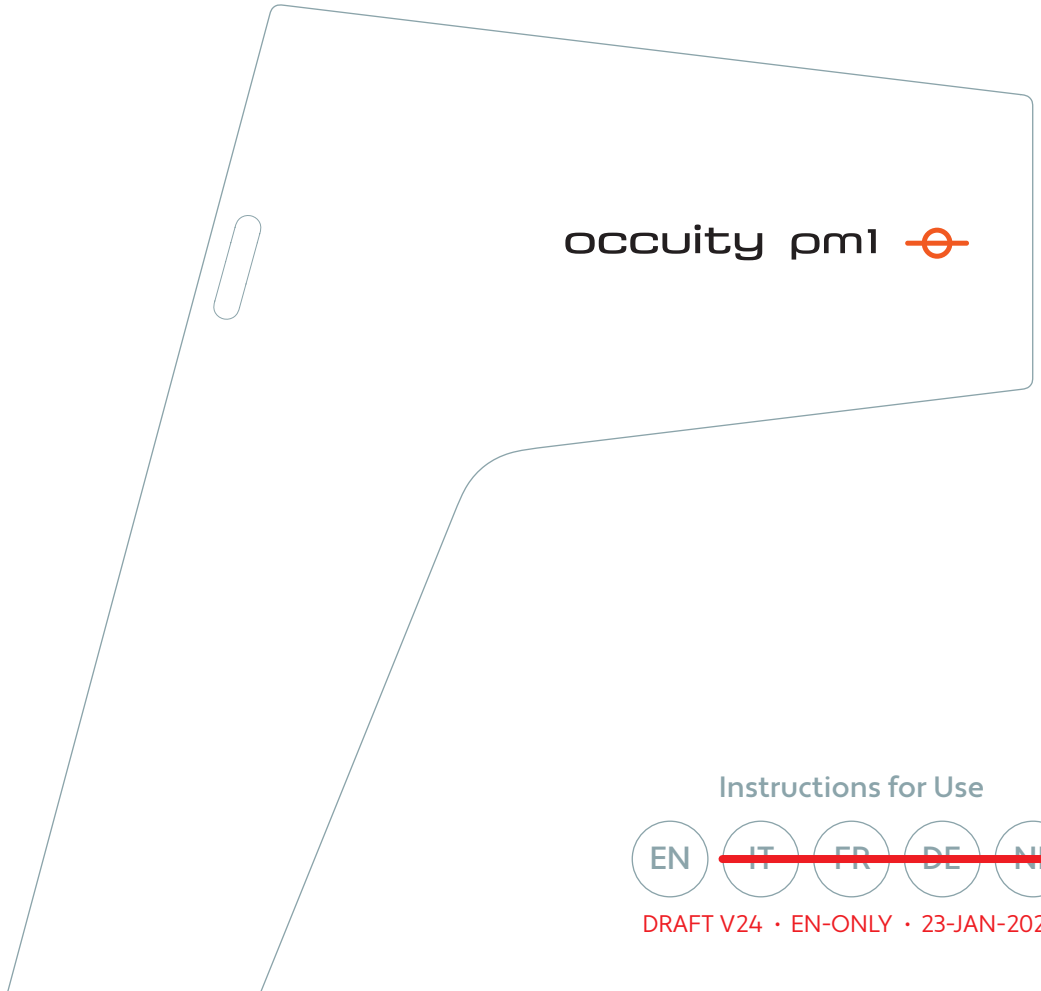


occuity pm1

Instructions for Use

EN ~~IT~~ ~~FR~~ ~~DE~~ ~~NL~~

DRAFT V24 · EN-ONLY · 23-JAN-2024

EN

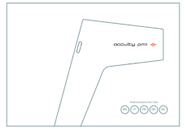
Occuity PM1 is a handheld ophthalmic device that quickly measures Central Corneal Thickness (CCT), without the need to touch or anaesthetise the eye.

