# tonocare


Keeler

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# 1.0 Introduction

Thank you for purchasing the Keeler TonoCare™.

These Instructions For Use are addressed to healthcare professionals using the TonoCare Non-contact Tonometer. The device should only be used by trained and qualified personnel.

## 1.1 Device Classification

CE Regulation 93/42 EEC: Class IIa
FDA: Class II

## 1.2 Indication for use

The Keeler TonoCare Tonometer is a hand-held, battery operated, non-contact tonometer intended to be used for measuring intraocular pressure (IOP) of the human eye with less than 3D in corneal astigmatism.

## 1.3 Warnings

The Keeler TonoCare should not used in patients with high corneal astigmatism (>3D).

## 1.4 Principle of operation

The Keeler TonoCare Tonometer uses the principle of air impulse tonometry - this is a variation of general applanation tonometry, however does not require direct contact with the surface of the eye.

Applanation tonometry is a technology to accurately measure IOP as an equivalent of the force required to flatten a defined area of the cornea by mechanical stimuli, as a direct application of the Imbert-Fick law.

The air impulse technique requires direction of a packet of air with restricted pressure and volume towards the central portion of the cornea, and the detection of the pre-defined flattening of the cornea via the electrical measurement of a light beam reflected from the corneal surface.

The device is intended to be used in accordance with these instructions. Please read them carefully and keep this document safe for future reference.

# 1.5 Symbols information

Please pay attention to the description of symbols below, as they will be used throughout the manual, device and packaging.


Follow instructions for use


Mandatory action sign


General warning sign


Warning:
Dangerous voltage


Warning:
Trip hazard


Warning:
Optical radiation hazard


Warning:
Non-ionizing radiation


Class II Equipment


Power supply polarity


Manufacturer's name and address


Date of manufacture

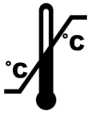
Catalogue number

Serial number


Do not use if package is damaged


Fragile


Keep dry



Temperature limits

Humidity limits

Atmospheric pressure limits


This way up


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


This symbol on the product or its packaging indicates it was put on the market place after August 2006, and this product shall not be treated as household waste

RoHS compliant


Material suitable for recycling

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# 1.6 Symbols used on controls and display

Please pay attention to the description of the symbols and sounds below, as they will be used on the device and display during operation.

## Device Controls


On/Standby button


Menu button


Return button


Manual trigger

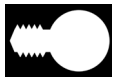
OD / OS button


Print button

## Sounds

**LOW PITCH** Bad or invalid readings

**HIGH PITCH** Valid set of measurements obtained

| Display Symbols | Description |
|---|---|
|  Light | Turn on / off illumination LEDs |
|  Sound | Turn on/off audible alerts |
|  Time | Set the system time |
|  Date | Set the system date |
|   IOP Format | Select the IOP format ( XX / XX.X) |
|  Pachymetry | Pachymetry options of OFF/ON/TRIGGER<br>(If set to 'TRIGGER', the pachymetry option only appears if the measured IOP value is greater than 15) |
|  Brightness | Set the brightness for the displays<br>(value between 1 and 15) |
|  Self Test | Initiate a self-test of the system |

# 1.7 Warnings and cautions

## Warnings and Cautions – failure to follow these instructions may pose a risk of injury

### Environment

- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C.
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment.
- The TonoCare cannot be used in the vicinity of sources known to cause electromagnetic disturbance (magnetic resonance imaging, computed tomography, radio-frequency identification, metal detectors, electronic article surveillance and other electromagnetic security systems).
- Do not bring the TonoCare into a magnetic resonance environment.
- Keep the front window and nozzle area away from large amounts of dust or fine particles.
- This product should be used in a room with subdued lighting.

### Installation and setup

- Please add mounting hole labels to covering the key holes unless wall mounting the TonoCare.
- Only mount on wall according to Keeler Instructions.
- Keep out of reach of children.
- Do not mount anything on the docking station other than the hand unit and forehead rest.
- The mains plug is the means of isolating the device from mains supply - ensure the mains plug is accessible at all times.
- Do not position the equipment so that is difficult to remove the mains plug from the wall socket.
- Do not fit mains power adapter into a damaged mains outlet socket.
- Route power cords safely to eliminate risk of tripping to user, or damage to device.
- TonoCare is not intended to be used with wireless technology. Do not plug a wireless dongle into the USB port on the docking station.

### Operation and use

- USA Federal law restricts this device to sale by, or order of a physician.
- The accuracy of IOP measurements is known to be affected by variations and changes in corneal rigidity due to differences in corneal thickness, intrinsic structural factors or corneal refractive surgery. It is recommended that these factors are considered during IOP measurement.
- Do not use if the product is visibly damaged, and periodically inspect for signs of damage.
- This product should not be immersed in fluids.

# 1.7 Warnings and cautions (continued)

## Warnings and Cautions – failure to follow these instructions may pose a risk of injury

### Operation and use (continued)

- Only use the approved Keeler accessories from the list in section 7.0, or the instrument may malfunction.
- The device will require a minimum 12 hour charge before first use.
- The device will require several 12 hour charge cycles before the battery functions optimally.
- To prevent condensation from forming, allow instrument to come to room temperature before use.
- Before using the TonoCare, press the Manual fire button to dispel any minute particles of dust or moisture which may have settled whilst the instrument was not in use.
- Check the function of the device in accordance with the instructions in section 3.2 prior to use on the patient.
- The patient should not be in the proximity of the docking station.
- Do not touch the electrical contacts on the docking station and the patient simultaneously.
- The forehead rest is composed of aluminium, and it is the only part which may touch the patient. The housing of the instrument is made of PC-ABS. Do not touch these parts if you have a known allergy to any of the materials.
- Do not use the forehead rest in the docking station for any other instrument, or the performance of the product may be compromised.
- Contact of the front window / nozzle area of the TonoCare with the eye of the patient should be avoided. If accidental contact occurs, clean the front window and surrounding area according to the cleaning instructions in section 4.2.
- The printer on the docking station contains a sharp serrated blade to help cut the paper. Exercise caution to avoid contact with this blade whenever replacing printer paper rolls or tearing printouts from the device.
- Always verify that the printout matches the readings on the hand unit.

### Maintenance

- To maintain device performance, and ensure its safety and effectiveness it should be serviced in accordance with the instructions in section 4.3.
- Only decontaminate/clean in accordance with the instructions given in section 4.2.
- If the device is not used regularly it must be recharged for at least 12 hours monthly to ensure optimum battery life.

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# 2.0 Installation

This chapter will instruct how to unpack and prepare the TonoCare for use.

When you open the package, check for any external damage or flaws, particularly damage to the case. If you suspect there is something wrong with the tonometer, contact the manufacturer or distributor.

