

Instruction for use
HEINE BETA X
Ophthalmoscope

HEINE BETA X Ophthalmoscope

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

Intended use

The HEINE BETA X direct ophthalmoscope is intended for transient examination of the ocular media (cornea, aqueous humor, lens, vitreous humor) and the retina. The instrument features an optical examination system and an illumination unit powered by a rechargeable battery.

The product may only be used by qualified medical professionals and in professional healthcare facilities.

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. This notes are important, but no related to hazardous situations.

Product overview

1 Spectacle rest
2 Viewing aperture
3 Lens wheel
4 Diopter readout
(plus = green, minus = red)
5 Switch: HEINE focusCONTROL
6 Viewing window
7 Aperture wheel
8 Filter lever
(polarisation filter, without filter, red-free filter)
9 On | Off switch and brightness control



Lens wheel (3) correction values:
in 1 diopter steps: -36 dpt to +38 dpt

Setting up

Before using the device for the first time, remove all protective films and fully charge the device.

Operation

Use the rotary push button (9) to switch the device on and off. You can also adjust the brightness of the ophthalmoscope by turning the control button. Turning the button quickly results in a large brightness adjustment. Turning it slowly, on the other hand, produces a fine adjustment.

The aperture wheel (7) provides you with 7 different apertures for your examinations, which can be used additional to the polarisation filter or the red-free filter.

The lens wheel (3) is used to adjust the refraction compensation. You can set this in the range of -36 diopters to +38 diopters. The respective correction values are visible via the display (4) (negative values are shown in red, positive values in green).

With the focusCONTROL toggle switch (5), you can easily switch between focus on the anterior segment of the eye (C – cornea) and fundus (F – fundus).

With the filter lever (8) you can switch on the polarisation filter or the red free filter.

Possible aperture settings (7):



From left to right: blue filter, fixation star with polar coordinates, large aperture, medium aperture, MicroSpot, slit aperture, hemispot

Possible filter settings (8):



From left to right: polarisation filter, without filter, red free filter

HEINE focusCONTROL (5):



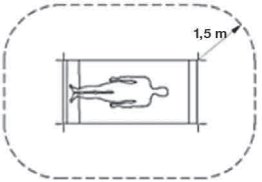
Above: Setting for focussing on the fundus (F – fundus)
Below: Setting for focussing on the anterior segment of the eye (C – cornea)

Hard-Reset:
Should a reset be necessary, it can be reset by pressing the on | off button for a period of 10 seconds.

Charging

⚠ Mount the power supply in a way that allows you to easily unplug it.

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



Charging via USB-C

Use the equipment provided with the BETA X Ophthalmoscope. Connect the USB cable to the USB-C port of the ophthalmoscope and the HEINE power supply.

The setting up and operation of the charging station is described in a separate instruction of use.

Battery indicator

Instrument	Charger	Battery	Charge indicator segments		
			Green - 1	Green - 2	Orange - 3
switched off	connected	100 %	on	on	on
		full (99 % – 66 %)	flashing	on	on
		sufficiently charged (66 % – 33 %)	off	flashing	on
		empty (≤ 33 %)	off	off	flashing
eingeschaltet	not connected	full (≥ 66 %)	on	on	on
		sufficiently charged (66 % – 33 %)	off	on	on
		empty (33 % – 10 %)	off	off	on
		Residual capacity (≤ 10 %)	off	off	flashing

Hygienic Reprocessing

The instruction is available:
- at www.heine.com
- in a paper version which you can request from the address listed

Maintenance

There is no regular maintenance required.

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 amounts with designated use and the observation of warning and safety information as well as the maintenance instructions up to 7 years. Beyond this period, the product may continue to be used if it is in a safe and good condition.

Charge your device during longer storage periods to protect the battery from deep discharge.

For the examination please use as little light as possible. Please ensure to switch off the light after each examination.

The instrument automatically switches off after 5 minutes if the brightness control is not operated.

The device only indicates the year of manufacture. The service life starts from the first of January of the year of manufacture.

Note to the user and | or patient:
All serious incidents that occur in connection with the product must be reported to HEINE Optotechnik GmbH & Co. KG and the member state's competent authority.

General Warnings

Check the correct operation of the device before use! Do not use the device if there are visible signs of damage or flashing light or unusally bright or dimmed lightning.

