

	Technical Specifications & Components	Document ID	-
		Issue Date	06 Dec 2022
	Optima Pocket	Issue No	1
		Page No.	1 of 5

1. Introduction

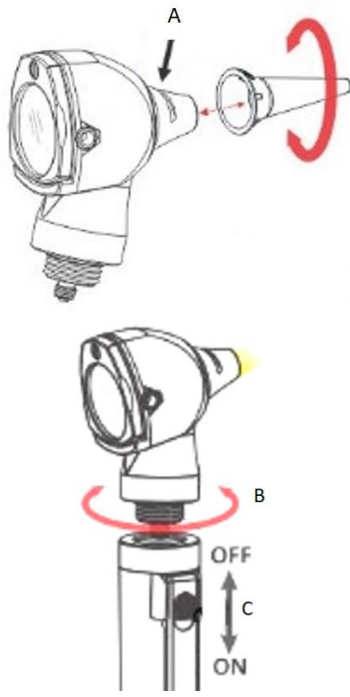
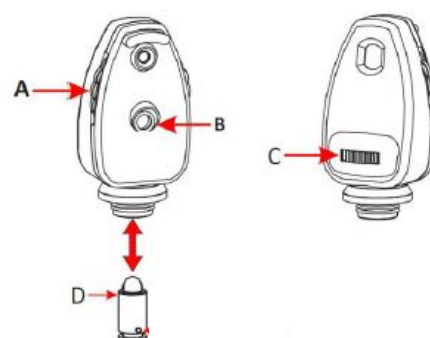
The Timesco Otoscopes are intended for use by qualified medical personnel to conduct the examination of the ear, the external auditory canal and the tympanum. The Timesco ophthalmoscopes are used to examine the interior of the eye including the retina, fovea, choroid, macula, optic disc and blood vessels.

2. Product Function & Performance

The intended users of the Timesco diagnostic devices are trained healthcare professionals. The care and maintenance of the device as per the instructions for use is required to ensure that the device performs as intended. Care and maintenance of the device is to be done by qualified facility personnel.

The tables below outline the principle of operation and mode of action for the Timesco Optima Pocket Otoloscope and Ophthalmoscope.

Table 1 Principle of Operation & Mode of Action.

Device	Product Function & Performance	Description
Optima Pocket Otoloscope		<p>A. Attach the disposable speculum, engaging with the groove on the inner cannula by twisting to lock the speculum in.</p> <p>B. Twist the otoscope head into the pocket handle.</p> <p>C. Push the power switch to turn on or off.</p>
Optima Pocket Ophthalmoscope		<p>A. Rotate the wheel to select the desired lens.</p> <p>B. The power of the selected lens is visible through the window.</p> <p>C. Rotate the wheel to select the desired aperture.</p> <p>D. The bulb can be replaced from the Ophthalmoscope head when required.</p>

QP50 F8 I1

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	Technical Specifications & Components	Document ID	-
		Issue Date	06 Dec 2022
	Optima Pocket	Issue No	1
		Page No.	2 of 5

3. Technical Specifications

The Optima Pocket is recommended to be operated and stored in the following conditions:

Table 2 Operating conditions for Optima Pocket.


Operating Conditions	
Temperature	10°C - 40°C
Humidity	30% – 75%
Ambient Pressure	70kPa – 106 kPa
Storage Conditions	
Temperature	-20°C - 60°C
Humidity	10% – 90% Non-condensing
Ambient Pressure	50kPa – 106 kPa

The Optima Pocket LED Otoscope features:


- A swivel 3X magnification lens
- Compatible with single-use Specula
- Insufflation Port for pneumatic testing of the tympanic membrane
- LED provides over 50,000 hours of use
- LED light output of 85K Lux.

The Optima Pocket Ophthalmoscope features:

Table 3 Optima Pocket Ophthalmoscope Lenses, Apertures and Filters.