## 2.1 Tools Required

- Safety knife

*For wall mounting:*

- Pencil
- Spirit Level
- Electric drill
- PH1 screwdriver

## 2.2 Packaging Content

Your TonoCare has been supplied with:

- A **hand unit** with pre-installed battery for IOP standalone measurement.
- A **docking station** for printing, data export and charging functions.
- A **metal wall mounting plate** with 4 screws and 4 rawlplugs for wall mounting of the docking station.
- A **power supply** for directly charging the hand unit (in transport) or via the docking station.
- A **roll of thermal paper** to be used in the printer located in the docking station.
- A **USB device** containing the Instructions For Use.
- An extendable **forehead stabilizer**.
- A **USB cable** to connect the docking station with a computer (not provided) for data export.

# 2.3 Table Top Installation

**1.** Position the product package so that the arrow points upward.

**2.** Use a safety knife to cut the tape sealing the box on the top, and remove the polystyrene layer covering the package contents.

Use caution to avoid injury from sharp edges when handling the safety knife, and the unsealed carton edges.

**3.** Lift the docking station from the package and place it in a clean area intended for the charging of the TonoCare when not in use. Before use remove the protective film covering the IR window on the docking station.

The TonoCare hand unit should not be used in the proximity of the docking station.

**4.** Pull open the printer door, found on the left-hand side of the docking station, and insert the roll of thermal paper provided. Proceed to section 3.3 for further instructions on installation / replacement of thermal paper.

**5.** Remove the hand unit from the package and allow the handle to fit the lower recess in the docking station and the measurement window to slide onto the top of the docking station. Before use remove the protective film covering the TonoCare display, the Front Window and the IR Window.

**6.** Take the forehead stabilizer from the package and allow it to be held by its magnets at the top of the docking station, in the area provided for it.

**7.** Remove the power supply from the package, plug it to the back of the docking station and after fitting the suitable adapter for your geography connect it to the AC inlet.

Route power cords safely to eliminate risk of tripping to user, or damage to device.

**8.** The LED indicator in the hand unit should now light up to indicate the TonoCare battery is charging.

**9.** Use the USB cable provided to connect the docking station to a computer (not provided) for data export.
The computer must be compliant to
EN 60601-1:2006 (see section 5.0)

# 2.4 Wall Mount Installation

Your TonoCare has been supplied with a wall mounting plate, 4 screws and 4 rawlplugs. Follow the instructions below for wall mounting.

**1.** Choose carefully the intended location for your TonoCare docking station with particular consideration to the routing of the power cable and the patient screening position. Ensure that the mains plug is accessible at all times, as this is the primary means of mains power disconnection.

The TonoCare hand unit should not be used in the proximity of the docking station. The docking station should not be fixed over live utilities, as the drilling process could interrupt the utility supply and cause injury. The recommended height is 1.2m (4 feet).

**2.** Use the metal plate as a template to mark the position of the retaining screws with a pencil, holding a spirit level to the base of the plate to guarantee horizontal alignment.

**3.** Drill the appropriate size holes following the marks left from the previous step.

Use extreme caution when operating the drill, following the instructions provided with the instrument.

**4.** Insert the rawlplugs in the holes drilled in the previous step, and fix the metal plate on the wall with the screws provided, using a PH1 screwdriver.

**5.** Position the docking station on the wall mounting plate so the 2 retaining pins on the metal plate slide into the holes in the rear of the housing, and the plate supports the unit from below.

**6.** You may now plug the power cable into the docking station, and connect it to mains power. The docking station will blink twice at power up. Once powered, rest the hand unit on the docking station for charging.

Charge the unit for a minimum of 12 hours before first use.

# 3.0 Using the TonoCare

This section will instruct the user on how to interpret the controls and indicators of the TonoCare, and how to perform the IOP measurement on a patient using the device.

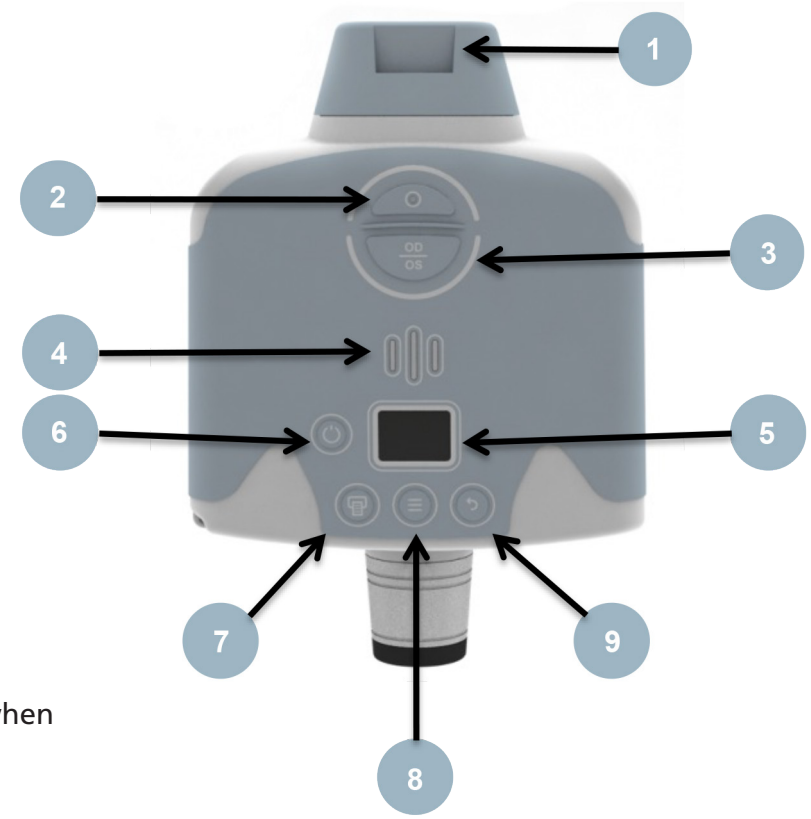
Familiarise yourself with the instructions for the measurement of the IOP using the TonoCare, before using the instrument on a patient.

## 3.1 Controls and indicators

### 3.1.1 Hand Unit

- *Top view*

**1.** Forehead rest mounting
**2.** Manual trigger
**3.** OD / OS button
**4.** LED indicator
**5.** Digital display
**6.** On / Off
**7.** Print button
**8.** Menu button
**9.** Return button




Note: The LED indicator on the TonoCare pulses when charging and remains solid when fully charged.