Do not use the device in fire- or explosive risk area.

Do not modify the device.

This product is not allowed to be entered or used in strong magnetic fields like MRI scanners.

Repairs shall only be carried out by qualified persons.

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

Do not use power supplies or cables if you notice any damage.

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

Lay cables in a protected position and ensure that no-one can fall over them.

Hazard from Light

Prolonged intense light exposure can damage the retina, so the use of the device for eye examination should not be unnecessarily extended, and the brightness should not be set higher than necessary for clear observation of the target structure. The exposure dose for photochemical retinal hazard is the product of irradiance and exposure time. If the irradiance is reduced by half, the exposure time may be twice as long to reach the maximum limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, 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.

ISO 15004-2:2007: Group 2

⚠ Warning – The light from this instrument may be harmful. The risk of eye damage increases with exposure time. Exposure with this instrument at maximum intensity for longer than 2 minutes 26 seconds exceeds the recommended threshold for hazard.

⚠ ANSI Z80.36-2021: Group 2

Caution – The light emitted by this device is potentially hazardous. The longer the exposure duration, the greater the risk of eye damage. Light exposure from this device exceeds the recommended maximum exposure (RME) of 2,2 J/cm² after 26 seconds at maximum intensity, unless the user takes additional steps to minimize exposure. The risk of retinal injury at an exposure of 2,2 J/cm² is low, but since some patients are more sensitive than others, caution is advised when this radiation level is exceeded. However, since there is a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 2 minutes 3 seconds.

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

Electromagnetic disturbances – Requirements and tests

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environments.

Statement for the operational environments	Inside professional healthcare facilities except for: near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances are high.
	The supply voltage quality should be that of a typical hospital environment.
	Floors should be wood, concrete or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Performance features of the ME system that have been determined to be essential to the performance	None
Necessary instructions for maintaining basic safety and essential performance with regards to electromagnetic disturbances for the expected life cycle	
Warning	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
A list of all cables, transducers and other accessories that are relevant for the EMC compliance	EMC compatibility is only ensured if original HEINE spare parts, accessories and power sources are used. The EMC compatibility when using power sources from other manufacturers must be evaluated by the user.
Test	**Compliance**
RF emissions CISPR 11	Group 1 Class B
Harmonic Emmissions	Passed*
Voltage fluctuations | Flickers	
Immunity	See attached immunity test levels

Immunity test levels

Test	Test level	
	IEC 60601-1-2 test levels	**Compliance test levels**
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: ±8 kV Air Discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	
Radiated RF EM fields (IEC 61000-4-3)	3 V/m 80 – 2700 MHz 80 % AM at 1 kHz	
Electrical fast transients | bursts (IEC 61000-4-4)*	± 2 kV 100 kHz repetition frequency	
Surges (IEC 61000-4-5)*	± 0.5 kV, ± 1 kV	
Conducted disturbances induced by RF fields (IEC 61000-4-6)*	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM: ±5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	
Power frequency magnetic fields (IEC 61000-4-8)	30 A/m; 50Hz or 60 Hz	
Voltage dips (IEC 61000-4-11)*	0 % U_T; 0.5 cycle; at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25|30 cycles Single phase: at 0°	
Short interruptions (IEC 61000-4-11)*	0 % U_T; 250|300 cycles	

*n | a: "Not applicable" in the internally powered mode

Technical specification

Environmental conditions for operation	+10 °C to +35 °C 30 % to 75 % rel. humidity 700 hPa to 1060 hPa
Environmental conditions for storage	+5 °C to +45 °C 45 % to 80 % rel. humidity 500 hPa to 1060 hPa
Environmental conditions for transport	-20 °C to +50 °C 10 % to 90 % rel. humidity 500 hPa to 1060 hPa
Nominal voltage	5 V
Nominal current	500 mA
Protection class	Internally powered Class II (charging)
Device classification according to IEC 62471	Group 2
Device classification according to ISO 15004-2	Group 2
Device classification according to ANSI Z80.36-2021	Group 2
Device classification according to ISO 10942	Group A
Cable	USB cable max. 2 m

Accessories

The corresponding accessories are listed at the following link:
www.heine.com/BETA-X-ophthalmoscope-accessories-IFU

