the ear speculum maybe sterilised at 134° for a dwell time of 10 minutes in a steam steriliser.

Single use - repeated use could cause infection.

5. Battery handles and start-up

5.1 Purpose

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

5.2 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 batteries of 1.5V (IEC standard reference LR6) into the case of the handle with the two plus poles towards the upper section of the handle.

Warning:

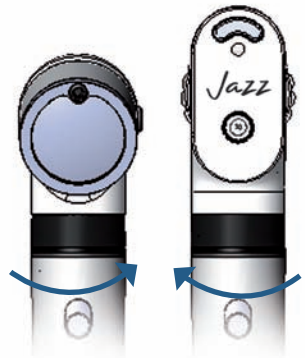
- Should the unit not be used for an extended period of time or whilst travelling, remove batteries from the handle.
- Insert new batteries when light intensity of the unit is reduced, thus affecting examination.
- For maximum light yield it is recommended to always insert new high-quality batteries on replacement.
- Never immerse handles in fluid. Ensure that no fluid or condensation penetrates into the handle.

Disposal

Please note that batteries are subject to separate disposal. For details ask your local authority and/or your environmental officer.

5.3 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.



Unscrew anti-clockwise *Screw on clockwise*

5.4 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.

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6. Otoscope and accessories

6.1 Purpose

Keeler Jazz Otoscopes described in these instructions have been produced for lighting and examination of the auditory canal, combined with Keeler ear speculum.

6.2 Insertion and removal of ear speculum

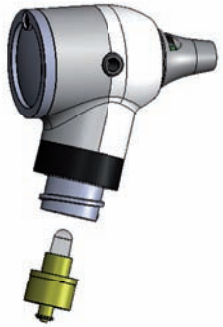
Position the selected speculum on the chromium plated metal cone of the otoscope. Turn speculum to the right until resistance is felt. The size of the speculum is marked on the outer surface.

6.3 Introduction of external instruments into the ear

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

6.4 Replacement of LED

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



Caution:

- LED may be hot
- Speculum are Applied Parts

6.5 Spare LEDs

1015-P-5298 Jazz Otoscope LED

6.6 Spare rings

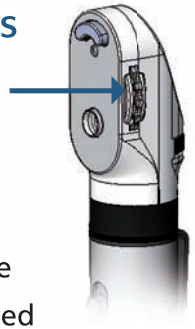
EP39-37051 Black
EP39-37342 Pink
EP39-37350 Blue

7. Ophthalmoscope and accessories

7.1 Purpose

Keeler Jazz Ophthalmoscopes described in these instructions have been designed for the examination of the eye and its background.

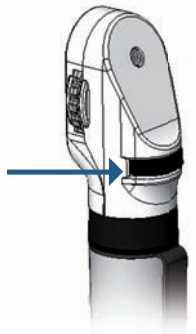
7.2 Lens wheel and correcting lenses



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.

7.3 Apertures and filters



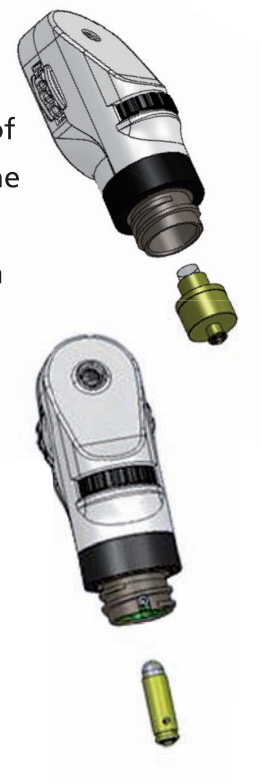
The following apertures and/or filters may be selected by the aperture and filter wheel:

Aperture	Function
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*

7. Ophthalmoscope and accessories

7.4 Bulb/LED replacement

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



Warning:

- The bulb/LED may be hot

7.5 Spare Bulbs/LEDs

1011-P-5530 Jazz Ophthalmoscope Bulb

1011-P-5522 Jazz Ophthalmoscope LED (Not available in Europe or USA)

7.6 Spare rings

EP39-37051 Black

EP39-37342 Pink

EP39-37350 Blue

8. 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.

