

· HEINE OMEGA 600 HEINE OMEGA 600 wired



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HEINE OMEGA 600

HEINE OMEGA 600 wired



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

Intended use

The HEINE OMEGA 600 and HEINE OMEGA 600 wired binocular indirect ophthalmoscope is a head worn AC-powered or battery powered device for transient use, containing illumination and viewing optics intended to examine posterior segments of the eyes.

The product must only be used by qualified medical professionals and in medical 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

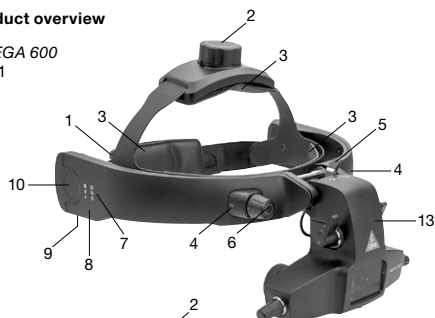
⚠ CAUTION! This symbol indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color yellow; foreground color black).

⚠ NOTE! This symbol indicates valuable advice. Notes are important, but not related to hazardous situations.

Product overview

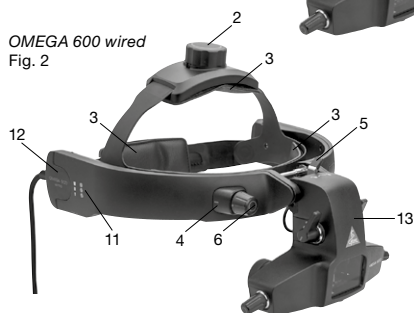
OMEGA 600

Fig. 1



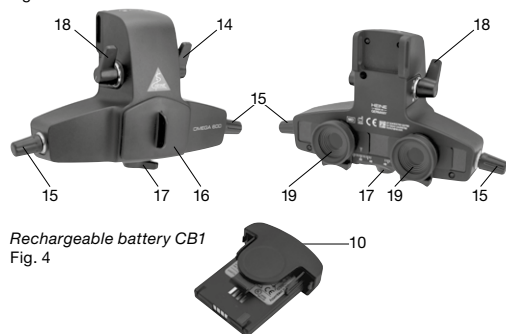
OMEGA 600 wired

Fig. 2



Optics unit (13) for OMEGA 600 and OMEGA 600 wired

Fig. 3



Rechargeable battery CB1

Fig. 4

- 1 Width adjustment
- 2 Height adjustment
- 3 Padding
- 4 Socket for brightness control
- 5 Adjustment lever
- 6 Brightness control
- 7 Charge status indicator
- 8 Battery compartment
- 9 USB-C socket
- 10 Rechargeable battery CB1
- 11 Power indicator
- 12 Power supply connection
- 13 Optics unit
- 14 Aperture selection lever
- 15 Illumination height adjustment
- 16 Dust cover
- 17 Stereoscopic adjustment lever
- 18 Filter selection lever
- 19 Eyepieces

Setting up

To put the OMEGA 600 into operation, insert the CB1 battery (10) into the instrument's battery compartment (8) by quickly pressing it in so that it audibly clicks into place. We recommend to charge the battery CB1 (10) of the device fully before first use.

To put the OMEGA 600 wired into operation, connect the power supply unit to a mains plug using the appropriate country-specific primary adapter. Fig. 5 and Fig. 6 describe the approach for changing the plug.

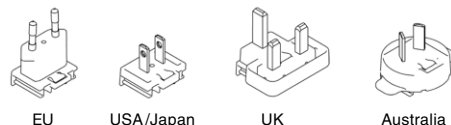


Fig. 5

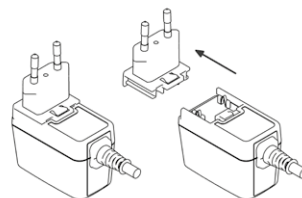


Fig. 6

⚠ Connect the power supply unit to the mains after checking the mains voltage indicated on the identification plate.

Mount the power supply in such a position where it can be easily unplugged. The LED indicates the operational readiness of the power supply. The power indicator (11) is automatically activated when the device is switched on.

To put the power supply out of operation just disconnect the power supply from the mains supply.

⚠ Do not pull the cable to disconnect the power adapter from the mains.

Charging of the OMEGA 600

⚠ Charge the device outside of the patient environment (at least 1.5 metres from the patient or patient support pursuant to IEC 60601-1, see Fig. 7).