# 3.1.1 Hand Unit (continued)

• *Isometric view from the user and left side*

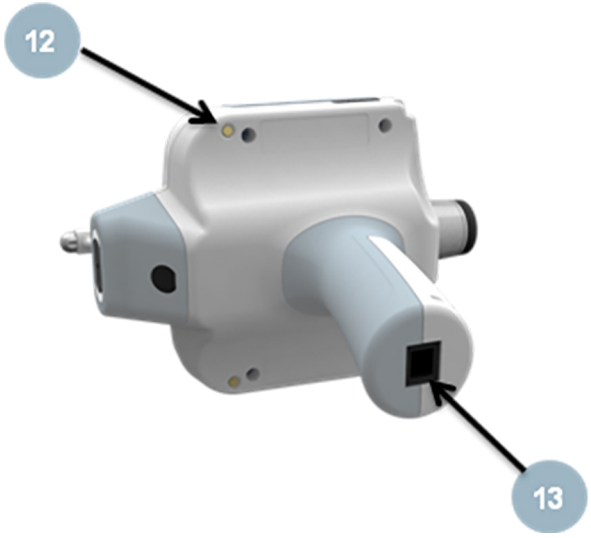
**10.** Forehead rest

**11.** Eyepiece


• *View from underneath the device*

**12.** Charging contacts

**13.** Power input

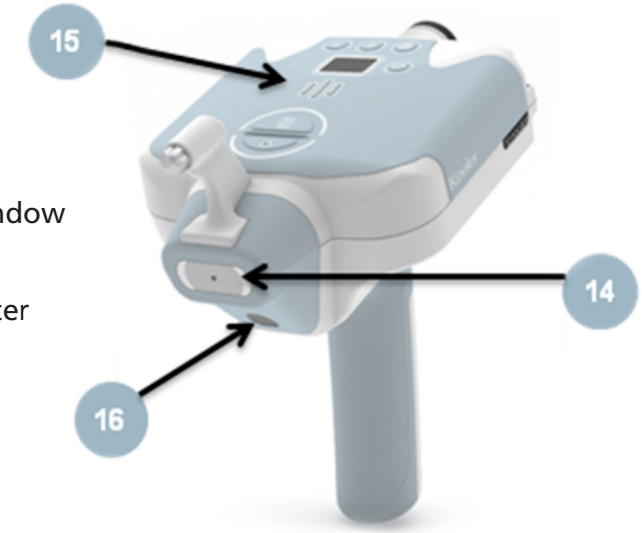



• *Patient view*

**14.** Puff tube and window

**15.** LED indicator

**16.** Infrared transmitter



# 3.1.2 Docking station

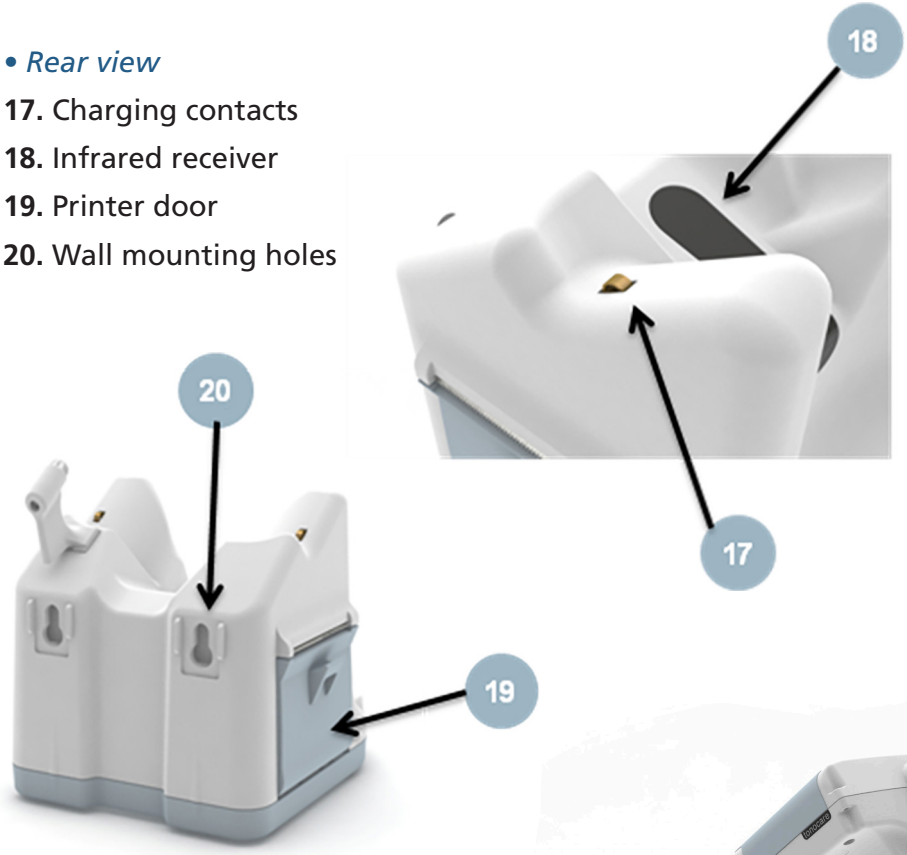
• *Rear view*

**17.** Charging contacts

**18.** Infrared receiver

**19.** Printer door

**20.** Wall mounting holes

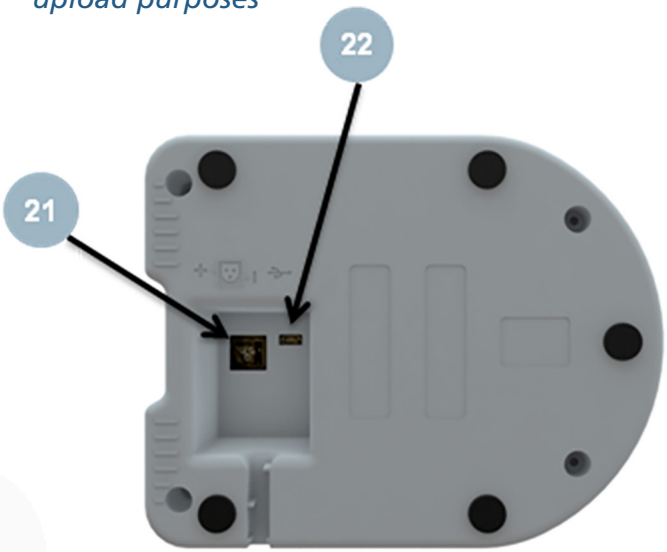



• *Underside view*

**21.** Power input

**22.** USB interface

• *Allows device to be connected to a PC for raw data upload purposes*




• *View to show position of Hand Unit with Docking Station*

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# 3.1.3 Menu Map

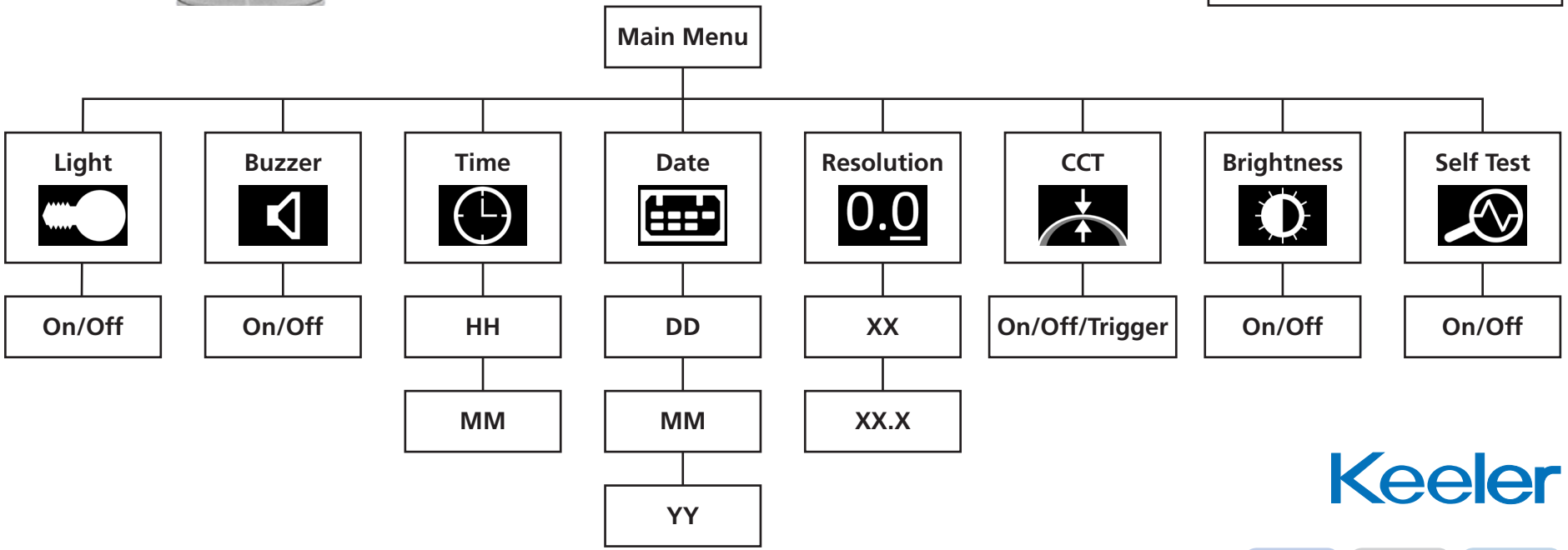
Press the menu button to open the software menu. Once in software menu, use the menu button to change your selection, the print button to confirm and the return button to move to the previous menu. Follow the menu map in the figure below for guidance.

**Confirm (Print button)**

**Change selection (Menu button)**

**Return to previous menu (Return button)**

The software revision is displayed during start-up

# 3.2 Measurement

## 3.2.1 Routine checks and functional tests

1. Before daily use visually examine the hand unit and docking station, looking for any signs of obvious damage. If you suspect the unit has been subjected to any impacts or moisture ingress do not use the device. Contact Keeler or your local service centre for advice.

2. Keeler recommends performing a weekly self-test on the hand unit to confirm functionality. This verifies operation of the puff generation system and the pressure sensor. To access the self-test facility, follow these steps:

   **a.** Power the unit up, ensuring it is plugged into the mains power supply.

   **b.** Rest the unit on its side on a flat surface, such as on a desk. Do not hold the unit.

   **c.** Press and hold the menu button and scroll through until the  icon appears on the display.

   **d.** Using the print or return button set this to **ON**.

   **e.** Press and hold the menu button again to exit the menu (approximately 2 seconds).

   **f.** The device will puff a number of times, and display a series of numbers as it progresses through the test.

   **g.** Once the self-test is complete the device will indicate that it has passed or failed on the display.

# 3.2 Measurement (continued)

Remember to prepare the patient before initiating the measurement. A patient's anxiety may delay the measurement and adversely affect its accuracy.

A single reading can be misleading as the IOP will vary in response to pulse, respiratory and diurnal fluctuations. Other factors may affect IOP, such as blinking, eye squeezing, fluid intake, physical activity, body position, etc. Up to 4 readings may be required in order to reduce the impact of these variants to a constant IOP. Keeler recommends using the average of four readings rather than any individual reading.

The TonoCare software will recognise the readings and give an audible notification when two consecutive readings are within 1mmHg of each other, indicating that further measurements may not be required.

