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### 1. Copyright

The information contained within this manual must not be reproduced in whole or in part without the manufacturer's prior written approval.

The manufacturer reserves the right to make changes to specifications and other information contained in this document without prior notice.

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### 2. Introduction

Thank you for purchasing the Keeler MIO.

These Instructions for Use are addressed to healthcare professionals using the MIO.



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

### 3. Indication for use

The Keeler MIO is intended to enable the head mounting of a smartphone running the KineXis mobile application, for use with a handheld condensing lens for ophthalmic diagnostic examinations. The Keeler MIO is to be worn only by healthcare professionals.

Please refer to the quick guide for further information on the installation and use of the software.



# 4. 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



Do not use if package is damaged



Fragile



Caution



Keep dry



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



Manufacturer's name and address



Temperature limits



Date of manufacture



**Humidity limits** 



**RoHS** compliant



Atmospheric pressure limits



Material suitable for recycling



This way up



## 5. Warnings and cautions



- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C.
- This product should be used in a room with subdued lighting.
- This product has been designed to hold phones with a weight up to 300 grams.
- Where the Universal Adaptor is applied to a mobile phone case, the case must be flat.
- Do not use if the product is visibly damaged, and periodically inspect for signs of damage.
- This product should not be immersed in fluids.
- Verify that the mobile phone is mounted securely before using with a patient
- USA Federal law restricts this device to sale by, or order of a physician.



### 6. Installation

This chapter will instruct how to unpack and prepare the MIO 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 head unit, contact the manufacturer or distributor.

Remove the MIO Universal Adaptor from the packaging.

Wipe clean the backside of the mobile phone/mobile phone case, from any dust or dirt.

Remove the adhesive label cover from the MIO Universal Adaptor and position the Adaptor to the back of the mobile phone, in the approximate position shown in the image.

Press firmly to ensure good adhesion to the mobile phone/phone case.





### 6. Installation (continued)

To mount the MIO Universal Adaptor to the Mount on the flexible arm of the MIO, ensure the lugs on the bayonet mechanism of the mount align with the corresponding features on the MIO Universal adaptor.

Push the adaptor onto the mount and rotate clockwise until the mechanism clicks into engagement. The mobile phone is now secured to the MIO flexible arm.

When required, the phone can be dettached from the flexible arm by roating it anti-clockwise and pulling away.



Adjust the size and height of the headband using the headband dials, so that the MIO is supported comfortably around and on top of the head.



Position the mobile phone approximately 250mm from the operators' face.



# 7. Software Setup

#### Initial Set-Up

- 1) Download KineXis from the App Store.
- 2) Register your device on www.KeelerMIO.com/register and your password will be sent out to you.

#### App Use

|                       | Task                                | Process  |
|-----------------------|-------------------------------------|--|
|                       | To log in to the application        | - Enter username and password on the login screen.   |
| Authorization         | To reset password                   | - Click 'Forgot Password' on the login screen and follow further instructions.   |
|                       | To create a patient profile         | - Click 'Patients' tab.<br>- Enter either a brief or full patient profile.   |
| Patient<br>Management | To keep patient profiles up to date | <ul><li>Click 'Patients' tab.</li><li>Search for the patient;</li><li>View patient details;</li><li>Update patient details.</li></ul>  |
| Examination recording | To record an examination            | <ul> <li>From a patient profile start an examination.</li> <li>Click the green button to start recording.</li> <li>Click same button to finish eye recording.</li> <li>Switch from eye to eye as required.</li> <li>Complete examination.</li> </ul> |



# 7. Software Setup (continued)

|                       | Task   | Process  |
|-----------------------|--|--|
| Examination<br>Review | To review the examination                            | <ul> <li>Review examination details.</li> <li>Play the recording(s).</li> <li>View the picture(s).</li> <li>Flag/unflag the examination as required.</li> <li>Edit/add a note to the examination if required.</li> <li>Close the examination.</li> </ul> |
| Picture<br>Extraction | To get pictures auto extracted by the system         | <ul> <li>This will happen automatically when the device is connected to the internet.</li> <li>Some delay may occur if a large video file is being processed, the images will continue to appear after the examination.</li> </ul>                       |
| LXtraction            | To manually create pictures based on the video taken | <ul> <li>Get all the available frames by accessing the video footage.</li> <li>Review the frames and saved required ones.</li> </ul>   |
| Data Sharing          | To share the examination details                     | - Convert the examination details to a password-protected PDF file Share the PDF to the specified email.   |

For more information on use of the KineXis Software visit www.keelermio.com/how-to-guides.



# 8. Cleaning

Only manual non-immersion cleaning as described should be used for this instrument.



Do not autoclave or immerse in cleaning fluids.

- 1. Wipe the external surface with a clean absorbent, nonshedding cloth dampened with de-ionised water / detergent solution (2% detergent by volume) or de-ionised water / isopropyl alcohol solution (70% IPA by volume).
- 2. 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.

# 9. Specifications

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

# 10. Spare parts & accessories

| Part Number |                       |
|-------------|-----------------------|
| 2199-P-7136 | Lens Cloth            |
| 2415-P-7037 | Instructions for Use  |
| EP79-21489  | MIO Universal Adaptor |

## 11. Warranty



No user serviceable parts – all preventative maintenance and servicing must only be performed by authorised Keeler representatives. Your Keeler product is guaranteed for 3 years and will be replaced, or repaired free of charge subject to the following:

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

This warranty does not extend to cover any accidental damage to any smartphone device mounted to the MIO.



### 12. Contact and disposal information



Keeler USA 3222 Phoenixville Pike,

Building #50

Malvern, PA 19355,

**United States** 

Toll Free: 1 800 523 5620

Tel: 610 353 4350

Fax: 610 353 7814

**Keeler Limited** 

Clewer Hill Road,

Windsor,

Berkshire

SL4 4AA

Freephone: 0800 521251

Tel: +44 (0)1753 857177

Fax: +44 (0)1753 827145

### Disposal of old Electrical and Electronic Equipment

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

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.



This symbol on the product or its packaging indicates that it was put on the marketplace after August 2006, and that this product shall not be treated as householdwaste.

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