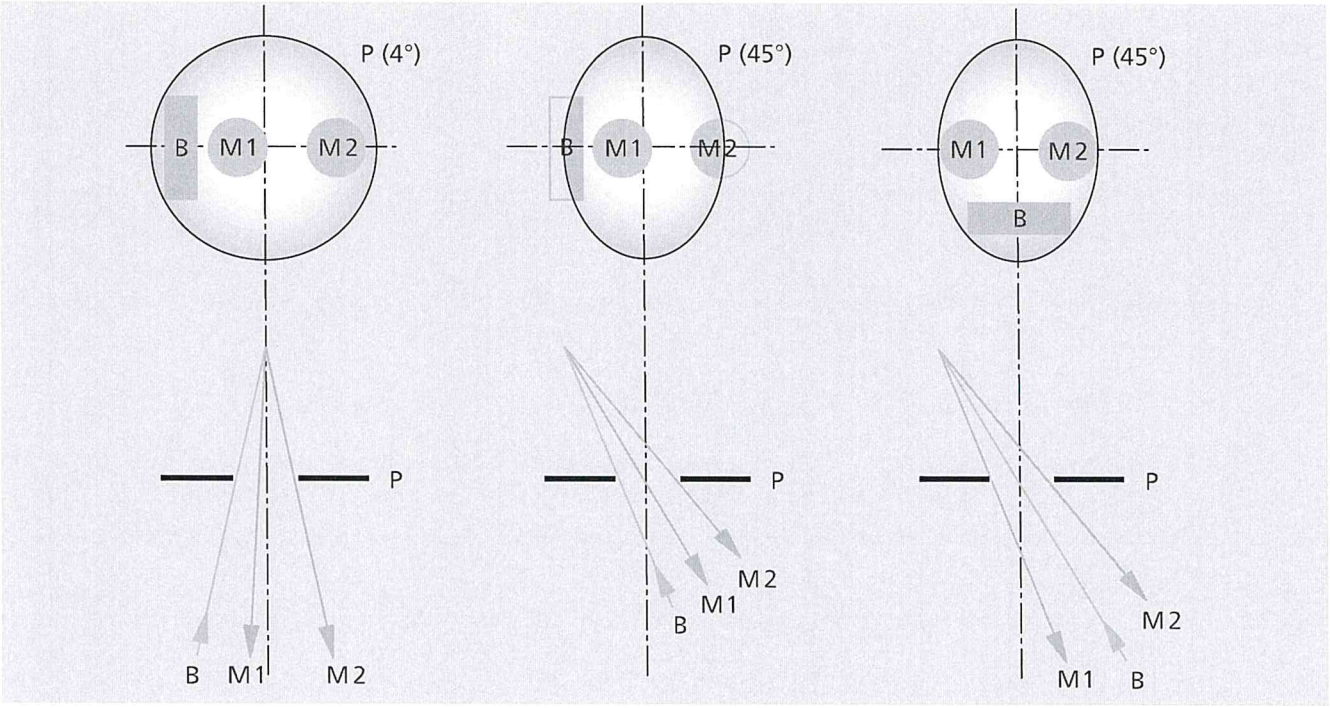


*Fig. 18*
*Stereoscopic observation with the slit lamp*

**Notes on handling the contact lens**

Before fitting a contact lens, the eye to be examined must be anaesthetised in an appropriate manner. In addition the pupil must be fully dilated for examination of the ocular fundus.

As the concave contact surface of a contact lens normally has a radius of curvature that is higher than that of the cornea, the intermediate space should be filled with 2 drops of physiological saline or methyl cellulose.

It is easier to put the contact lens onto the eye, if the patient looks upwards and the eyelid is lifted slightly. Any air bubbles will disappear if the contact lens is slightly twisted and tilted.

If, after the examination, the lens should adhere, then one should slightly impress the globe at the margin of the sclera (with a glass rod or similar implement).

After use, the contact lens must be cleaned with water and a cotton swab to prevent any residues, e.g. methyl cellulose, from drying out and adhering.

For disinfection, disinfectants such as CLORINA (manufactured by Lysoform, Dr. Rosemann GmbH, Berlin) may be used (5% solution, for 10 minutes). The lens must then be rinsed with distilled water and dried with a sterile swab.

Contact lenses must on no account be boiled or heated excessively in any way. Similarly, alcohol should not be used for cleaning or disinfection.

## 3.7 Fluorescence observation and slit lamp microscopy in contact lens fitting

Sodium fluorescein has been used as a dye in medicine for more than 100 years for physico-chemical and biological investigations. In 1881, EHRLICHER introduced it to ophthalmology. Since about 1938, it has also been applied to contact lens fitting. The method is based on the fact that the fluorescence light can be spectrally separated from an exciting light. Structures absorbing the fluorescein dye are contrasted much better against the non-fluorescing environment. Fluorescein, for example, stains damaged cells and fills intercellular spaces.

Especially in contact lens fitting this method is used to check the fit of hard contact lenses as well as the inspection of the cornea after contact lenses have been worn. This method not only permits the fit of contact lenses and the lachrymal flow to be assessed, but also allows superficial injuries of the corneal epithelium to be detected. Even minute corneal defects that may remain undiscovered by normal slit examination can be revealed in this way.