## 3.2.2 Preparing the unit

**1.** Before lifting the hand unit from the docking station, check the LED indicator is steady on to ensure full battery capacity. A full battery will last up to 2 days of intensive use. Performance will deteriorate over time.

**2.** Remove the hand unit from the docking station and press the power on button. The hand unit will enter standby mode if not used for more than 90 seconds.

## 3.2.3 Preparing the patient

**1.** Ensure that the patient is comfortable and in a relaxed position.

**2.** Ask the patient to remove their contact lenses or spectacles if worn and to breathe normally. The patient's eyes should be fully open and blinking normally throughout the complete measurement procedure.

**3.** In order to reassure the patient, you can demonstrate the measurement procedure using the Manual trigger button towards one of the patient's fingers. Re-set (long press OD/OS) the device after the demonstration.

# 3.2.4 Obtaining a measurement

**1.** If you haven't done it in the previous step, use the manual trigger / demo button to dispel any minute particles of dust or moisture which may have settled whilst the TonoCare was not in use.

The TonoCare is set to automatically select the right eye as the first eye to be measured. If you wish to select the left eye, press the OD/OS button. Ensure you are recording the measurement for the intended eye.

**2.** Hold the hand unit with the dominant hand, and position the device so it is aligned with the patient's eye from a distance of about 30 cm or 12 inches.

**3.** Move the device in towards the patient until the forehead rest is positioned against their forehead. You may choose to rest your fingers on the forehead rest to gain more stability.

**4.** Ask the patient to focus on the green target inside the device.

**5.** Using your preferred eye, look through the eyepiece so that you can see the patient's eye. Keep moving the instrument forward whilst aligning the positioning ring to the patient's iris. Centre the measurement area with the pupil of the patient's eye and make note of the reflected LED crescents. These should be central on the pupil as well.

**6.** When the device is approximately 15mm (0.5 inches) away from the patient's eye, a cross will appear to indicate the position of the device relative to the eye. Move the device so that the edges of the cross are just inside the corners of the measurement brackets*.

The cross must not be larger than the measurement area, as this would indicate that the device is too close to the eye.

**7.** Once the cross reaches the correct alignment position, a gentle air impulse will trigger an IOP reading. Ensure eyelids and eyelashes are clear of the measurement brackets to obtain accurate results.

If no applanation was recorded during the puff, a low pitch tone will be heard (if sounds are enabled in the menu setting) and two stars (**) will be shown on the internal display.

**8.** Ensure an IOP reading has been recorded on the device.


** Correct position and size of cross in measurement area*

# 3.2.4 Obtaining a measurement (continued)

**8.** Slowly move the device backwards and allow the patient's eye to rest for a few seconds, maintaining the alignment position.

**9.** When the patient is ready for another reading, move the device closer until the alignment cross appears again and another reading is triggered.

**10.** Repeat the previous steps for further readings until the measurement averaged from the individual readings is acceptable.