Erläuterung der verwendeten Symbole
Explanation of utilized symbols
Explication des symboles utilisés
Explicación de los símbolos utilizados
Spiegazione dei simboli utilizzati
Förklaring av symboler som används
Verklaring van de gebruikte symbolen
Forklaring af de anvendte symboler
Symbolforklaring
Käytettyjen symbolien selitys
Explicação dos símbolos utilizados

CE	CE-Kennzeichnung kennzeichnet die Übereinstimmung mit der Europäischen Medizinprodukte-verordnung (EU) 2017/745. The CE mark indicates that the product complies with the medical device regulation (EU) 2017/745. Le marquage CE indique que le produit est conforme ou au règlement (UE) 2017/745 relatif aux dispositifs médicaux. La marca CE indica que el producto cumple el Reglamento europeo sobre productos sanitarios (UE) 2017/745. Il marchio CE indica la conformità con il regolamento sui dispositivi medici (UE) 2017/745. CE-märkning markerar en överensstämmelse med förordningen om medicinka produkter (EU) 2017/745. CE-markering duidt de overeenstemming aan met de verordening betreffende medische hulpmiddelen (EU) 2017/745. CE-mærkningen angiver overensstemmelse med forordningen om medicinsk udstyr (EU) 2017/745. CE-merket angir at produktet er i samsvar med forskriften om medisinsk utstyr (EU) 2017/745. CE-merkintä tarkoittaa, että laite lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 kanssa. O símbolo CE identifica a concordância com o regulamento de Dispositivos Médicos (EU) 2017/74.
REF	Katalog- oder Bestellnummer Catalogue- or order number Numéro de catalogue ou de commande Número de catálogo o de pedido Codice catalogo e di dell'ordine numero Katalog- eller Beställningsnummer Catalogus- of Bestelnummer Katalog- eller Ordrenummer Katalog- eller bestillingsnummer Luettelo- tai viitenumero Número de catálogo ou pedido
SN	Seriennummer Serial number Numéro de série Número de serie Numero di serie Seriennummer Seriennummer Seriennummer Serienummer Sarjanumero Número de série

	Hersteller Manufacturer Fabricant Fabricante Produttore Tillverkare Fabrikant Producent Produsent Valmistaja Fabricante
	Herstelldatum (Bezieht sich auf den ersten Januar des Herstelljahres) Date of manufacture (Refers to the first January of the year of manufacture) Date de fabrication (Se réfère au premier janvier de l'année de fabrication) Fecha de fabricación (Se refiere al primer día de enero del año de fabricación) Data di produzione (Si riferisce al primo gennaio dell'anno di produzione) Tillverkningsdatum (Avser den första januari tillverkningsåret) Productiedatum (Verwijst naar de eerste januari van het productiejaar) Produktionsdato (Henviser til den første januar i produktionsåret) Produksjonsdato (Gjelder den første januar i produksjonsåret) Valmistuspäivä (Viittaa valmistusvuoden tammikuun ensimmäiseen päivään) Data de fabricação (Refere-se ao primeiro de janeiro do ano de fabricação)
	Getrennte Sammlung von Elektro- und Elektronikgeräten (Europäische WEEE Richtlinie) Product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal according to local provisions. (European Waste Electrical and Electronic Equipment Directive, WEEE) Tri sélectif des appareils électriques et électroniques (Directive européenne DEEE) Desechado separado de aparatos eléctricos y electrónicos (Directiva Europea RAEE) Raccolta differenziata di apparecchi elettrici ed elettronici (direttiva europea RAEE) Separat insamling av elektriska och elektroniska apparater (det europeiska WEEE-direktivet). Gescheiden inzameling van elektrische en elektronische apparaten (Europese AEEA richtlijn) Produkter med dette symbolet skal ikke avhendes sammen med vanlig husholdningsavfall, men krever separat kassering i henhold til lokale bestemmelser. (European Waste Electrical and Electronic Equipment Directive, WEEE) Separat indsamling af elektrisk og elektronisk udstyr (det europæiske WEEE-direktiv). Sähkö- ja elektroniikkalaitteille tarkoitettu erillinen keräyspiste (eurooppalainen WEEE-standardi). Coleção separada de aparelhos elétricos e eletrônicos (Diretrizes Europeias WEEE).
	Zulässiger Temperaturbereich in °C für Lagerung und Transport Temperature limits in °C for storage and transport Plage de température admise en °C pour le stockage et le transport Rango de temperatura permitida en °C para almacenar y transportar el producto Temperatura ammessa in °C per conservazione e trasporto Tillåtet temperaturintervall i °C för lagring och transport Toegestane temperaturen in °C voor opslag en transport Tilladt temperaturområde i °C ved opbevaring og transport Temperaturbegrensning i °C for oppbevaring og transport Näyttää pakkauksen sallitun säilytys- ja kuljetuslämpötilan (°C) Limite de Temperatura em °C para armazenamento e transporte
	Zulässiger Temperaturbereich in °F für Lagerung und Transport Temperature limits in °F for storage and transport Plage de température admise en °F pour le stockage et le transport Rango de temperatura permitida en °F para almacenar y transportar el producto Temperatura ammessa in °F per conservazione e trasporto Tillåtet temperaturintervall i °F för lagring och transport Toegestane temperaturen in °F voor opslag en transport Tilladt temperaturområde i °F ved opbevaring og transport Temperaturbegrensning i °F for oppbevaring og transport Näyttää pakkauksen sallitun säilytys- ja kuljetuslämpötilan (°F) Limite de Temperatura permitida em °F para armazenamento e transporte