It uses advanced technology to help the operator align to the centre of the eye and automatically begin scanning. PM1 captures data hundreds of times per second before calculating a precise CCT measurement.

PM1

Cradle

Power Supply
UK / EU

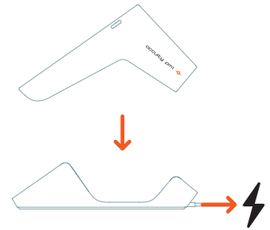


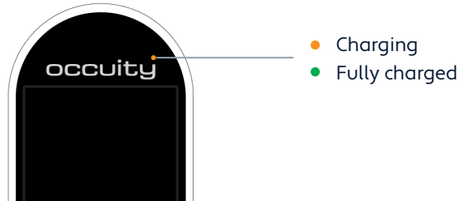
Instructions for Use

Case

1 — 2 — 3

1	2	3
Carefully remove PM1 and its accessories from the Case and observe safety warnings	Connect the Cradle to the Power Supply provided Connect the Power Supply to the mains outlet	Place PM1 on the Cradle and fully charge the battery





Intended use

PM1 is intended to be used only by a Healthcare Professional in Optometry and Ophthalmology clinics to measure the Central Corneal Thickness (CCT) of the eye for aiding the assessment of:

- Intraocular pressure (IOP) for glaucoma assessment
- Pre, during and post-surgical assessment including but not limited to LASIK, LASEK or intra-ocular lens exchange treatments
- Screening for conditions including but not limited to keratoconus (through assessment of corneal ectasia) or Fuchs' endothelial dystrophy

General safety

PM1 is safe to use under the indicated methods of operation, which should not be deviated from. Failure to comply may pose a danger to the patient or operator.

⚠ WARNING

No modification of the equipment is allowed. Contact your local distributor or visit occuity.com/support

Before PM1 is used, patients should remove contact lenses to prevent inaccurate CCT measurements from being reported.

Laser safety

PRECAUTION

PM1's laser aperture should not be directed at any material that might easily overheat or ignite.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

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 15 minutes or 100 measurements per person per day.

Charging safety

⚠ WARNING

Do not touch the patient and the USB connector simultaneously.

Position the Cradle at least 1.5 m from the patient. The Cradle must only be powered by the Power Supply provided. The use of an alternative power supply will void the warranty and may be dangerous.

PM1 must only be charged using the provided Cradle. While PM1 is charging, it cannot be used to take a measurement. During charging and operation, it is normal for PM1 and the Cradle to be warm.

The rechargeable battery inside PM1, like all lithium-ion batteries, will lose capacity over time. If PM1 is no longer chargeable due to battery degradation, contact your local distributor or visit occuity.com/support

Electrical safety

⚠ WARNING

Do not operate PM1 if it is known or suspected to be damaged.

Tampering with or removing any part of PM1 or its accessories will void the warranty. There are no user controls or user-serviceable parts inside PM1.

The use of accessories, transducers and cables not provided with PM1 may result in electromagnetic emissions or decreased electromagnetic immunity.

PM1 should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, PM1 should be observed to verify normal operation in the configuration in which it will be used. Portable RF communications equipment should be used no closer than 30 cm to any part of PM1, otherwise PM1's performance may be degraded.

PM1 is a precision electronic optical instrument. Reasonable care should be taken when making an electrical connection and handling all electronic devices.

To isolate PM1 from mains power, unplug the Power Supply. Position the Cradle so that the Power Supply remains accessible. It is recommended that the Power Supply is inspected for electrical safety annually.

Equipment safety

⚠ WARNING

PM1 provides no explosion protection from static discharge or arcing components.

Do not operate the product in the presence of explosive gases such as flammable mixtures of anaesthetic and oxygen, or nitrous oxide.

No peripheral equipment should be connected to PM1. It should only be used in conjunction with Occuity-accredited accessories.