**11.** When two consecutive readings are within 1mmHg an audible high pitch notification will be heard indicating that sufficient readings may have been taken (if sounds are enabled in the menu settings). If successive readings are not within 1mmHg of each other, Keeler recommends taking up to four readings and using the average.

**12.** Press the OD/OS button to switch from left to right eye, or vice-versa.

**13.** Press and hold the OD/OS button to clear all the readings.

**14.** Pressing the print button will produce a paper printout from the printer installed in the docking station. The infra-red window in the docking station and hand unit should be unobstructed, and aligned within 1m (3 feet). The Docking Station LED will flicker during the transmission of the IR data and then extinguish when printing.

**15.** If the docking station is connected to a computer, pressing the print button will export the raw data to the computer, as long as the serial port has been enabled as described below.

# 3.2.5 Repeatability and reproducibility

Repeatability and reproducibility of TonoCare were assessed by measuring a manometrically controlled test eye.

Repeatability was measured using a single TonoCare device and a series of approximately 50 individual readings for each of 5 pressure values spaced evenly between the 5 to 50mmHg working range. Readings were cross referenced with a reference pressure meter and a Pulsair IntelliPuff device. Failed readings were rejected and averages of 3 subsequent readings were calculated to give a set of approximately 16 measurements at each of the 5 pressure values. Results demonstrate standard deviations ranging from 0.14mmHg to 1.11mmHg within the 5 to 50mmHg pressure range respectively.

Reproducibility was assessed by analysing measurements from three different TonoCare units by two different operators across 5 pressure values spaced evenly between the 5 to 50mmHg working range. Two measurements (an average of 4 readings) at the 5 pressure values were taken for each of the six test cases (each operator using each of the three TonoCare devices).

An Analysis of Variance (ANOVA) conducted on the data indicates a p-value of less than 0.05 and an R-square value of 98% or 99%, which signifies excellent reproducibility across operator and across devices.

# 3.2.6 Clinical performance data

## Summary

The Keeler TonoCare Non-Contact Tonometer (NCT) was compared with the Perkins Applanation Tonometer (AT) in order to assess whether the TonoCare meets the requirements of ISO 8612 (comparable to ANSI Z80.10) in design compliance testing.

The Perkins AT uses the same basic principle as the Goldmann AT, namely, varying the force applied to applanate a fixed area of the cornea. Both instruments have an applanating 'cone' comprised of two prisms with apices joined together to apply an external force to the cornea to indent and flatten its surface. There are several scientific articles referring to both instruments as reference standard tonometers and specifically the Perkins AT as the portable counterpart to the Goldmann AT (Wessels,I.F et al.,1990), (Carlos Garcia-Resua et al 2006), useful in domiciliary visits and for patients with mobility issues.

Two experienced observers acquired data from 144 qualifying eyes, measuring IOPs ranging from 7mmHg-23mmHg in 50 participants and IOPs greater than 23mmHg in 22 participants. The results of the study show that the IOP measurements taken with the TonoCare NCT when compared to the reference Perkins tonometer (AT) do not exceed the ±5mmHg tolerance in the three IOP ranges in 143 eyes with only 1 eye exceeding this tolerance for IOP measured >23mmHg. This falls well below the requirement that no more than 5% of the paired differences between TonoCare and the reference tonometer should be outside the ±5mmHg tolerance in the three IOP ranges.

Overall the mean of IOP differences between TonoCare and Perkins AT was <0.01 mmHg, with a median of -0.2mmHg, indicating that the TonoCare NCT is equivalent to the applanation tonometer.

# 3.2.6 Clinical performance data (continued)

## Methods

The study conducted was a single visit, single- centre, non-randomized, non-masked paired crossover study. The study obtained IOP measurements on each eligible eye with the TonoCare and the reference standard Perkins tonometer.

Subjects were recruited according to the following inclusion and exclusion criteria.

**Inclusion Criteria**

- Subjects must be over 18 years of age
- Subjects must have healthy corneas with no contraindications for IOP measurements

**Exclusion Criteria**

- Subjects with only one functional eye
- Subjects with one eye having poor or eccentric fixation
- High corneal astigmatism (>3D)
- Corneal scarring, corneal surgery (including laser corneal surgery)
- Microphthalmosis
- Buphthalmos
- Contact lens wearers
- Dry eyes
- Lid squeezers
- Nystagmus
- Keratoconus
- Any other corneal or conjunctival pathology or infection

A total of 74 eligible participants were recruited, with 2 participants (2.7%) excluded. The reason for exclusion of two participants was due to excessive blinking or anxiousness resulting in the participant holding their breath. From the included 72 participants, IOP was measured in both eyes of all participants with TonoCare and Perkins AT, giving paired IOP measurements for a total of 144 eyes.

# 3.2.6 Clinical performance data (continued)

## Results

Table 1 below gives summary of IOP characteristics of the group, showing measurements to have similar distributions.

**Table 1: Summary of TonoCare and Perkins AT IOP measurements.**

| | TonoCare | Perkins AT |
|---|---|---|
| **N, eyes (patients)** | 144 (72) | 144 (72) |
| **Mean IOP, mmHg** | 21.2 | 21.2 |
| **Median IOP, mmHg** | 18.0 | 17.0 |
| **SD*, mmHg** | 7.9 | 8.0 |
| **Range, mmHg** | 11.8 to 46.3 | 11.0 to 41.0 |
| **IOP 7 to 16mmHg, n (%)†** | 42 (29.2) | 51 (35.4) |
| **IOP 17 to 23mmHg, n (%)†** | 58 (40.3) | 49 (34.0) |
| **IOP >23mmHg**, n (%)†** | 44 (30.6) | 44 (30.6) |

No pairing structure is summarised in this table. *Standard deviation.

† Only Perkins AT IOP categories are used for sub-group analyses, n is given in terms of eyes.

** In order to obtain measurements in this range, an inversion procedure was performed on a subset of participants while taking IOP measurements.

Table 2 categorises the absolute differences between TonoCare and Perkins AT IOP measurements >5mmHg overall, and within 3 IOP subgroups. A difference greater than the tolerance of ±5mmHg occurred in 1 (0.7%) eye out of 144, well below the maximum level of 5% according to the standard.

**Table 2: Differences between TonoCare and Perkins AT IOP measurements >5mm Hg overall, and within 3 IOP subgroups.**

| | | IOP Group† | | | |
|---|---|---|---|---|---|
| | | **7 to 16mmHg** | **17 to 23mmHg** | **>23mmHg**** | **Total** |
| **Difference*** | Does not exceed ±5mm Hg | 51 | 49 | 43 | 143 |
| | Exceeds ±5mmHg | 0 | 0 | 1 | 1 |
| | Total | 51 | 49 | 44 | 144 |

* IOP TonoCare – IOP Perkins AT. †Based on Perkins AT measured IOP.

** In order to obtain measurements in this range, an inversion procedure was performed on a subset of participants while taking IOP measurements.

