

HEINE QUALITY
MADE IN GERMANY


HEINE® iC2 Funduscope



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HEINE® iC2 Funduscope

 Please read and follow these instructions for use of and keep them for future reference.


Intended Use


The HEINE® iC2 Funduscope is a hand-held, non-invasive, internally powered digital ophthalmoscope, which is intended for recording, saving and displaying pictures of the internal part of the eye, in particular the ocular media and the ocular background.

The device is intended for transient application. It should only be operated by qualified medical personnel within a professional health facility.

 **For U.S. only:**
Federal law restricts this device to sale by or on the order of a Physician or Practitioner!

Warnings and Safety Information

 **CAUTION!** This symbol indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color yellow; foreground color black).

 **NOTE!** This symbol indicates valuable advice in terms of installation, operation, maintenance or repair. Notes are important, but not related to hazardous situations.

Product overview

- 1 Controller for adjusting the dioptré compensation
- 2 Double-stage release button for switch on the device and for picture recording
- 3 Micro USB-port
- 4 Charger indicator
- 5 Data matrix code and serial number of the device
- 6 Mounting case for the smartphone
- 7 Protective cover



Setting up

Installation of the app

Install the iC2 app on your smartphone. The app is available in the AppStore.

To avoid any possible malfunctions, please use the smartphone without SIM-card.

Choose a mounting case, which is suitable for the used smartphone. Insert the smartphone into the appropriate mounting case so it is firmly seated. Make sure that the camera is in the correct position.


Setting up of the connection between the iC2 and the smartphone

The connection between the iC2 and the smartphone is possible, using the data matrix code or the choice of the available devices in the list.

- Start the iC2 App on your smartphone
- Switch on the iC2, using the release button (second pressure point)
- The description of the further steps for the connecting the smartphone with the iC2 is included in the app.
- The connection is via *Bluetooth*® wireless technology

Connecting the mounting case with the iC2

Insert the guide pins, attached to the mounting case, into the guide rails of the iC2 so it is firmly seated.

 Make sure that the mounting case is securely attached to the iC2.


Operation

- Use the iC2 only with the corresponding app.
- Adjust the brightness as low as necessary during the application and ensure that the light is switched off after each application.


The iC2 is controlled by operating elements located on the iC2 and in the iC2 app.

The device provides the following functions:

- Create a patient file / Recording of patient data
- Picture recording
- Filter selection
- Storage of pictures
- Three-level brightness setting via the setting menu of the app.

 Protecting patient data is users' sole responsibility (e. g. Protection of the smartphone with a pin, data transmission via a secure connection). Ensure that your smartphone is adequately protected against access by third parties.

An electrical conducting connection between smartphone, PC and a mains power source is not permissible during the recording of the picture.

-  The pictures are stored in a file in the picture database of the smartphone. This file should only be viewed and changed with the iC2 app.
- Carry out periodically a back-up of your data to avoid a loss. A back-up of the data is for example possible with the iCloud.

Switch off the device

Switch off the device after each application. This is possible through the following procedure:

- Closing the iC2 app causes the device to switch off automatically
- If there is no *Bluetooth*[®] connection between the iC2 and the app for five minutes and the double-stage release button isn't pushed, the device will switch off automatically.

Reset the device

If the device does not react, it can be reset by pushing the release button for 30 seconds. This procedure has no influence on the data of the iC2 app.

Application duration

The iC2 is intended for a transient application of less than < 5 minutes with a 15 minutes break until the next application.


Charging

Charging via USB

Please connect the USB cord, which is attached to the power supply, to the micro USB charging port (3).

Wireless charging

When using the iC2 charging station, insert the device into the charging station until it lies full-facedly.

-  Pay attention to the fact that no foreign objects are between the device and the charging station.
- When replacing the iC2 in the charger, ensure that the charger and the iC2 aren't contaminated.

The setting up and operation of the iC2 charging station is described in a separate instruction of use. Due to local regulations, the iC2 charging station may not be available in your country.

Charge Indicator


When the iC2 is charged via USB, the LED will flash green.

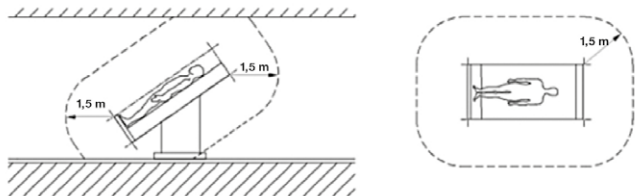
When the battery is fully charged, the LED will be constant green.

When using the iC2 charging station, the charging procedure is indicated by the charging station.

When the battery reaches a critical charge state, the LED will light up orange. The device must now be recharged.

Apart from the charge indicator LED, the charging status can also be seen in the settings via the submenu "iC2 Connection". In addition, the charge status is indicated by a bar graph display in the picture capture mode.

 Charge the device outside of the patient environment (1.5 m).



Hygienic reprocessing

The instruction is available:

- online at www.heine.com
- in a paper version which you can request from the address listed


Maintenance

The device is maintenance free.

Service

The device has no components serviceable by the end-user.


General notes

 The warranty for the entire product is invalidated if non-genuine HEINE products or non-original parts are used and if repairs or modifications are made to the device by persons not authorized by HEINE. For more information, please visit www.heine.com.

The expected life cycle, when the device is normal used and the warning and safety information as well as the maintenance instructions are observed, is up to 5 years.

Beyond this period, the product may continue to be used if it is in a safe and good condition.

General warnings

 Use only CE marked USB power supplies (5 V) from reputable manufacturers that conform with the safety requirements from the IEC 60950-1 Information technology or IEC 60601-1 Medical electrical equipment.

Check the correct operation of the device before use! Do not use the device if there are visible signs of damage or the light begins to flash.

Do not use the device in fire or explosive risk area (e.g. oxygen saturated or anaesthetic environments).

This product is not allowed to enter or be used in areas with strong magnetic fields e.g. MRI scanners.

Do not modify the device.

Use only original HEINE parts, spare parts, accessories and power sources.

Repairs shall only be carried out by qualified persons.

Store and use the device in dry and dust-free environments only!

Light exposure hazard



Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for the funduscope, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

Disposal



The product must be recycled as separated electrical and electronic devices. Please observe the relevant state-specific disposal regulations.

The appendix contains following tables

- Electromagnetic disturbances – Requirements and tests
- Technical specification
- Explanation of the used symbols