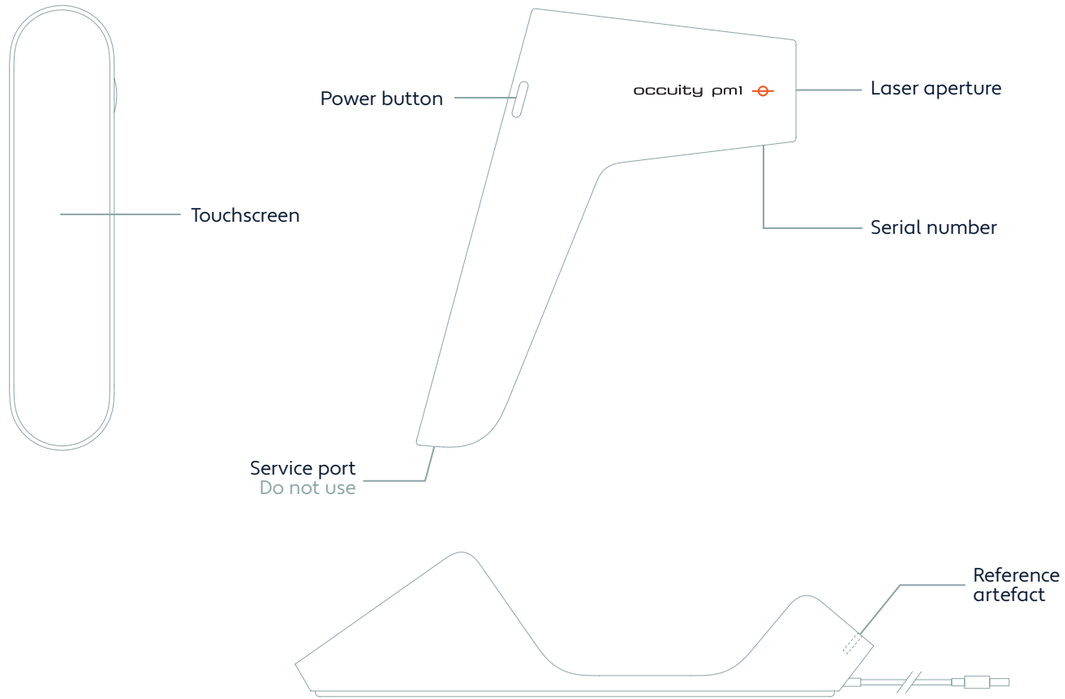
Always take care when handling PM1 to avoid accidental damage. Use the provided Case to transport PM1 and its accessories. Do not allow PM1 to get wet.

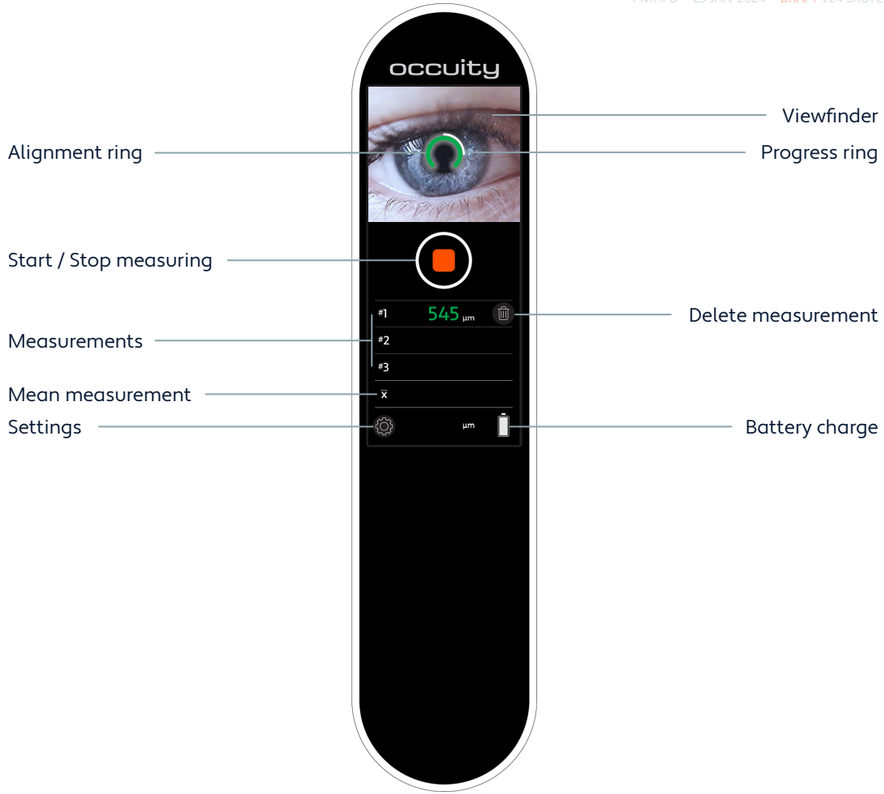
PM1 does not require calibration.