Correct fluorescence observation requires a suitable excitation light source and a properly dosed concentration of fluorescein in the lachrymal film, fluorescein is inserted into the conjunctival sac either by drops or with a fluorescein strip.

The yellow-green fluorescence light is not monochromatic, the emission maximum is at $\lambda$ = 530 to 535 nm. Hence, for excitation a radiation of $\lambda$ < 530 nm is necessary. The efficiency of fluorescence is highest with blue light excitation in the wavelength range $\lambda$ = 450 to 500 nm. The halogen lamp of the slit lamp serves as excitation source. A cobalt blue filter is swung into the optical path of the slit lamp serving as an exciter filter. Stray light that would reduce contrast must be blocked for observation and photographic documentation by using a barrier filter. For this, a yellow filter with $\lambda$ = > 530 nm is used. This filter blocks the blue exciting light and transmits only the yellow-green fluorescence and longer wavelengths.

### Concentration of sodium fluorescein

The optimum fluorescence effect is achieved with a sodium fluorescein concentration of 0.2 to 0.4% in the lachrymal fluid.

This concentration is obtained by dripping 1 drop of 2% sodium fluorescein into the conjunctival sac of a patient with normal lachrymal secretion. The reaction time is about 1 to 2 minutes. In the case of hyposecretion, however, this concentration will be too high. As a result there will be no fluorescence, but only a brownish coloration of the lachrymal film. This can be remedied by either using 1% sodium fluorescein or by adding a drop of physiological saline.

In the case of hypersecretion, the above mentioned concentration of sodium fluorescein will be too low. Thus, a higher dose should be applied.

In essence the use of fluorescence observation with the slit lamp in contact lens fitting has the following applications:

- Inspection of the outer anterior segment of the eye before inserting a contact lens
- Inspection of the fit of the contact lens on the eye with and without sodium fluorescein
- Inspection of the anterior eye segment and particularly of the cornea on removal of the contact lens after it has been worn over a long period
- Thorough inspection of the contact lens.

These inspections can be performed as follows:

**Inspection of the anterior eye segments**

This inspection is carried out using diffuse or direct focal illumination with a wide, fully opened slit. The cornea is examined for scars, vascularisation, neovascularisation, infiltrates, abnormal changes of the tissue of the corneal back surface, ring-shaped lipoid inclusions at the corneal limbus, and inclusions with keratoconus. Sclera and lids are examined for irregularities, the conjunctiva for congestion and possible anomalies. It is also possible to assess the lachrymal fluid.

**Inspection of contact lens fit**

Conditions: diffuse illumination and a magnification of approximately 12x. The following parameters may be assessed: fit of the lens and centration, lens movement (direction and speed), presence of air bubbles or foreign bodies under the lens and the state of the lachrymal fluid.

With hard contact lenses, the size of the contact lens relative to the palpebral fissure, the hydrophobic state of the contact lens and the distribution of the lachrymal fluid under the contact lens (fluorescein image) can be assessed. Also lenses may be checked for any grease or dirt deposits. With soft contact lenses, the size of contact lens movement in the region of the limbus, the size of the contact lens relative to the cornea and the state of the edge of the contact lens (wrinkled or wavy, tightly fitted, pressure exerted on conjunctiva) are assessed. Furthermore, blood vessels can be examined to determine if the contact lens dislocates or squeezes them which may cause irritation of the conjunctiva.

**Inspection of the cornea**

The examination is performed with direct focal illumination (by optical section), direct or scattering sclero-corneal illumination. The cornea is checked for dots, abrasions, and erosions as well as possible deformation (air bubble pits, oedemas). Furthermore it can be examined for changes in the deeper corneal layers, in the conjunctiva (pressure sores, allergic reactions, problems with caring agents) and of the eye-lids.

**Inspection of contact lens**

Contact lenses are inspected with diffuse and direct focal illumination. The lens should be supported during the inspection. The surfaces of the contact lenses are checked for scratches, burr and polishing marks. The edges of the contact lenses are examined for cracks, chips, defects and possible deposits.

**Interpretation of fluorescence patterns under contact lenses with a spherical back surface**

Flat fitting

The fluorescence image of a flatly fitted contact lens on a spherical cornea shows a round, dark contact zone in the centre surrounded by a wide fluorescing ring that becomes brighter towards the periphery. The fluorescence intensity increases continuously towards the edge (intense yellow-green). A flatly fitted spherical contact lens on a toric cornea forms a central dark contact zone in the shape of an ellipse, the long axis of which corresponds to the flatter corneal meridian. With increasing toricity the ellipse becomes flatter and longer. With a steeper meridian, the contact lens juts out from the cornea and shows a zone of increasing fluorescence.

Parallel fitting

A contact lens fitted parallel to a spherical cornea shows a central, evenly round, dark contact zone surrounded by a fluorescing ring that becomes brighter towards the periphery. The dark zone covers about

70 to 72%, the yellow-green ring about 28 to 30% of the area. The marginal area must jut out gently and continuously from the cornea with smooth transitions. If this is not so, the contact lens surface has a defect and should be removed immediately from the cornea.