Summary parameters of differences between pairs of TonoCare and Perkins AT IOP measurements are given in Table 3 below, for the full sample and by each IOP group. Overall the mean of IOP differences between TonoCare and Perkins AT was <0.01 mmHg, with a median of -0.2mmHg. The 95% limits of agreement, based on the mean of IOP differences ±1.96 × the standard deviation of the IOP differences was -3.4mmHg to +3.4mmHg.

# 3.2.6 Clinical performance data (continued)

**Table 3: Summary measures of IOP differences taken with TonoCare and Perkins AT measurements, summarised overall, and within 3 IOP subgroups.**

| | | IOP Group† | | | |
|---|---|---|---|---|---|
| | | **7 to 16mmHg (n=51)** | **17 to 23mmHg (n=49)** | **>23mmHg** (n=44)** | **Overall (n=144)** |
| **Summary measure [mmHg]** | Mean | 0.3 | 0.2 | -0.6 | 0.0 |
| | Median | 0.2 | 0.2 | -0.9 | -0.2 |
| | SD* | 1.3 | 1.5 | 2.1 | 1.7 |
| | IQR§ | -0.4 to 1.2 | -0.8 to 1.0 | -1.8 to 0.1 | -1.0 to 1.0 |
| | Range | -3 to 4 | -4.0 to 4.0 | -3.8 to 6.2 | -4.0 to 6.2 |

† Based on Perkins AT measured IOP. *Standard deviation. §Interquartile range.

** In order to obtain measurements in this range, an inversion procedure was performed on a subset of participants while taking IOP measurements.

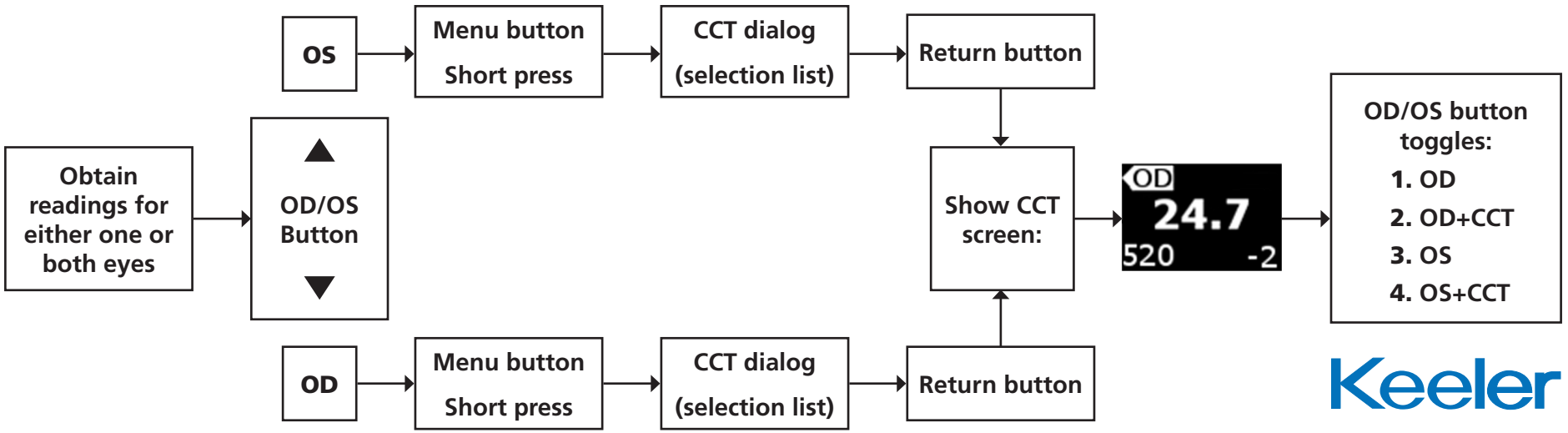
It was concluded by the investigators that there are no clinically meaningful differences in IOP measurements among the tonometers, and that the TonoCare conforms to the standard as detailed.

# 3.2.7 CCT correction

1. Press and hold the menu button to open the software menu. Follow the menu map in section 3.1.3 to ensure the CCT correction function is enabled.
2. Follow the instructions in section 3.2.4 to retrieve an IOP measurement. Once a suitable average reading is obtained, follow the CCT workflow shown below. The CCT group selected for the patient should correspond to the one measured separately by a pachymeter. Use the menu button to confirm your selection.
3. The CCT screen will show the CCT group and the correction applied under the relevant eye.

The accuracy of IOP measurements is known to be affected by variations and changes in corneal rigidity due to differences in corneal thickness, intrinsic structural factors or corneal refractive surgery. It is recommended that these factors are considered during IOP measurement. The biomechanical properties of an individual cornea may vary, resulting in changes of the relative stiffness or rigidity of the cornea and altering the measurement. Other factors to consider include corneal edema and other corneal abnormalities potentially affecting rigidity (e.g., keratoconus, corneal transplant, crosslinking) in addition to intrinsic structural factors and corneal refractive surgery.

## TonoCare CCT Workflow



# 3.2.8 Printing data

The measurement results can be printed by pressing the print button on the hand unit.

This will automatically include the date and time (if set).

A space is included for manually recording the name of the patient.

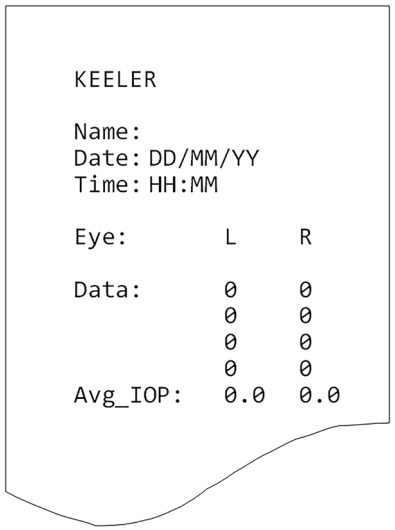
The last four individual readings are printed as whole numbers ‘XX’.

The average IOP is calculated and printed to one decimal place ‘XX.X’.

Always verify that the data on the printout and data on the TonoCare Export application matches the readings on the hand unit.

The printer on the docking station contains a sharp serrated blade to help cut the paper. Exercise caution to avoid contact with this blade whenever replacing printer paper rolls or tearing printouts from the device.

*Example:*




The TonoCare docking station can also be connected to a USB port on a PC. It will appear as a serial port in the system.

To receive the measurement data, the port needs to be configured as follows:

- Baud rate: 115200
- Data bits: 8
- Stop bits: 1
- Parity: none
- Flow control: none

Pressing the print button will send the results to both the printer and the USB port.

# 3.3 Replacing the printer paper

**1.** Access to the printer paper is via the printer cover. Using your fingertip, locate the lip on the top of the cover and gently pull towards you to open the printer housing.

**2.** Remove any leftover paper roll.

**3.** Place the new roll of paper into the paper holder, making sure the free end is loose at the top of the roll and oriented as shown.

