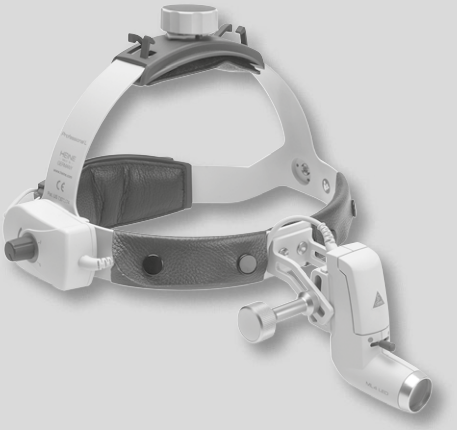
HEINE QUALITY
MADE IN GERMANY

HEINE® ML4 LED HeadLight



CE

HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6 · 82205 Gilching · Germany
E-Mail: info@heine.com · **www.heine.com**

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HEINE® ML4 LED HeadLight

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

Intended Use

Supplied internally with electrical power, the headlight is designed for short-term local illumination of the body, with the exception of the eyes, to support diagnosis during a therapeutic or surgical intervention.
The instrument may be used only by qualified medical personnel in 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.

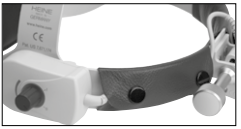
Warnings and Safety Information

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 set up, operation, maintenance or repair, as applicable. Notes are important, but not related to hazardous situations.

Setting up

Only operate the **ML4 LED** with the HEINE® mPack, the mPack UNPLUGGED or the plug transformer for the headband rheostat (Cat.No. X-095.16.330).



Take care that the cable is fastened tightly to the headband in the provided buckles (see Fig. 1).

Exposure to high mechanical strains and kinking of electrical cables on the headlights must be prevented.

Fig. 1 Safe cable routing
headband ML4 LED

Adjustment of the **headband Professional L** (see Fig. 2): To adjust for the head size, the headband can be widened or tightened by turning the turnbuckles at the top (1) and the back. (2).

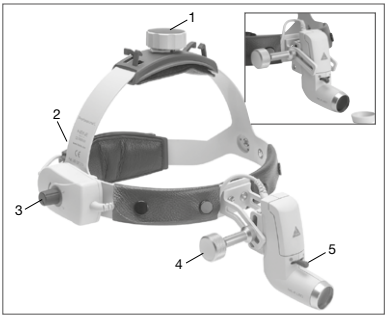


Fig. 2 Headband Professional L (see tall fig.)
optical protection cover (see small fig.)

Fitting the headband rheostat

You can fit the headband rheostat (1) either on the left or the right side of the headband (see Fig. 3). The headband rheostat (1) can then be used for stepless adjustment of the brightness.

It is recommended that the mPack rheostat is set to „0“.

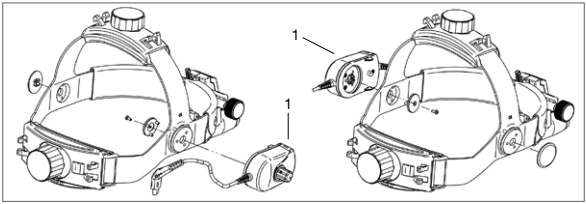


Abb. 3 Fitting the headband rheostat

Operation

To set up the ML4 LED with mPack or EN50, connect the short cord from the brightness control with the connecting cord mPack UNPLUGGED/Cinch and fix this to the back part of the headband (Fig. 4). Connect the instrument to the Cinch-socket of the mPack or EN 50. The rheostat (1) (Fig. 3) is used to adjust the brightness and to turn the device on and off.

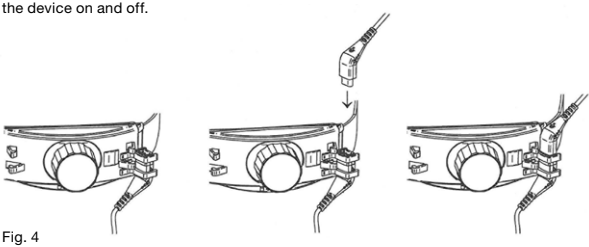


Fig. 4

To use the ML4 LED with the mPack UNPLUGGED first remove the rear cover of the headband (Fig. 5).