The fluorescence image of a parallel fitted contact lens on a toric cornea shows a central, dark contact zone with peripheral indentations in the steeper meridian. With increasing toricity of the cornea, a dark bone-shaped or butterfly-shaped contact zone is created. The contact lens rests on the flatter meridian, in the steeper meridian it juts out from the cornea. The marginal zone must project gently.

Steep fitting

The fluorescence image of a steeply fitted contact lens on a spherical cornea shows a central fluorescing "lake", surrounded by a paracentral, narrow and dark fluorescence ring. This dark ring is adjoined by a fluorescing ring (at the marginal zone of contact lens) having a brightness that increases continuously towards the edge.

All transitions must be smooth.

The fluorescence image of a steeply fitted contact lens on a toric cornea shows paracentral, dark, sickle or kidney shaped contact zones towards the steeper meridian. They are surrounded by a lachrymal lake that becomes increasingly oval with increasing toricity. At the periphery it merges with the fluorescing ring of the marginal zone of the contact lens which becomes brighter towards the edge.

After every observation with sodium fluorescein the eye should be rinsed thoroughly with physiological saline to avoid infection.

## 3.8 Assessment of lachrymal film

The assessment of the lachrymal film and the inspection of the lachrymal apparatus should be performed at the very beginning of the examination, particularly before contact lens fitting, as the quantity and composition of the lachrymal fluid may change in the course of examinations and measurements as well as during the lens fitting process.

The daily lachrymal secretion amounts to about 0.5 ml to 1.0 ml. During sleep, however, no lachrymal fluid is produced. If the daily secretion rate is less (hyposecretion), there is the danger of hypoxia of the cornea as the aqueous phase as oxygen carrier is too weak. With soft contact lenses, additionally dehydration occurs. In the case of hypersecretion of lachrymal fluid, there are generally no problems in contact lens application.

Before the first application of contact lenses, the ophthalmologist must check whether the quantity of the lachrymal fluid of the eyes allows the wearing of contact lenses and the composition of the lachrymal secretion lies within the normal range. Every contact lens needs a certain lachrymal film so that it can float with minimal friction. Soft contact lenses additionally require a certain tear humidity to remain elastic. Depending on lens type, material and wearing mode a daily quantity of up to 1 ml lachrymal fluid is necessary. This quantity corresponds to the daily production of a healthy person. A lack of tears may make wearing contact lenses a risk.

The quality and quantity of the lachrymal film can be examined simply and reliably with the slit lamp. The break-up time and thus the stability of the lachrymal film is an important criterion for symptom-free wearing of contact lenses. To determine this break-up time, the lachrymal fluid of the patient is stained with sodium fluorescein drops without application of a local anaesthetic. A cobalt blue filter is brought into the optical path of the slit lamp. While the corneal surface

is continuously observed through a yellow filter, the time between lid blinking and the appearance of the first dry spots (breaking up of the lachrymal film) is measured. This interval is described as break-up time (BUT). During this examination, one must ensure that the patient is not dazzled (retinal irritation - reflex secretion) as this would falsify the examination result. If the break-up time is between 0 and 10 seconds, the patient suffers from an acute lack of mucin. If this time is between 10 and 25 seconds, mucin production is disturbed and the lachrymal film is labile. With a break-up time of more than 25 seconds the lachrymal film is regarded as stable.

This examination can be performed more conveniently, if a video system (such as the Model 020 Video Compact Camera) is used on the slit lamp. In this way, details of the observation process can be differentiated and assessed more easily by slow motion or single frame sequences on the monitor screen. When the examination is recorded on a video recorder with an integrated electronic counter the BUT can be determined easily and precisely. This recording method is an instant user-friendly, low-cost solution preferable to normal photography which provides only "still pictures" with no continuous visualisation and requires time for film processing.

### 3.9 Other examination methods

Apart from the examination methods covered so far, slit lamps may also be used for other examinations and treatments. To enhance the contrast of objects with a high portion of red (e.g. fundus), green filters (red-free filters) are required.

Observations in polarised light have also been performed but so far these examinations have not resulted in generally useful applications. For this reason polarising filters are not incorporated in slit lamps as standard.

Of particular interest and special importance is the use of the slit lamp not only for observation but, with suitable accessories, as a measuring instrument.

As the slit lamp is such a widely used instrument, the cost of a measuring instrument can be reduced considerably by making use of the mechanical and optical elements of the slit lamp. The most popular example is the applanation tonometer used to measure the intraocular pressure. Further examples are attachments for measuring the thickness of the cornea, the depth of the anterior chamber as well as length and angle measurements on the cornea. These instruments will be covered in detail in section 5.

The slit lamp, however, is not only used as examination instrument. The corneal microscope, can assist in, for example, minor operations on the cornea, such as the removal of foreign bodies. With the slit illuminator the affected area can be appropriately lit. Thanks to the large working distance between microscope and eye, procedures are simplified.