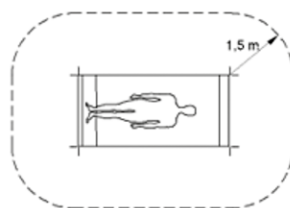


Fig. 7

Charging via USB

For charging, connect the USB power supply unit (e.g. E4-USB) to the USB-C socket (9) of the device.

 In charging mode, the LED lighting is switched off and the illumination of the device is no longer supplied with power.

 Do not let the power cable become taut as this could damage the device or pose a tripping hazard.

A description of how to start up and operate the E4-USB power supply unit is provided in a separate instruction for use.

Charging via Wall Charger CW1

Use the Wall Charger CW1 to charge the battery CB1 (10) of the device. The blue LED on the Wall Charger CW1 indicates contact with the device. The charge status indicator (7) is located on the battery compartment (8) of the device.

 Make sure that no foreign objects come between the device and the Wall Charger CW1. When using the Wall Charger CW1 to charge the device, make sure that Wall Charger CW1 is not contaminated in any form.

The setting up and operation of the Wall Charger CW1 is described in a separate instruction of use.

Charging via Charging Case CC1

Use the Charging Case CC1 to charge the battery CB1 (10) of the device. Turn the OMEGA 600 off. Remove the battery CB1 (10) from the battery compartment (8) and insert it into the Charging Case CC1. The charge status indicator of the Charging Case CC1 is located on the upper side of it.

 Make sure that no foreign objects come between the battery CB1 (10) and the Charging Case CC1. When using the Charging Case CC1 to charge the battery CB1 (10), make sure that the Charging Case CC1 is not contaminated in any form.

The setting up and operation of Charging Case CC1 is described in a separate instruction of use.

Charge status indicator (7)

The charge status indicator (7) of the device is located on the battery compartment (8) of the device.

The charge status indicator (7) is automatically activated when the device is switched on.

Orange/green/green: 66–100 %

Orange/green: 33–66 %

Orange: 10–33 %

Orange flashing: <10 %

Operation

Initial optical set up

Remove the protective dust cover (16) and place aside for reattaching after the examination. Unlock the adjustment lever (5) so that the optics unit (13) is free to move. Place the instrument on your head and adjust the height and circumference by means of the width adjustment (1) and height adjustment (2), respectively, until a comfortable fit is achieved. The rear part of the headband can be adjusted according to personal preference. Adjust the optics unit (13) to a position as close as possible to your eyes and centred to your face, then lock it in this position using the adjustment lever (5). Adjust the eyepieces (19) horizontally to match your own personal pupillary distance. The initially mounted eyepieces (19) incorporate +2D lenses that can be exchanged with neutral lenses (0D). Switch on the light by turning the brightness control (6) clockwise. You should now see the illumination spot being centred to your view at a distance of about 40 cm and you should be able to observe a pencil-sized object sharply focused at this distance. If you cannot focus on the pencil-sized object, you may have to adjust your distance to the object. Alternatively, you may try exchanging the initially mounted eyepieces (+2D lenses) (19) with the eyepieces containing neutral lenses (0D). More details on how to interchange the eyepieces (19) can be found in the section "Maintenance". If the illumination spot is not centred, you can adjust it vertically by twisting the illumination height adjustment (15) and you can adjust it horizontally by simply rotating the whole instrument slightly to the desired side. If a proper alignment has not been achieved, repeat steps as above. Correct adjustment of eyepieces (19) which match your own personal pupillary distance is particularly important when examining through small pupils. Each user should adjust the setting to match their own personal pupillary distance.

Setting the brightness

Adjust the brightness by using the brightness control (6). To increase the brightness, turn the brightness control (6) clockwise. Once you reach a latch, you are operating in the highest brightness range in standard mode. If you turn the brightness control (6) further clockwise and over the latching mechanism, you switch into the visionBOOST setting. When the end stop is reached, the highest brightness range in the visionBOOST is operating.

To decrease the brightness or to turn the device off, turn the brightness control (6) counterclockwise. When the end stop is reached, the device is turned off.

It is recommended to start with the lowest possible brightness and then increase as required for the examination. The visionBOOST might be used for the examination of patients with media opacities, e.g. cataract.

Aperture selection lever (14)

Three different aperture sizes and a diffuser aperture can be selected by means of the aperture selection lever (14). The choice of aperture depends mainly on the size of the patient's pupil. The diffuser is useful for the examination of the periphery.

Filter selection lever (18)

In addition to the unfiltered option, the filter selection lever (18) can be used to select an interference red-free filter, a blue filter or a yellow filter. These are switched into the illumination beam.