Standard operating conditions

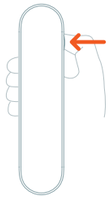
PM1 must be used within the specified limits.

Temperature	10 to 35 °C
Relative Humidity	30 to 80 %
Pressure	800 to 1060 hPa

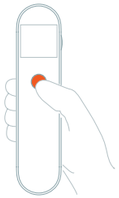

Power button
occuity pm1
Laser aperture
Touchscreen
Serial number
Service port
Do not use
Reference
artefact

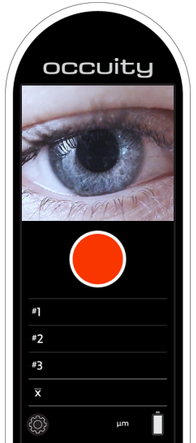

occuity
Viewfinder
Alignment ring
Progress ring
Start / Stop measuring
#1
545 µm
Delete measurement
Measurements
#2
#3
Mean measurement
x̄
Settings
µm
Battery charge

1 Press the power button to turn on PM1

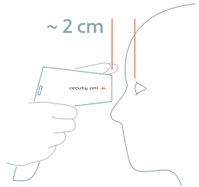


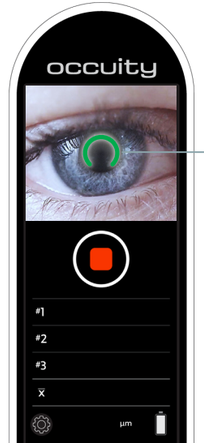
2 Ask the patient to look straight ahead, then press Start

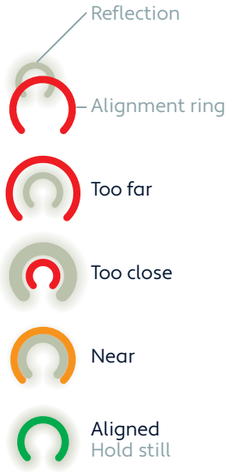




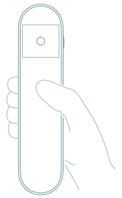
3 Align PM1's viewfinder to the reflection in the centre of the eye

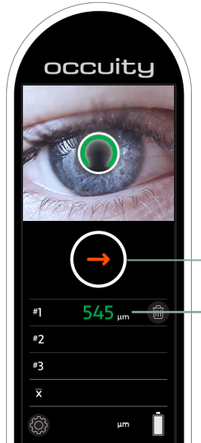


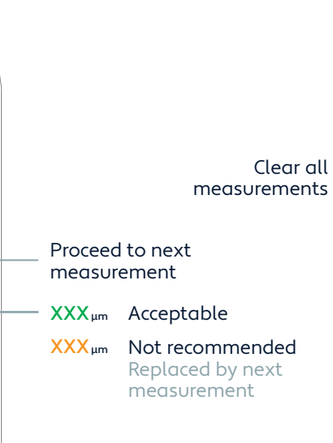




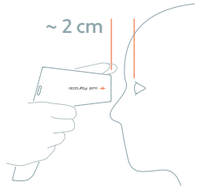
4 Wait until the Progress ring is complete PM1 will play a sound as it collects data