# 4. Documentation of findings.

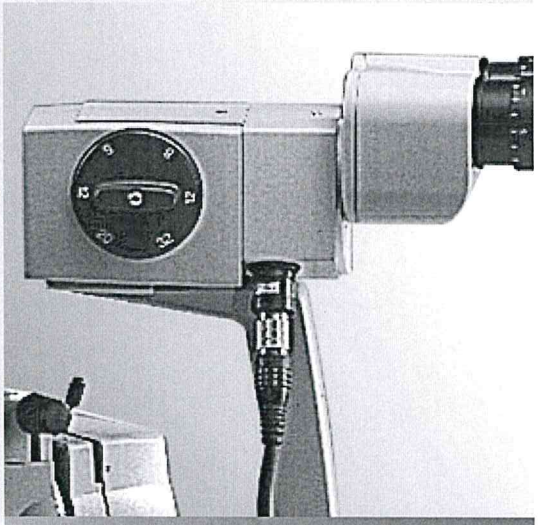

*Fig. 19*
*Model 020*
*Video Compact Camera*

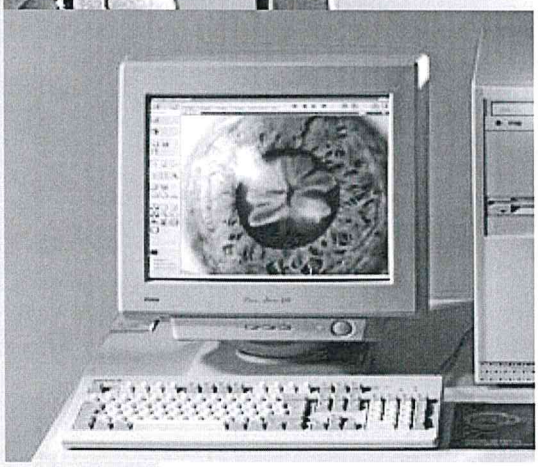

*Fig. 20*
*VISUPAC Software*

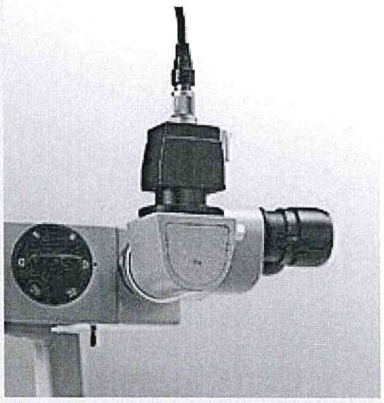

*Fig. 21*
*TV-attachment*
*with 3CCD camera*

## 4.1 Video documentation

In recent years, video documentation has gained general acceptance for slit lamp examinations because a "still" photograph is much less meaningful than a dynamic film record. Only with this technique can the progress of slit lamp examination be represented realistically as the examiner sees it or he is used to seeing it: as a complex picture.

Further advantages over photographic records include lower light levels for the patient as well as the fast availability of results. As film development is not necessary, costs are also reduced. Often it is useful to explain to the patient, findings or the condition and fit of a contact lens during an examination. This saves time-consuming theoretical explanations later. This modern technique is well suited for documentation, information and educational purposes.

For the SL 115 Classic, SL 120/130 various options of video documentation are available.

**For SL120/130 Slit Lamps:**

- Commercial 1/2" TV cameras mounted via a 50/50 beam splitter with a sliding prism, TV adapter f=75 mm and TV coupling (standard C thread/ C mount). Cf. Fig. 21. For special requirements a 3CCD camera can also be fitted easily.
- The Model 020 Video Compact Camera constitutes a decisive milestone in the development towards an integrated video documentation system. It mounts directly between the microscope body and binocular tube without the need for an intermediate piece or TV adapter. This miniature camera has an outstanding resolution. Due to its low weight, it does not impair the mobility and ease of handling of the slit lamp.
- Retrofitting of the SL 115 Classic with a 1/2" miniature camera mounted via a video compact adapter.