**4.** Extend a few centimetres of paper out of the housing. While holding the end of the paper, close the cover by gently pushing the lip at the top towards the docking station until it is fully closed and clicks into place.

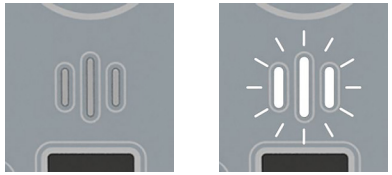
The printer on the docking station contains a sharp serrated blade to help cut the paper. Exercise caution to avoid contact with this blade whenever replacing printer paper rolls or tearing printouts from the device.

# 3.4 Charging your TonoCare

When not in use Keeler recommends storing your TonoCare on the docking station, so that it is maintained fully charged and ready for use.

*The LED on the TonoCare pulses when charging.*

*Once fully charged the LED will be continuously lit.*



The LED on the Docking Station will not change when the TonoCare hand set is stored on the Docking Station.

# 4.0 Product care and maintenance

Follow the instructions from this section for the safe care, cleaning and maintenance of your TonoCare.

## 4.1 General product care

Always inspect the product before use, checking for normal start-up.

Do not attempt to perform product disassembly, reassembly or repair. These should only be done by personnel trained and qualified by Keeler, following the instructions in the service manual.

Do not store the product in a dusty environment, as the dust may enter the puff system, and be dispelled to the patient's eye during use.

## Regular inspection

Inspect your power supply unit and cable for damage regularly.

Before inspecting, disconnect the power supply from the TonoCare and the mains supply.

If the outer insulation of the cable appears to be damaged discontinue use immediately. Contact your local dealer for a replacement.

# 4.2 Cleaning

Do not autoclave or immerse in cleaning fluids. Always disconnect power supply from source before cleaning. Disinfect the unit carefully following the procedures and cleaning solutions described below.

## Clean the puff tube lens weekly

1. Moisten a cotton bud with water/detergent solution (2% detergent by volume).

2. Move the tip of the bud around the lens in a circular motion.

3. After one circle the bud should be discarded to avoid smearing on the lens.

4. Look at the puff tube lens from the patient's side - if traces of tear film can still be seen, repeat above steps until clear.

Care should be taken not to damage the puff tube assembly during cleaning.

Never use a dry cotton bud or tissue to clean the puff tube lens. Never use a silicone impregnated cloth or tissue to clean the puff tube lens.

## Clean the hand unit daily and between patients

1. 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 using water/isopropyl alcohol solution with optical surfaces such as the front window. These should only be cleaned with a water/detergent solution.

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.

# 4.3 Maintenance

## If your TonoCare is dropped please return it to your local authorised Keeler Service Centre.

Keeler recommends annual service of your TonoCare to ensure the best performance of the device.

There are no user replaceable parts inside the device, including the battery. The battery must only be replaced by trained service personnel following the instructions in the Service Manual.

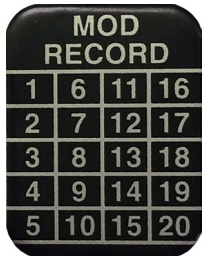
If you notice a significant reduction of the battery's performance, contact Keeler or your authorized distributor for its replacement.

If the TonoCare is dropped by accident the same service centre or distributor can verify if the device is still in calibration.

The unit performs a self-function check when switched on and will indicate if a fault is found. A further self-test can be activated from the menu (refer to section 3.2.1).

Do not attempt to perform any unauthorized repairs, as this could endanger the product and patients. Do not allow unauthorized parts to be fitted in your product.

On request, Keeler will provide necessary circuit diagrams, component parts lists, descriptions and calibration instructions to assist service personnel in device repair.




The MOD RECORD label on the rear of the device is used to indicate the status of the device in relation to significant changes.

## 4.4 Fault Codes

If an Error Code between 00 to 34 is seen on the screen, restart the device and check its function. If the device does not clear please return it to your nearest authorised Keeler Service Centre.

# 5.0 Specifications and electrical ratings

## TonoCare Hand Unit

| | |
|---|---|
| **Electric shock protection** | Class II (or internally powered) |
| **Complies with** | Electrical Safety (Medical)<br>IEC 60601-1:2005+AMD1:2012.<br>IEC 60601-1-2:2014<br>BS EN ISO 15004-1:2009 |

***The Mains plug is the means of isolating the device from the mains supply – ensure the mains plug is accessible at all times.***

* If connecting the TonoCare to a computer, the computer shall comply with the requirements of EN 60601-1:2006

** Whenever the device is connected to other equipment, the combination shall comply with the requirements of EN 60601-1:2006

| | |
|---|---|
| **IP rating** | IPX0 |
| **Dimensions** | 220 x 136 x 206mm (H x W x D) |
| **Weight** | 1.044Kg |
| **Calibrated range** | 5mmHg to 50mmHg |
| **Accuracy** | +/-5mmHg (95% confidence level) |
| **Displayed accuracy** | Display accuracy to 1 decimal place e.g. 12.3 |
| **Working distance** | 11mm from surface of patient's cornea to front surface of the window. |
| **Display** | OLED 0.95" |
| **Illumination system** | LED, white and infrared |

***The ME Equipment includes the hand unit, the docking station, the forehead rest and the power supply.***

## Docking Station

| | |
|---|---|
| **Electric shock protection** | Class II |
| **IP rating** | IPX0 |
| **Dimensions** | 153 x 155 x 183mm (H x W x D) |
| **Weight** | 0.725Kg |
| **Power Supply Unit** | Switch mode, multi-plug type<br>(110 – 240V)+/- 10%<br>350-700mA<br>**Compliant to:**<br>EN 60601-1, EN 61000-6-2,<br>EN 61000-6-3 |
| **Power supply output** | 30 VA (12V DC 2.5A) |
| **Frequency** | 50/60 Hz |

## TonoCare & Docking Station Environmental Conditions

| | Operation | Storage | Transport |
|---|---|---|---|
| **Temperature limits** | +10˚C to +35˚C | -10˚C to +55˚C | -40˚C to +70˚C |
| **Humidity limits** | 30% to 90% | 10% to 95% | 10% to 95% |
| **Pressure limits** | 800 to 1060hPa | 700 to 1060hPa | 500 to 1060hPa |

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# 5.0 Specifications and electrical ratings (continued)

It is well established that exposure of the eye to intense light sources for extended periods of time poses a risk of retinal photic injury. Many ophthalmic instruments illuminate the eye with intense light. The light levels on the TonoCare have been set at the lowest level possible.

No visible retinal lesions have been identified as a result of using Pulsair tonometers, however, young children and persons with diseased eyes may be at a higher risk. The risk may also be slightly increased if the person being examined has had any exposure with the same instrument or another ophthalmic instrument using an intense visible light source during the previous 24 hours. This will apply particularly if the eye has been subjected to retinal photography.