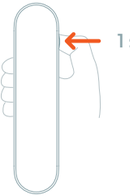


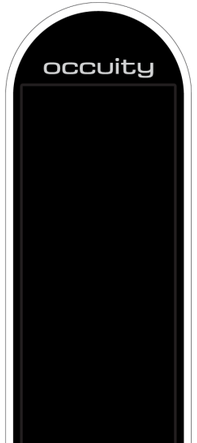


5 Repeat steps 2 to 4 twice to calculate the mean measurement



6 Hold the power button to turn off PM1

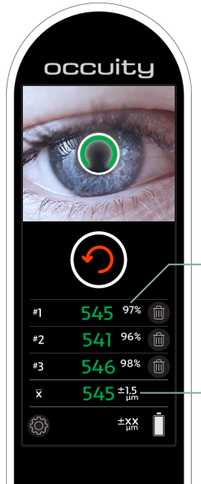




Statistics

If statistics are enabled in Settings, PM1 will show additional data to assist with the clinical interpretation of the measurements.

When statistics are shown, PM1 will retain measurements that are not recommended for use. Press Delete to remove individual measurements.



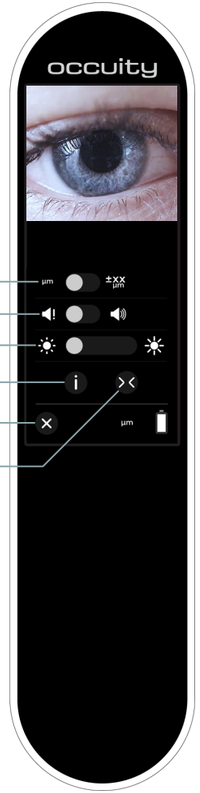
Percentage confidence that each measurement is accurate to ± 10 µm

An accurate measurement is close to the true value

Standard error (SE) indicating the precision of the mean measurement

A precise measurement is made of consistent data

Settings



Hide / Show statistics

Essential sounds only / All sounds

Display brightness

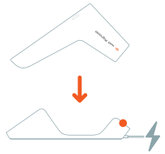
Device information

Return to measurements

Verification

Verification

After inactivity, change in environmental conditions or impact shock, PM1 may request verification in the Cradle.



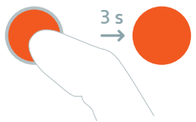
Place PM1 in the powered Cradle to initiate verification. Ensure there are no obstructions between PM1's laser aperture and the Cradle's reference artefact, and that both optical surfaces are clean.

If PM1 is only reporting measurements that are not recommended for use, verification can be manually started from Settings to confirm PM1's functionality.

Alignment override

After pressing Start measurement, PM1 projects a ring of light onto the eye and uses it to detect alignment before laser scanning. In the presence of bright ambient light, PM1 may not be able to detect the projected ring of light.

To override alignment detection, press and hold the Start measurement button for 3 seconds to begin laser scanning.



Sleep

After 20 seconds of inactivity, the touchscreen will turn off and PM1 will enter sleep mode. Tap the touchscreen to wake PM1. After 20 minutes of inactivity, PM1 will turn off automatically.

Display symbols

PM1's battery charge is low. Return PM1 to the Cradle to charge.

PM1 is in the Cradle. Charging will begin when PM1 sleeps or is turned off.

PM1 is too warm. Return PM1 to acceptable conditions.

PM1 is too cold. Return PM1 to acceptable conditions.

PM1 has experienced an error. Restart PM1.

PM1 is due verification. Return PM1 to the Cradle.

PM1 has experienced a drop. Check for damage.