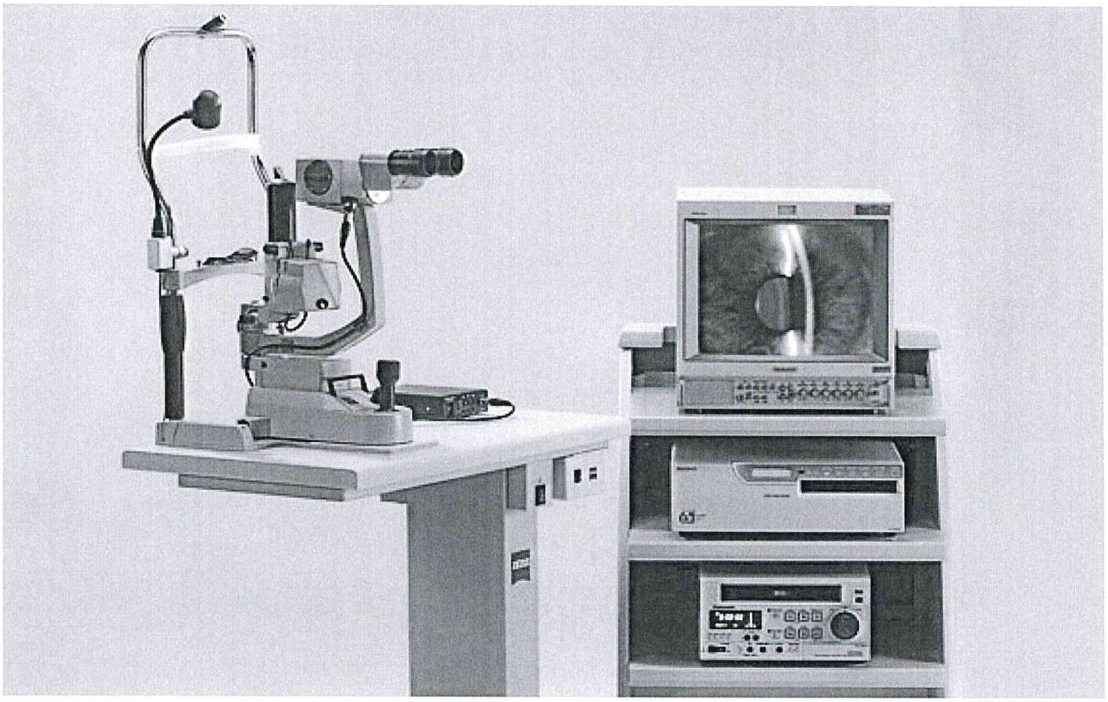

*Fig. 22*
*SL 120 Slit Lamp with video recording equipment and video printer*

In addition to slit illumination, fill-in illumination should be used to achieve better illumination of the whole eye.

To fully utilise the available image quality a TV system that transmits and records the colour and synchronising signals separately is used, such as S-VHS or HI 8 (Y/C). A complete video system for slit lamps consisting of Model 020 Video Compact Camera, monitor, video recorder and video printer is shown in Fig. 22.

The VISUPAC digital image recording and editing system for slit lamps rounds off the range of documentation options.

## 4.2 Digital image recording and editing

### VISUPAC

The VISUPAC digital image recording and editing system for slit lamps (Fig. 20) allows convenient storage, editing and management of images obtained with the slit lamp. The integration of a professional SQL database ensures fast access to all data at high system stability. Besides, the functionally designed graphic user interface adds to fast operation.

Software features include extensive image editing functions such as sharpening, blurring, zoom, inverting, contrast and brightness adjustment, slide show, etc., thus providing optimum postprocessing of images.

Graphic and text elements are easily created and inserted. These elements are part of a layer overlaid to the image. They may at any time be revealed or hidden, edited and deleted.

Another function allows transfer of a contour, such as a circle or rectangle, from one image to other images for comparison of a region of interest. Reference marks ensure geometrically correct transfer of the contour in terms of position, size and orientation.

For data import and export, of course, the DICOM standard (**D**igital **I**maging and **CO**mmunications in **M**edicine) can be used. This allows patient information to be included and transferred along with the image file.

# 5. Accessories.

The uses of a slit lamp can be extended by a wide range of accessories for measurement, examination and documentation.

The most widely used accessories are:

**Applanation tonometers**
for measurement of intraocular pressure

**Micrometer eyepieces**
for length and angle measurements on the eye, particularly for contact lens fitting

**Contact lenses**
for examination of the iridocorneal angle, central and peripheral fundus

**TV cameras, co-observation tubes**
for the documentation of findings and for educational and training purposes

**Digital image archiving**
for the documentation of findings, image processing and storage

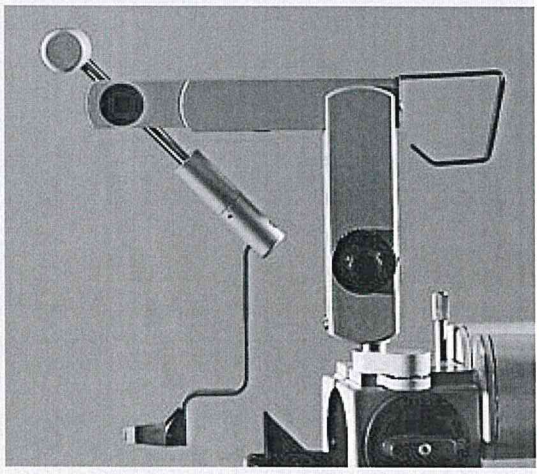

*Fig. 23*
*AT 020*
*Applanation Tonometer*

## 5.1 Measurement of intraocular pressure

The most widely used accessory for the slit lamp is the Goldmann applanation tonometer. It is used for measuring the intraocular pressure. Today, compared with other techniques, this method is characterised by high accuracy, reliability and simplicity. The design and measuring principle of this instrument is well known as many papers have been published on it.

In practical use it is important that the tonometer is correctly mounted on the slit lamp. For routine measurements, it must be possible to move the applanation tonometer into a working position quickly and easily. On the other hand, it should not hinder normal work with the slit lamp. These requirements are met by the applanation tonometer models AT 020 (Fig. 23) and AT 030 (Fig. 24) that have been specially designed for the slit lamps SL 120/130. With an appropriate tonometer holder however, the AT 020 Applanation Tonometer may also be used on earlier slit lamp models and the SL 115 Classic Slit Lamp.

### Tonometer measurement

Before the measurement of the intraocular pressure the illumination of the slit lamp must be adjusted: maximum illuminated field, open slit, a blue filter, and the slit projector swung out laterally to about 50°, 8x or 12x microscope magnification.