The interference red-free filter can be used to view changes of the retina (e.g. new vessels or retinal nerve fiber layer defects) and highlights whitish portions of the retina, if present.

The blue filter can be used to do fluorescein angiography.

The yellow filter can be used to reduce discomfort for the patient and photochemical hazard by reducing blue light.

Stereoscopic adjustment lever (17)

This feature ensures the best possible stereopsis for any pupil size and from any observation angle possible (e.g. peripheral view). When examining a dilated pupil head on, it is recommended to move the stereoscopic adjustment lever (17) into the forward position. When examining the periphery of the eye or in case of undilated pupils, it is recommended to move the stereoscopic adjustment lever (17) towards the side position (turn to your left). The stereoscopic adjustment lever (17) can be positioned anywhere between these two settings to select the optimum 3 dimensional view in any possible situation. The illumination beam can be adjusted vertically by the illumination height adjustment (15).

Use of the flip-up function

While wearing the instrument, the optics unit (13) can be folded up into the rest position. To bring the optics unit (13) back into the working position, simply fold it down again. There is no need to readjust the instrument.

Teaching mirror (TM)

The available teaching mirror can be attached to the optics unit (13) instead of the dust cover (16).

To be able to follow the examination of the main observer, the secondary observer stands next to the main observer and looks into the TM attached to the device from the side. The observation beam is split by the divider mirror, which approximately halves the brightness of the image for both the main and the secondary observer.

 The TM is intended for training purposes only.

Hygienic reprocessing

The instruction is available:

- online at www.heine.com

- in a paper version which you can request from the address listed

Maintenance

There is no regular maintenance required. The following maintenance should be done outside of the patient environment (at least 1.5 metres from the patient or patient support pursuant to IEC 60601-1, see Fig. 7) and when deemed necessary.

Changing the position of the brightness control (6)

The position of the brightness control (6) can be fitted on the right or left side onto the preferred socket for brightness control (4). To remove the brightness control (6), turn the device off and pull the dial out to gain access to the retaining screw. Remove the screw to detach the holder by using the enclosed offset screwdriver (see Fig. 8). Gently pull out the holder off the socket for brightness control (4) paying attention to the retaining clips. Remove the cover from the other socket for brightness control (4) and insert the holder by aligning the retaining clips. Insert the screw and tighten hand tight with the enclosed offset screwdriver (see Fig. 8). Reinsert the brightness control (6). Cover the spare socket for brightness control (4) with the cover. To activate the brightness control (6), remove the battery CB1 (10) from the OMEGA 600 or unplug the OMEGA 600 wired. Once power is reapplied the brightness control (6) will be fully functional.



Fig. 8

Change of paddings (3)

To change the paddings (3), carefully pull on the corresponding padding (3), which is attached to the device via a Velcro fastening. To attach the paddings (3) to the device, press the corresponding padding (3) onto the Velcro fastener.

Change of eyepieces (19)

To remove the eyepieces (19) unscrew them counterclockwise until they detach. To attach the eyepieces (19) screw them clockwise until they are hand tight.

Service

Exchange of the battery CB1 (10)

⚠ Exchange the battery CB1 (10) outside of the patient environment (at least 1.5 metres from the patient or patient support pursuant to IEC 60601-1, see Fig. 7).

Turn the OMEGA 600 off and disconnect the USB power supply unit. Remove the battery CB1 (10) from the battery compartment (8) by gently pulling and pushing the mechanical interlock at the same time. Do not touch the contacts on the battery CB1 (10). After inserting a new battery (10) make sure that the mechanical interlock is engaged.

Removing and reinserting of the battery CB1 (10) will reset the system.

The battery CB1 (10) only needs to be replaced if it can no longer be charged to a sufficient capacity. This is usually the case when the operating time of the battery CB1 (10) is reduced.

For the rechargeable batteries (10) two-year guarantee, please tell us the serial number of both the newly installed rechargeable battery (10) and your OMEGA 600:

www.heine.com/OMEGA600/battery-change

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.

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.

Charge your device during longer storage periods to protect the battery from discharge or store the battery and the device separate from each other.

Let the device accommodate to ambient conditions when it is cold.

Change the ocular lenses only in a clean environment in order to avoid dust to enter the indirect ophthalmoscope.

During non-use or storage of the device, cover the observation optics with the dust cover (16) to avoid dust on the exterior side of the glass.

Only use the indirect ophthalmoscope when the lenses are clean.