Verification has failed. See Troubleshooting.

PM1 does not turn on
→ Check PM1 is charged by placing it on the Cradle. Turn PM1 off by holding the power button, then press the power button again. Check for damage and that the operating conditions are acceptable.

PM1 does not charge when placed on the Cradle
→ Ensure the Cradle is connected to the correct Power Supply, powered at the mains outlet, and PM1 is sat correctly.

PM1 takes longer than usual to turn on
→ PM1 is tuning its scanning system to the surrounding environment to ensure functionality.

PM1's charging indicator is flashing
→ PM1 is experiencing a charging issue. Remove PM1 from the Cradle and ensure it is within acceptable environmental conditions. Ensure PM1 and the Cradle are free from obstuctions.

PM1 is reporting measurements that are not recommended for use
→ Move PM1 and the patient away from bright light sources. Ensure the patient stays still and looks straight ahead. Use both hands to stabilise PM1. If required, touch the patient's forehead with the second hand to improve stability, ensuring local infection control procedures are followed. Ensure PM1 is aligned to the centre of the reflection in the eye until the Alignment ring turns green.

PM1 has failed verification
→ Ensure there are no obstructions between PM1's laser aperture and the Cradle's reference artefact, and that both optical surfaces are clean. Check PM1 and the Cradle are free from visible damage. Ensure the Cradle is placed on a steady surface and that PM1 is not being handled during verification.

Cleaning

PM1 is designed to avoid contacting the patient. Cleaning should be performed according to local clinical protocols and is recommended between patients to avoid cross-contamination.

To clean the enclosure of PM1 and the Cradle, only use a 70% isopropyl alcohol wipe. Allow PM1 and the Cradle to dry before use. Other cleaning products may damage the plastic enclosure.

Only clean PM1's glass laser aperture using a lint-free lens cloth. Check the laser aperture is free from residue before use. Only clean the Cradle's reference artefact using a lint-free lens cloth.

Do not touch the patient unless adequate PPE and infection control measures have been implemented.

Model	PM1 · SKU1 EU 5065007477007
Device type	Pachymeter
Device overall dimensions	17.5 x 15 x 4.5 cm
Mass	345 g
Laser safety class (BS EN 60825-1)	Class 1
Laser wavelength	1310 nm ± 20 nm
Laser power	30 µW (nomimal)
Measurement units	µm
Recommended patient age group	≥ 6 years old
Corneal thickness range measured	300 to 800 µm
Measurement accuracy	± 10 µm
Measurement resolution	1 µm
Scanning range	< 5 mm
Scanning frequency	100 Hz
Scanning time	Up to 10 s
Minimum working distance	16.5 mm from aperture
Charge time	Up to 4 hours
Power supply model	GlobTek GTM46101-1005-USB
Power supply input requirements	100 to 240 V AC at 50/60 Hz
Battery type	Li-ion · 7.4 V · 1050 mAh
Auto power-off when idle	20 minutes
Enclosure material	Polycarbonate
Diffuser material	Acetal copolymer
Rated product life	3 years

Environmental limits

Storage

Temperature	-10 to 55 °C
Relative Humidity	30 to 80 %
Pressure	800 to 1060 hPa

Transport

Temperature	-20 to 60 °C
Relative Humidity	10 to 80 %
Pressure	800 to 1060 hPa

Device labelling

EU MDR PENDING

CE mark, notified body 1912

Subject to WEEE Directive

Read Instructions for Use

Manufacturer

Date of manufacture

SN Serial number

MD Medical device

EC REP European representative

Regulatory compliance

PM1 is designed to comply with:
IEC 60601-1:2006 Medical Electrical Equipment
BS EN 15004-1:2007 Ophthalmic Instruments
BS EN 60825-1:2014 Safety of Laser Products
~~EU MDR 2017/745 Medical Device Regulation~~
EU MDR PENDING