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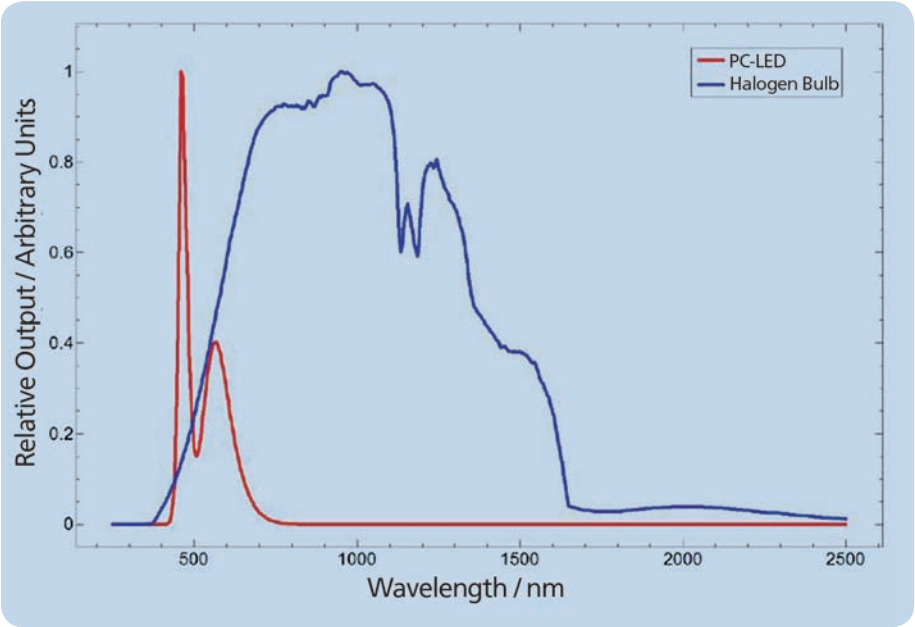
9. Specifications and electrical ratings

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 60601-1:2006 Electromagnetic compatibility EN 60601-1-2:2007 Ophthalmic instruments - fundamental requirements and test methods ISO 15004-1:2006 Optical radiation hazard ISO 15004-2:2007			
Environment		**Temperature**	**Humidity**	**Pressure**
	Use:	+10°C to +35°C	30% to 90%	800 hpa to 1060 hpa
	Storage:	-10°C to +55°C	10% to 95%	700 hpa to 1060 hpa
	Transport:	-40°C to +70°C	10% to 95%	500 hpa to 1060 hpa

9. Specifications and electrical ratings



Caution

• **PC-LED -** 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 30 minutes.

• **Halogen bulb -** 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 30 minutes.

9. Specifications and electrical ratings

Guidance and manufacturer's declaration - electromagnetic compatibility

The Jazz Otoscope and Ophthalmoscope have been tested regarding their ability to operate in an environment containing other electrical/ electronic equipment (including other medical devices).

The purpose of this testing is to ensure the Jazz Otoscope and Ophthalmoscope are not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the Jazz Otoscope and Ophthalmoscope.

Despite the testing of the Jazz Otoscope and Ophthalmoscope that has been undertaken, normal operation of the Jazz Otoscope and Ophthalmoscope can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the Jazz Otoscope and Ophthalmoscope are classed as medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the Jazz Otoscope and Ophthalmoscope are configured and installed/put into service, in accordance with the instructions/guidance provided herein and are used only in the configuration as supplied.

The Jazz Otoscope and Ophthalmoscope have been tested (and should be used only with) the Jazz battery handle and lamp supplied.

If the Jazz Otoscope and Ophthalmoscope are used with battery handles other than the one supplied, or with lamps other than those recommended, this may result in increased emissions or decreased immunity of the Jazz Otoscope and Ophthalmoscope, in relation to EMC performance.

It should be noted that the Jazz battery handle and lamps provided with the Jazz Otoscope and Ophthalmoscope should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

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

For the purposes of EN60601-1-2, the Jazz Otoscope and Ophthalmoscope have an essential performance. This essential performance is that the light output should remain on.

9. Specifications and electrical ratings

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
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.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC61000-3-3	Not Applicable	

9. Specifications and electrical ratings

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) IEC61000-4-2	± 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 IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95 % dip in U_T) for 0.5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3A/m	If incorrect operation occurs, it may be necessary to position the Jazz Otoscope / Ophthalmoscope further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

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

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9. Specifications and electrical ratings

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**
			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. **Recommended separation distance (*d*)**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	$d = 1.2 \sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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 metres (m). Fields 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 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.

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

9. Specifications and electrical ratings

Recommended separation distances between portable and mobile RF communications equipment and the Jazz Otoscope / Ophthalmoscope

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 2.5GHz $d = 2.3\sqrt{P}$
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 d in metres (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.

10. 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 device has been used in compliance with these instructions
- Proof of purchase accompanies any claim.

Bulbs/LEDs are guaranteed for 1 year from date of purchase.

11. Contact, packaging and disposal information

Manufacturer

Keeler Limited
Clewer Hill Road
Windsor
Berkshire
SL4 4AA

Freephone: 0800 521251
Tel: +44 (0) 1753 857177
Fax: +44 (0) 1753 827145

USA Sales Office

Keeler Instruments Inc
3222 Phoenixville Pike
Building #50
Malvern, PA 19355
USA

Toll Free: 1 800 523 5620
Tel: 1 610 353 4350
Fax: 1 610 353 7814

Disposal of old Electrical and Electronic Equipment

(Applicable in the European Union and other European Countries with separate Collection Systems).

This Symbol on the Product or on its Packaging and instructions indicates that it was put on the market place after August 2005 and 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).

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