Colour Coded Lenses	+ 1 2 3 4 6 8 10 15 20
	- 1 2 3 4 6 8 10 15 20
Apertures and Filters	

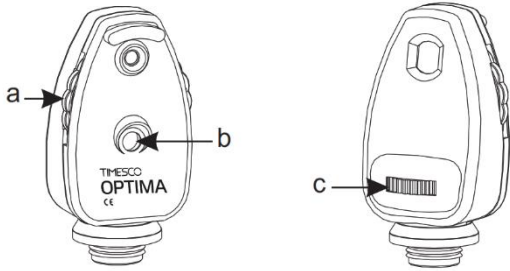
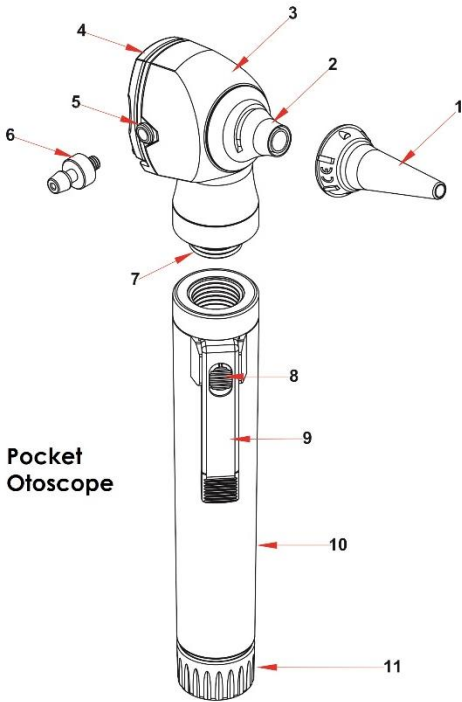
Apertures and filters from left to right – Standard spot, Small spot, Half-moon, Red-free aperture, Fixation aperture.

	Technical Specifications & Components	Document ID	-
		Issue Date	06 Dec 2022
	Optima Pocket	Issue No	1
		Page No.	3 of 5

4. Components

The otoscopes and ophthalmoscopes are simple devices which are based on well-established designs. The table below provides an overview of the key functional elements of the devices.

Table 4 Otoscope & Ophthalmoscope key functional elements.

Device	Key Functional Elements	Description
Optima Pocket Ophthalmoscope		A. Lens Selector
		B. Lens Power Window
		C. Aperture Selector
Optima Pocket Otoscope & Handle		1. Disposable Speculum
		2. Inner Cannula
		3. Otoscope Chamber
		4. Magnifying Lens (3x)
		5. Insufflation Port
		6. Insufflation Adaptor
		7. Screw Fitting
		8. Power Switch
		9. Pocket Clip
		10. Diagnostic Handle
		11. Pocket Handle Cap

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	Technical Specifications & Components	Document ID	-
		Issue Date	06 Dec 2022
	Optima Pocket	Issue No	1
		Page No.	4 of 5

5. Material Specification

The tables below outline the material specification for the Optima Pocket LED Otoscope, Ophthalmoscope and Handle.

Table 5 Optima Pocket LED Otoscope material specification.



Part	Material	Image
LED Assembly for Optima Pocket	Stainless Steel (AISI 303)	
Outer Cover For Optima Pocket	Stainless Steel (AISI 303)	
Metal Cannula For Optima Pocket, EU & US Pattern	Stainless Steel (AISI 303)	
Chamber for Optima Pocket Otoscope.	Nylon (PA-6) Black	
Inner Cannula for Optima Pocket	Nylon (PA-6) Black	
Magnifying Lens For Optima Pocket	PMMA	
Fiber Bundle 3.5mm	A2, Ø 3.5 mm	
O Ring, Epdm70, Dia. 12x1.6mm	Synthetic Rubber	

Table 6 Optima Pocket Ophthalmoscope material specification.

Part	Material	Image
Optical System	ABS + PMANT + Glass	
Lens Wheel	ABS + PMMANT	
Eyebrow Rest	TPS	
Aperture Wheel	ABS + Glass + Stainless Steel	
Lens Cover	ABS Black	


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	Technical Specifications & Components	Document ID	-
		Issue Date	06 Dec 2022
	Optima Pocket	Issue No	1
		Page No.	5 of 5

Table 7 Optima Pocket Handle material specification.

Part	Material	Image
End Cap Inner Nut	Stainless Steel (AISI 303)	
End Cap	Nylon PA6	
Pocket Clip (Electro Plated)	Stainless Steel	
Outer Cover	Stainless Steel (AISI 303)	
Lens Cover	ABS Black	
Clip End	ABS	
On/Off Button	ABS	
Inner Sleeve	ABS	
Barrel	Nylon (PA6)	

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