The patient's eyes must be anaesthetised as usual, and to avoid blinking, both eyes should be anaesthetised. If necessary, the fixation light should be used to fix the gaze. Next, a drop of sodium fluorescein solution is to be dripped into the conjunctival sac of both eyes, if necessary, by means of a strip of blotting paper.

The patient should look about 6° to the right. During measurement, the patient's eyes must be wide open. The examiner can assist in this by opening the

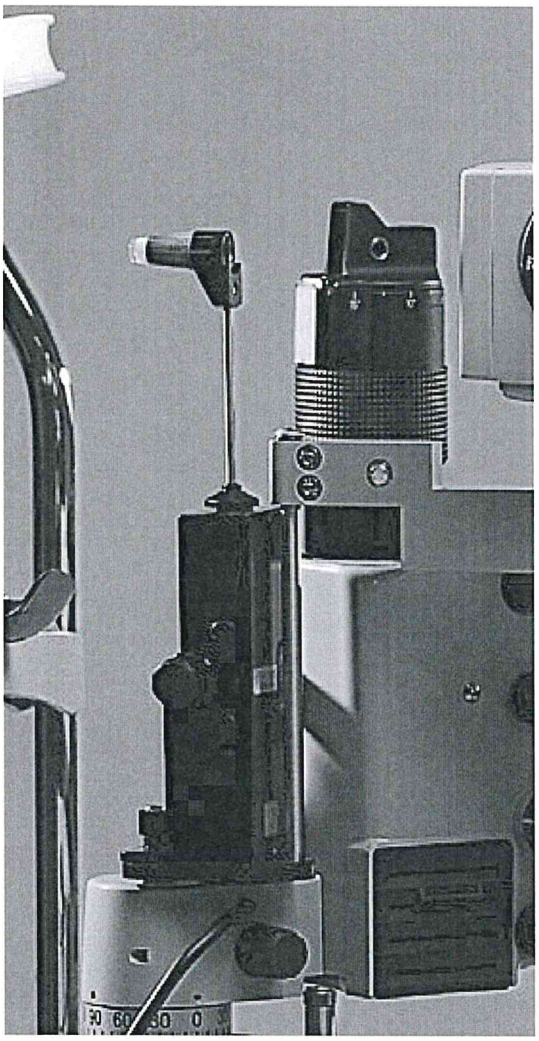

*Fig. 24*
*AT 030 Applanation Tonometer*

patient's eyelids with thumb and forefinger.

Care should be taken however not to exert inadvertent pressure on the globe by the fingers which should rest only on the bony eye socket.

The measuring body of the applanation tonometer contains an image doubling prism. With this prism, the lachrymal film ring between measuring body and cornea is divided into two green fluorescing semicircles.

Both semicircles must be the same size.

The corresponding vertical adjustment is performed with the slit lamp.

The width of the rings should be about 0.2 - 0.3 mm and should oscillate with the pulse beat.

For measurement, the measuring cell is brought into contact with the cornea. The pressure on the cornea is increased, starting from scale division 1 on the measuring drum, until the inner edges of the rings just contact each other (Fig. 25). The corresponding value is then read from the measuring drum and converted to kPa using a conversion table.

It is advisable to take a trial measurement first on both eyes. Then three measurements are taken successively on each eye to cover short-term variations of the intraocular pressure. Finally, the mean value should be calculated.

If the measurement takes too long, the corneal epithelium will dry out to a greater or lesser extent and in this case, measurements will be invalid. Therefore, the measuring time should be short and measurements should be taken on each eye alternately. Any symptoms caused by drying out will disappear quickly without further treatment.

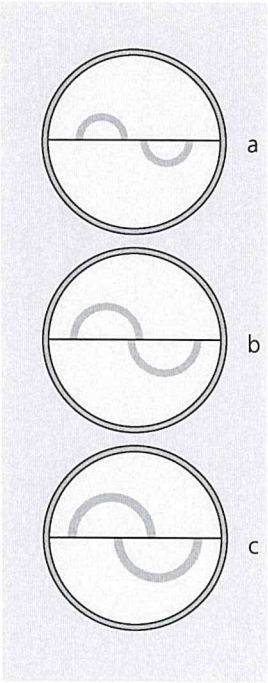


*Fig. 25*
*Measuring patterns of applanation tonometer*

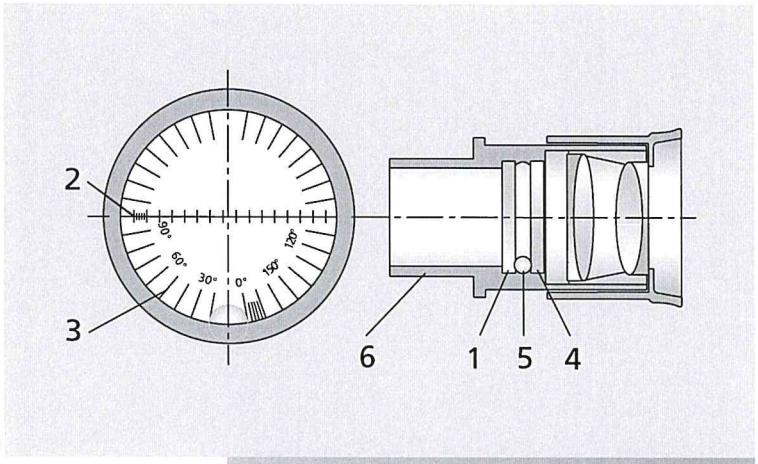


*Fig. 26*
*Micrometer eyepiece*
*(eyepiece field of view)*

1 Reticle
2 Linear scale, 0.2 mm interval
3 Tabo angle scale, 2° interval
4 Front window
5 Reading ball
6 Eyepiece socket