Laser classification

Class 1 laser product
(BS EN 60825-1:2014 + A11:2021)
Group 1 ophthalmic instrument
(BS EN 15004-2:2007)

Declaration

PM1 is intended for use in the electromagnetic (EM) environment specified. The user of PM1 must ensure that it is used in the correct environment. Hereby, Occuity declares that the radio equipment type PM1 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at occuity.com/legal

Emissions

As per IEC 60601. PM1 is intended for use in professional healthcare environments, such as High Street Optometrists, including those directly connected to the public low-voltage power supply network. PM1 is not intended for use in high electromagnetic field environments such as near HF Surgical Equipment, or outside the RF-shielded room of magnetic resonance imaging systems.

The Cradle uses RF energy to charge PM1. It uses frequency and backscatter modulation within the 110-205 kHz band and the effective radiated power is <8 W. PM1 must emit electromagnetic energy to perform its intended function.

In the unlikely event that PM1 interacts with other electronic equipment, measures should be taken to minimise interference, such as relocation.

EM compatibility compliance

RF Emissions (CISPR 11)	Group II Class B
Harmonic emissions (IEC 61000-3-2)	Compliant
Voltage fluctuations emissions (IEC 61000-3-3)	Compliant
Electrostatic Discharge immunity (ESD) (IEC 61000-4-2)	± 8 kV contact ± 15 kV air
Radiated RF field immunity (IEC 61000-4-3)	3 V/m
Power frequency magnetic field immunity (IEC 61000-4-8)	30 A/m
Proximity magnetic fields immunity (IEC 61000-4-39)	13.56 MHz 7.5 A/m 134.2 kHz 65 A/m
Fast transients immunity (IEC 61000-4-4)	± 2 kV
Surge immunity (IEC 61000-4-5)	± 1 kV line-to-line ± 2 kV line-to-ground
Voltage dips and interruptions (IEC 61000-4-11)	Compliant
Conducted RF field immunity (IEC 61000-4-6)	3 V/m 6 V/m in ISM bands

Disposal

PM1 contains electronic components. At the end of its shelf life, it must be properly disposed of in compliance with local regulations. EU directives and national regulations prohibit the disposal of PM1 in domestic waste or by municipal waste disposal companies.

Contact your local distributor or visit occuity.com/support for the latest advice on how to recycle PM1.

Complaints

In the unlikely event of needing to make a complaint about PM1, contact your local distributor, or email complaints@occuity.com

If during the use of this device you believe a serious incident has occurred, report it to Occuity Ltd. and the competent local authority.

Support

For support and warranty claims, contact your local distributor or visit occuity.com/support

Warranty

Occuity Ltd. warrants its new equipment to be free from defects. Any device that is proven to be defective will be replaced, at Occuity Ltd.'s discretion, free of charge, up to one year from the date of purchase, unless otherwise governed by local legislation or an extended warranty has been purchased.

This warranty covers all repairs and servicing of parts that prove defective due to manufacturing. This warranty does not apply to any defect that is the result of an accident, misuse, mishandling, neglect, improper repair, or improper modification unless by authorised technicians of Occuity Ltd.

Occuity news

For Occuity product announcements and updates, subscribe at occuity.com

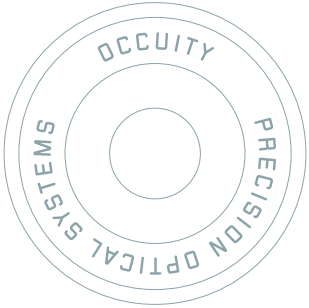
Legal

EC REP European Healthcare & Device Solutions (Ireland) Ltd, Stratton House, Bishopstown Road, Cork, T12 Y9TC, Ireland
europeandevicesolutions.eu

Occuity Ltd, The Blade, Abbey Square, Reading, RG1 3BE, UK
occuity.com

Retain this document for future reference.

Designed by Occuity in the UK and California


OCCUITY
PRECISION OPTICAL SYSTEMS