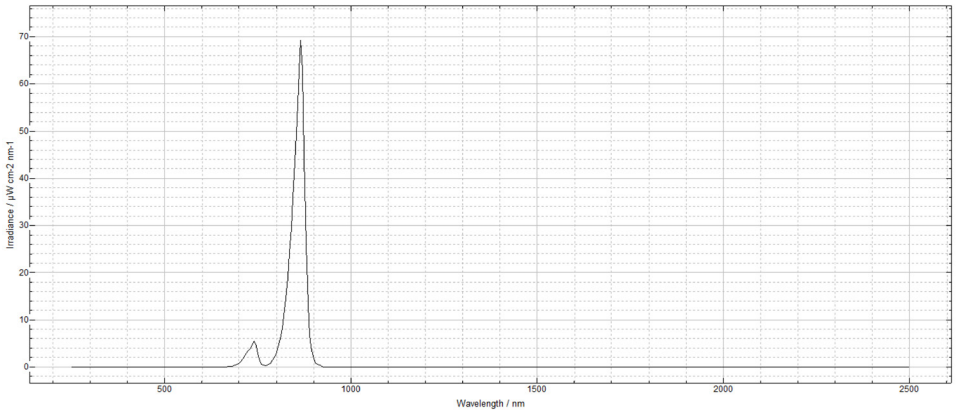


*Figure 1: Spectral irradiance of instrument at patient plane*

| Parameter | Wavelength (nm) | Storage | Transport |
|---|---|---|---|
| ES-CL | 250-400 | 2.358 E-05 | µW cm-2 |
| EUV-CL | 360-400 | 2.707 E-07 | mW cm-2 |
| EA-R | 305-700 | 1.027 E-02 | µW cm-2 |
| EIR-CL | 770-2500 | 2.73 | mW cm-2 |
| EVIR-R | 380-1400 | 1.664 E-05 | W cm-2 |

*Table 2: Calculated photochemical source radiances*

# 6.0 Specifications and electrical ratings (EMC)

The Keeler TonoCare is a medical electrical instrument. The instrument requires special care concerning electromagnetic compatibility (EMC). This section describes the suitability in terms of electromagnetic compatibility of this instrument. When installing or using this instrument, please read carefully and observe what is described here.

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

# 6.0 Specifications and electrical ratings (EMC) (continued)

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The Keeler TonoCare is intended for use in the electromagnetic environment specified below. The customer or the user 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<br>± 15 kV air | ± 8 kV contact<br>**± 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<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/output lines<br>**100kHz repetition frequency** | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge. IEC 61000-4-5 | ± 1 kV line(s) to neutral | ± 1 kV line(s) to neutral | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips IEC 61000-4-11<br><br>Voltage Interruptions IEC 61000-4-11 | <5% $U_T$<br>(> 95% dip in $U_T$) for 0.5 cycle<br><5% $U_T$<br>(> 95% dip in $U_T$) for 1 cycle<br>40% $U_T$<br>(60% dip in $U_T$ ) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$ ) for 500ms<br><5% $U_T$<br>(>95% dip in $U_T$) for 5s | 0 % $U_T$; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % $U_T$; 1 and 5 cycles<br>and<br>70 % $U_T$; 25/30 cycles:<br>Single phase: at 0°<br><br>0 % $U_T$ for 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment.<br><br>If the user of the Keeler TonoCare requires continued operation during power mains interruptions, it is recommended that the instrument be powered from an uninterruptible power supply. |
| Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment. |

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

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# 6.0 Specifications and electrical ratings (EMC) (continued)

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The Keeler TonoCare is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | **Group 1** | The Keeler TonoCare 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<br>CISPR 11 | **Class B** | The Keeler TonoCare 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<br>IEC 61000-3-2 | **N/A, Class A < 75W** | |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | **N/A, Class A < 75W** | |

# 6.0 Specifications and electrical ratings (EMC) (continued)

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The Keeler TonoCare is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 Test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80MHz to 2.7GHz | 3 V<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Keeler TonoCare, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1.2 \sqrt{p}$<br>$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz<br>$d = 2.3 \sqrt{p}$ 800MHz to 2.5GHz<br><br>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).<br>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]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:  |

**Note 1** At 80MHz and 800MHz, the higher frequency range applies.

**Note 2** These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[1] Field strengths from fixed transmitters, such as base stations ( 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 Keeler TonoCare is used exceeds the applicable RF compliance level above, the Keeler TonoCare should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Keeler TonoCare.

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

# 6.0 Specifications and electrical ratings (EMC) (continued)

**Recommended separation distances between portable and mobile RF communications equipment and the Keeler TonoCare**

The Keeler TonoCare is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Keeler TonoCare can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Keeler TonoCare 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** | | |
|---|---|---|---|
| | 50 kHz to 80MHz<br>$d = 1.2\sqrt{p}$ | 80MHz to 800MHz<br>$d = 1.2\sqrt{p}$ | 800MHz to 2.5GHz<br>$d = 2.3\sqrt{p}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.74 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d 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 guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# 7.0 Accessories and warranty

## Accessories supplied with the TonoCare

| Part Number | Description | Part Number | Description |
|---|---|---|---|
| 2418-P-5002 | TonoCare docking station | 2208-L-7008 | Printer paper roll |
| 2418-P-5021 | Wall mounting kit | EP79-40370 | USB cable (docking station to PC) |
| 2418-P-7000 | Forehead rest | 2415-P-7007 | Instruction for Use and TonoCare Export App on USB device |
| EP29-32777 | Power supply | | |

## TonoCare warranty

The TonoCare and its components are covered by warranty that they meet their performance standards and are free from any defects in materials or workmanship. Within 2 years from delivery by Keeler, the manufacturer shall at no charge to the customer, upon written notice from the customer, repair or replace any components which are defective in material or workmanship.

The customer agrees that it shall have no remedy in the event of any breach of the foregoing warranty other than as provided above. This warranty is exclusive, and in lieu of all other warranties, expressed or implied, and all implied warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

The obligations of the manufacturer as set forth in this warranty are expressly conditioned on the following:
(i) No alterations or repairs of any malfunction of the system shall be made to the system except by the manufacturer or his authorized representative, without the prior written approval of the manufacturer or his authorized representative (and in no case will the manufacturer assume responsibility for repairs or alterations made by those other than the manufacturer or his authorized representative).

And (ii) The customer shall give notice to the manufacturer or their authorized representative of any malfunction of the system and shall not use the system for any diagnostic purpose thereafter.

# 8.0 Contact, packaging and disposal information


Keeler Ltd
Clewer Hill Road
Windsor
Berkshire SL4 4AA
United Kingdom

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

Keeler Instruments Inc.
3222 Phoenixville Pike #50
Malvern
PA 19355
United States

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 its packaging indicates that it was put on the market place after August 2006, 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.

CE 0088 EP59-70038 Issue F

Keeler