General Warnings

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

Do not use power supplies where damage has been detected.

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 presence of flammable gases / liquids, or in an oxygen rich environment.

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.

Do not use the device including its accessories and options outdoors.

Heating during operation is normal and harmless.

Make sure that the device is not exposed to direct sunlight.

For examination of the posterior segments of the eyes, use the indirect ophthalmoscope only in combination with ophthalmoscopic lenses.

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 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: Group 2 (LED)
Caution – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. An exposure time with this instrument at maximum intensity of longer than (see table exposure guideline) will lead to the guideline hazard value being exceeded.

ANSI Z80.36-2016: Group 2 (LED)
Caution – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm2, unless additional action is taken by the user to minimize exposure, after ___ min (see table exposure guideline). The risk of retinal injury at an exposure of 2.2 J/cm2 is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm2, the user should avoid exposures longer than ___ min. (see table exposure guideline).

Exposure Guidelines

Data for the highest brightness setting in visionBOOST

	Working distance	Duration according to ANSI Z80.36-2016	Duration according to EN ISO 15004-2:2007
Without ophthalmoscopolens	400 mm *	30 sec	2 min 44 sec
With ophthalmoscopolens***	400 mm **	28 min	169 min

*) from instrument
**) from instrument to HEINE A.R. Aspheric Ophthalmoscopy Lens (A.R. 16D), diameter: 54 mm, focal length: 16 dpt.
***) HEINE A.R. Aspheric Ophthalmoscopy Lens (A.R. 16D), diameter: 54 mm, focal length: 16 dpt.

Disposal

-  The product must be recycled as separated electrical and electronic devices. Please observe the relevant state-specific disposal regulations.
-  Dispose the rechargeable battery (10) at your local collection point.

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.
Note	Flickering of the LED of the OMEGA 600 wired is possible because of radiated electromagnetic fields.
	Brief illumination of the LED during charging of the OMEGA 600 is possible because of electrostatic discharge.
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 spower sources are used as described in the chapter „Accessories“. 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
Conducted emissions (EN 55011/CISPR 11)*	Passed
Radiated emissions (EN 55011/CISPR 11)	
Harmonic current emissions (IEC 61000-3-2)*	
Voltage changes, voltage fluctuations and flicker (IEC 61000-3-3)*	
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 1kHz	
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	30 A/m; 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 OMEGA 600 and OMEGA 600 wired

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 45 % to 80 % rel. humidity 500 hPa to 1060 hPa
Classification according to EN ISO 15004-2:2007 and ANSI Z80.36-2016	Group II The classification was performed together with a Ø54mm/16 Diopter HEINE ophthalmoscopy lens.

Technical Specification OMEGA 600

CB1	Li-Po cell
Input	USB 2.0 Type C: 5 V, 1.2 A
Power consumption	6 W
Protection class	Charging: class II Operating: internally powered
Charging time	typ. 1.5 h
Operating time (at maximum charge capacity)	typ. 4 h
Operating time visionBOOST)	typ. 1.5 h
Weight	475 g incl. rechargeable battery

Technical Specification OMEGA 600 wired

Input	100–240 V~ / 50–60 Hz / 160–80 mA
Power consumption	6 W
Protection class	Class II
Weight	655 g

Accessories

CW1 – Wall Charger	X-095.17.320
CC1 – Charging Case	X-000.99.091
E4-USBC (USB-C cord approx. 2 m)	X-000.99.300

Options

TM2 – Teaching Mirror	C-000.33.212
OMEGA 600 Breath Shield	C-000.33.019
Fundus charts Pad with 50 pcs.	C-000.33.208

Spare parts

CB1 – OMEGA 600 Battery	X-007.99.687
OMEGA 600 eyepiece +2D	C-000.17.116
OMEGA 600 eyepiece 0D	C-000.17.115

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
Käyttöttyjen symbolien selitys
Explicação dos símbolos utilizados