The image scale in the eyepiece plane is then 1x. With other magnifications, an appropriate scale factor must be applied. The eyepiece contains a reticle with a linear diameter scale of 15 mm graduated in 0.2 mm intervals. The angular scale of 360° for the measurement of the inclination angle is graduated in 2° intervals. The artificial horizon required for the angle measurement is provided by a gravity ball.

For the measurement of the inclination angle the image scale does not matter, it is only important that the object field is sufficiently large for setting the magnification on the slit lamp.

Additionally 10x micrometer eyepieces are available. The reticle in this eyepiece has a 10 mm linear scale graduated in 0.1 mm intervals. For routine check-ups it is also possible to take survey length measurements by placing an appropriately sized slit on the object to be measured and the slit length read from a scale (SL 115 Classic/120/130).

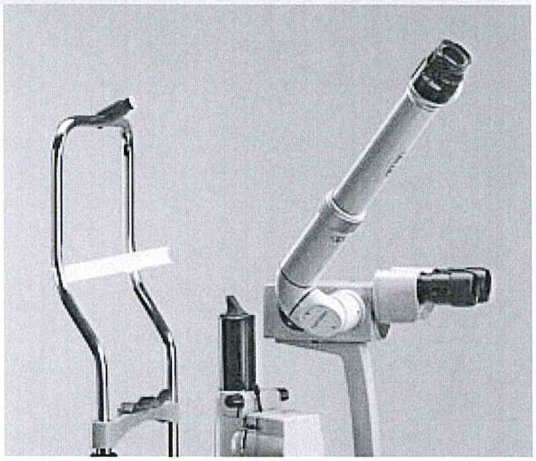

*Fig. 27*
*Slit lamp*
*with co-observation tube*

## 5.2 Length and angle measurement

Not only for the ophthalmologist, but also for the contact lens fitter it is of great advantage that he can take length and angle measurements on the SL 115 Classic/ 120/130 Slit Lamps with the appropriate accessories. It is possible, for example, to measure the diameter of cornea and pupil or the height of the palpebral fissure, and to determine the axis of a toric contact lens. These measurements are taken with a special eyepiece (Fig. 26) that fits into the binocular tube of the slit lamp in place of the standard eyepiece. To take measurements a medium magnification of 12x should be selected.

## 5.3 Miscellaneous

Beside the wide range of accessories for the slit lamp discussed above, the co-observation tube should be mentioned as it is particularly useful for educational and training purposes (Fig. 27).

# 6. History of the slit lamp

## and development of the photography of the optical section

As important as the slit lamp is for today's ophthalmologic practice, as interesting, is the history of its development allowing its special technical features to be understood by those who are familiar with the function and operation of the modern slit lamp.

In judging the historical development of the slit lamp one must consider that the introduction of the instrument always had to be accompanied by the introduction of new examination techniques. These, however, were influenced not so much by the work of the engineers but rather by the efforts and foresight of the ophthalmologists involved. In other words, it was not so much the quality and performance of a slit lamp that was important for its general acceptance, but rather the practicability of the relevant examination methods.

Accordingly there were two conflicting trends in the development of the slit lamp. One trend originated from clinical research and aimed at an increase in functions and the introduction and application of increasingly complex and advanced technology. The other one originated from ophthalmologic practice and aimed at technical perfection and a restriction to useful methods of application.

Diseases of the eye are best diagnosed by visual inspection than by palpation. For visual inspection of the outer eye, magnifying aids had been used in the past. However, it was not as easy to observe the inner eye, particularly the fundal retina and choroid.

The first to succeed in this was Hermann von HELMHOLTZ (1850) with the invention of the ophthalmoscope. This is regarded as the birth of modern ophthalmology. Up to this fundamental invention, it had been a long road for medicine and especially for ophthalmology.