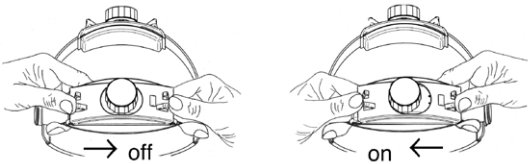


Fig. 5

Then attach the mPack UNPLUGGED to the rear of the headband. To do so, hold the headband in your left hand and push the mPack UNPLUGGED to the left, until it clicks into place (Fig. 6).



Fig. 6

Selecting viewing angle and field of view (Fig. 2)

Without S-Guard

After loosening the locking screw (4), the light head can inclined and the angle of the light direction can be adjusted.

After adjustment, re-tighten the screw (4).

With S-Guard

Before putting on the loupes, select your inter-pupillary distance (PD) or an average value on the scale. Unscrew the retaining screw and slide the eyepieces to one side symmetrically.

Unscrew the fixing screw (4) and locate the nosepad on the bridge of the nose.

Adjust the eyepieces so that they nearly touch the protective lenses.

Shine the ML4 LED onto an object at your normal working distance and adjust the eyepieces so that the object is centered in both eyepieces. After adjustment, re-tighten the screw (4). The loupes are correctly adjusted when you see a clearly-defined, round, shadow-free field of view. The slider (5) allows up or down adjustment of size of the light field.

Consumable material and options

For applications in the dental area:
If necessary, use a yellow filter in order to avoid the composite filling material hardening, as this blocks UV radiation.

The plug-on polarisation filter P2 enables a differentiation and low-reflex examination of tissue surfaces due to polarized light. Only in combination with HR 2.5x binocular loups, ready to use. The polarisation filter P2 is not a replacement for a yellow filter as it may harden composite filling material.

The setup and operation of the HEINE power sources are described in a separate instruction document.

Hygienic reprocessing

The instruction is available:
- 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 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.

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

General Warnings

Check the correct operation of the device before use! Do not use the device if there are visible signs of damage.

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

Do not modify the device.

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

The device and its accessories are not sterile. Avoid touching with sterile hands, areas or instruments.

Danger from loose, falling parts. Please check before every use that all the parts are tightened safely.

Route the supply cable in such a way that nobody can trip over it.

Do not shine the light directly into the eyes.

Never ever hold magnifying glasses or any other optical system in front of the light of the LED-headlight.

Only use the lens protector as transport protection. Store the lens protector in the transport case. Do not use in the surgical rooms.

Note the operating time of the power source. You may want to have a charged spare power source ready for use.

Jerky, fast movements can alter the position of the lamp housing.

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

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 Medizinprodukterichtlinie 93/42 EWG. The CE mark indicates that the product complies with the European medical device directive 93/42/EEC. Le marquage CE indique la conformité à la directive européenne 93/42/CEE relative aux dispositifs médicaux. El marcado CE indique la conformidad con la directiva europea 93/42 /CEE relativa a los productos sanitarios. Il marchio CE indica la conformità con la direttiva europea sui dispositivi medici 93/42 CEE. CE-märkning markerar en överensstämmelse med det europeiska direktivet för medicinska produkter 93/42 EEG. CE-markering duidt de overeenstemming aan met de Europese Richtlijn betreffende medische hulpmiddelen 93/42 EEG. CE-mærkningen angiver overensstemmelse med det europæiske direktiv 93/42/EØF om medicinsk udstyr. CE-merket angir at produktet er i samsvar med rådsdirektiv 93/42/EØF om medisinsk utstyr. CE-merkintä tarkoittaa, että laite vastaa eurooppalaisen lääkinnällisiä laitteita koskevan standardin 93/42 ETY vaatimuksia. O símbolo CE identifica a concordância com a Diretriz Européia para Dispositivos Médicos 93/42/CEE.
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 do 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 at your local collection point. Les batteries doivent être rapportées à un point de collecte central. Desechar en un punto limpio de la comunidad. Smaltimento in un centro di raccolta comunale. Avfallshantera på ett kommunalt insamlingsställe. Batterijen moeten bij een recyclinginzamelpunt worden ingeleverd. Bortskaffelse på et kommunalt indsamlingssted. Kasseres hos ditt lokale avfallshåndteringsanlegg. Laite 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 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)
	Nicht in die Lichtquelle sehen. Do not look into light source. Ne pas regarder la source lumineuse. No mirar directamente la fuente de luz. Non guardare direttamente verso la sorgente luminosa. Se inte in i ljuskällan. Kijk niet in de lichtbron. Se ikke ind i lyskilden. Ikke se inn i lyskilden. Älä katso valonlähteeseen. Não olhe diretamente para a fonte de luz.
UDI	Unique Device Identification