	CE-Kennzeichnung kennzeichnet die Übereinstimmung mit der Europäischen Medizinprodukteverordnung (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 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 medicinska 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 simbolo CE identifica a concordância com o regulamento de Dispositivos Médicos (EU) 2017/74.
	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
	Hersteller Manufacturer Fabricant Fabricante Produttore Tillverkare Fabrikant Producent Produsent Valmistaja Fabricante
	Herstelldatum Date of manufacture Date de fabrication Fecha de fabricación Data di produzione Tillverkningsdatum Productiedatum Produktionsdato Produksjonsdato Valmistuspäivä Data 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). Separat indsamling af elektrisk og elektronisk udstyr (det europæiske WEEE-direktiv). Produkter med dette symbolet skal ikke kasseres sammen med vanlig husholdningsavfall, men krever separat kassering i henhold til lokale bestemmelser. (European Waste Electrical and Electronic Equipment Directive, WEEE) Sähkö- ja elektroniikkalaitteille tarkoitettu erillinen keräyspiste (eurooppalainen WEEE-standardi). Coleção separada de aparelhos elétricos e eletrônicos (Diretrizes Europeias WEEE).
	Batterien müssen einer zentralen Sammelstelle zugeführt werden. Dispose the rechargeable batteries at your local collection point. Mise au rebut au point de collecte local. Desechar en un punto limpio de la comunidad. Smaltimento in un centro di raccolta comunale. Avfallshantera på ett kommunalt insamlingsställe. Afvoer naar een gemeentelijke inzamellocatie. Bortskaffelse på et kommunalt indsamlingsted. Avhend hos ditt lokale avfallshåndteringsanlegg. Laitte on hävitettävä paikalliseen keräyspisteeseen. Proceda à eliminação do aparelho em um ponto de coleta municipal.
	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 Tillått temperaturområde i °C ved opbevaring og transport Temperaturbegrensning i °C for oppbevaring og transport Näyttää pakkauksen sallitun säilytys- ja kuljetuslämpötilan (°C). Limite de Temperatura permitida 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 Tillått 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 Tillått luftfugtighed ved opbevaring og transport Fuktighetsbegrensning for oppbevaring og transport Sallittu ilmakestoitus 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 Salilittu 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 forsigtigt! Varo särkymisvaaraa! Perigo de quebra!
	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 bruksanvisningen. (Baggrundsfarve: Blå; forgrundsfarve: Hvid) Følg bruksanvisningen! (Bakgrunnsfarge: blå, forgrunnsfarge: hvit) Käyttöohjetta on noudatettava tarkasti. (Täustaväri: sininen, etualan väri: valkoinen) Siga as instruções de uso! (Cor de fundo: azul, cor de primeiro plano: branco)
	Unique Device Identification
	Medical Device
	Gebrauchsanweisung Instructions for use Mode d'emploi Manual de instrucciones Istruzioni per l'uso Bruksanvisning Gebruiksaanwijzing Brugsanvisning Bruksanvisning Käyttöohjeet Instruções de utilização

	Nur in geschlossenen Räumen benutzen. For indoor use only. Utiliser uniquement dans des locaux fermés. Sólo utilizar en espacios cerrados. Utilizzare solo in ambienti chiusi. Får endast användas i slutna rum. Uitsluitend in afgesloten ruimten toepassen. Må udelukkende benyttes i lukkede rum. Skal kun brukes i lukkede rom. Käyttö on sallittu ainoastaan suljetuissa tiloissa. Utilizar apenas em espaços fechados.
	The Regulatory Compliance Mark (RCM) The Regulatory Compliance Mark (RCM) Marque réglementaire de conformité (RCM) The Regulatory Compliance Mark (RCM) The Regulatory Compliance Mark (RCM) The Regulatory Compliance Mark (RCM) The Regulatory Compliance Mark (RCM) The Regulatory Compliance Mark (RCM) Vaatimustenmukaisuusmerkki (RCM) (RCM)- Marca de Conformidade Regulamentar
	Geräte der Schutzklasse II Class II equipment Appareil de classe de protection II Aparato de clase de protección II Apparecchio di classe di protezione II Apparat i skyddsklass II Apparaat van beschermingsklasse II Apparatet i sikkerhedsklasse II Klasse II-utstyr Suojausluokan II laite Aparelho da classe de proteção II
	Wechselstrom (AC) Alternating current (AC) Courant alternatif (CA) Corriente alterna (CA) Corrente alternata (AC) Växelström (AC) Wisselstroom (AC) Vekselstrøm (AC) Vekselstrøm (AC) Vaihtovirta (AC) Corrente alternada (CA)
	Gleichstrom Direct current DC Tension continue Tensión continua (CC) Tensione continua Likspänning Gelijkspanning Jævnspænding DC Likestrøm dc Tasajännite Tensão contínua (CC)
	Ladestandanzeige Charge status indicator Indicateur de l'état de charge Indicador del estado de carga Indicatore dello stato di carica Indikator för laddningsstatus Indicietlampje oplaadstatus Ladestatusindikator Ladestatusindikator Lataustilan merkivalo Indicador do estado de carga