	Zulässige Luftfeuchtigkeit für Lagerung und Transport Humidity limitation for storage and transport Humidité admise pour le stockage et le transport Humedad del aire permitida para almacenar y transportar el producto Umidità atmosferica ammessa durante il trasporto e la conservazione Tillåten luftfuktighet för transport och lagring Toegestane luchtvochtigheid voor opslag en transport Tilladt luftfugtighed ved opbevaring og transport Fuktighetsbegrensning for oppbevaring og transport. Sallittu ilmankosteus kuljetuksen ja varastoinnin aikana Umidade do ar admissível para o armazenamento e transporte
	Zulässiger Luftdruck für Lagerung und Transport Pressure limitation for storage and transport Pression atmosphérique admise pendant le transport et le stockage Presión de aire permitida para almacenar y transportar el producto Pressione atmosferica ammessa durante il trasporto e la conservazione Tillåten lufttryck för lagring och transport Toegestane luchtdruk voor opslag en transport Tilladt lufttryk ved opbevaring og transport Trykkbegrensning for oppbevaring og transport Sallittu ilmanpaine kuljetuksen ja varastoinnin aikana Pressão do ar admissível para o armazenamento e transporte
	Vorsicht Bruchgefahr! Fragile, handle with care! Fragile ! Manipuler avec soin Atención. Frágil. Attenzione: pericolo di rottura! Försiktigt! Risk för brott Voorzichtig, kans op breuk! Forsigtig, risiko for brud! Ømtålig, behandles forsiktig! Varo särkymisvaaraa! Frágil, manuseie com cuidado!
	Trocken lagern! Keep dry! Conserver au sec ! Conservar en un lugar seco! Evitare ambienti umidi! Förvaras torrt! Droog bewaren! Opbevares tørt! Hold tørt! Säilytetään kuivassa paikassa! Armazenar em ambiente seco!

	Gebrauchsanweisung verbindlich befolgen. (Hintergrundfarbe: blau, Vordergrundfarbe: weiß) Follow instructions for use! (Background color: blue, foreground color: white.) Suivre le mode d'emploi. (Couleur de fond : bleu ; couleur du premier plan : blanc) Seguir obligatoriamente las instrucciones de uso. (Color de fondo: azul, color de primer plano: blanco) Attenersi obbligatoriamente alle istruzioni per l'uso. (Colore dello sfondo: blu, colore in primo piano: bianco) Bruksanvisningen ska alltid följas. (Bakgrundsfärg: blå, förgrundsfärg: vit) De gebruiksaanwijzing is bindend en dient gevolgd te worden. (achtergrondkleur: blauw, voorgrondkleur: wit) Følg altid brugsanvisningen. (Baggrundsfarve: Blå; forgrundsfarve: Hvid) Følg bruksanvisningen! (Bakgrunnsfarge: blå, forgrunnsfarge: hvit.) Käyttöohjetta on noudatettava tarkasti. (Taustaväri: sininen, etualan väri: valkoinen) Siga as instruções de uso! (Cor de fundo: azul, cor de primeiro plano: branco)
UDI	Unique Device Identification
MD	Medical Device

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