*Fig. 28*
*Carl Zeiss*

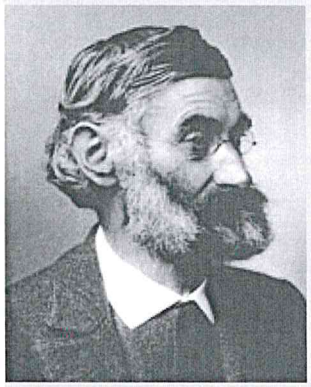

*Fig. 29*
*Ernst Abbé*

*Fig. 30*
*Allvar Gullstrand*

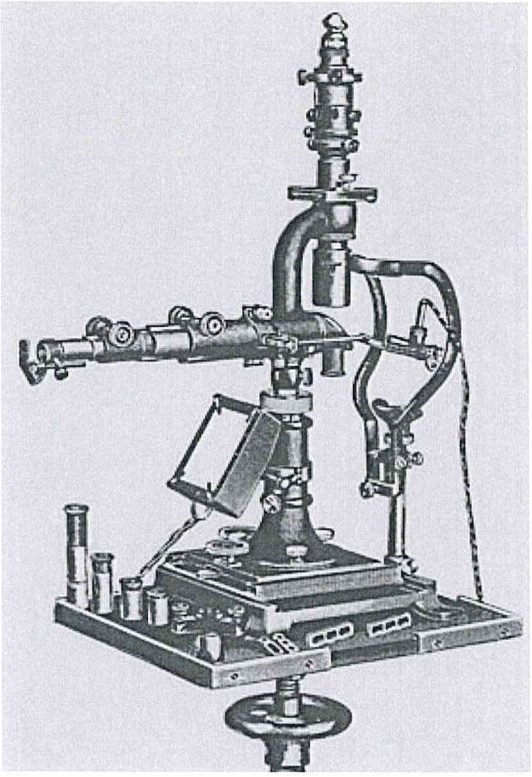

*Fig. 31*
*Large Gullstrand Opthalmoscope (1911)*

In ophthalmology, the term "slit lamp" is almost the only one used today. It would be more correct, however, to call it a "slit lamp instrument". Today's instruments are a combination of two separate developments, that of the corneal microscope and that of the slit lamp. The corneal microscope is the older instrument.

Magnifying visual aids – even binocular ones – were known, of course, before the eighties of the previous century, such as the sphere loupe (approx. 50 D) by HARTNACK.

Periscopic "plug lenses" (Steinheil-Coni; about 1866) were the predecessors of telescopic spectacles. They could, however, also be used as a loupe after HARTNACK. Around the turn of the century, these devices were followed by assorted types of binocular loupe. Before 1872, LIEBREICH used a monocular microscope as cornea microscope. The first independent development in this field however was the "corneal loupe" the Rostock mechanic WESTIEN made for W.v. ZEHENDER in 1886. It enjoyed great popularity and underwent several technical changes. Its optics classified the instrument as telescopic spectacles with a power of 10x. In ZEISS, at this time a GREENOUGH type reflected light microscope was made. In 1899, the Jena physicist CZAPSKI developed a new stand with an illumination system for horizontal use. Soon it was fitted with an arc guide permitting the instrument to be swivelled and a wooden cross-slide stage with face frame. By changing eyepieces and objectives, magnifications between 13x and 35x could be selected.

The major difference compared with the instrument of v. ZEHENDER was the image reversing prism system according to the French engineer PORRO. Because of this, it was possible to use the astronomical KEPLER telescope system that allows higher magnifications. On corneal microscopes, the magnification is intentionally limited to 40x to avoid the problems of patient movement. Today's cornea microscopes are mostly a combination of a KEPLER telescope with a GALILEAN magnification changer.

The first concept of a slit lamp dates back to 1911 and the great ophthalmologist Alvar GULLSTRAND and the "large reflection-free ophthalmoscope". In the same year, GULLSTRAND was awarded the Nobel prize. The instrument was manufactured by ZEISS. It consisted of a special illuminator that was connected by a small stand base through a vertically adjustable column. The base was freely movable on a glass plate. The illuminator employed a Nernst glower which was converted into a slit through a simple optical system. This slit was imaged into the eye by an aspheric ophthalmoscopic lens. A binocular telescopic lens was used for observation. The ophthalmoscope lens and telescopic lens were both held in one hand. Image contrast arose from differences in light scattering from different media. This instrument, however, did not receive further attention. The term "slit lamp" did not

appear again in the literature until 1914.

There is no description of slit lamp findings by GULLSTRAND himself. The first relevant description was found in 1914 in the "Klinische Monatsblätter" written by ERGGELET.

In the period after 1912, also the first retina camera was developed after NORDENSON. The first photographs are known to have been published by NORDENSON in 1915. In 1925, the first retina camera containing an arc lamp as a high-intensity light source was produced at ZEISS by closely following the principles of the "large reflection-free ophthalmoscope" of GULLSTRAND.

Up until 1919, various improvements to the GULLSTRAND slit lamp were made by HENKER, VOGT et al. First, a mechanical connection was made between lamp and ophthalmoscopic lens. This illumination unit was mounted to the table column with a double articulated arm. The binocular microscope was supported on a small stand and could be moved freely across the tabletop. Later, a cross-slide stage was used for this purpose. VOGT introduced KOEHLER illumination, and the reddish shining Nernst glower was replaced with the brighter and whiter incandescent lamp (nitra lamp).

In 1914, Henker devised an experimental setup whose principle was rejected at first but regained importance in a modified form many years later. With this system the double articulated arm of the microscope illumination system was not fixed to the table spindle but to the microscope column. This was the first combined connection of microscope and illumination system for co-ordinate motion.

Special mention should also be made of VOGT's experiments between 1918 and 1920 with a GULLSTRAND slit lamp produced by ZEISS. On this instrument, the nitra lamp was replaced with a carbon arc lamp with a liquid filter. At this time the great importance of colour temperature and the luminance of the light source for slit lamp examinations was recognised and the basis created for examinations in red-free light.

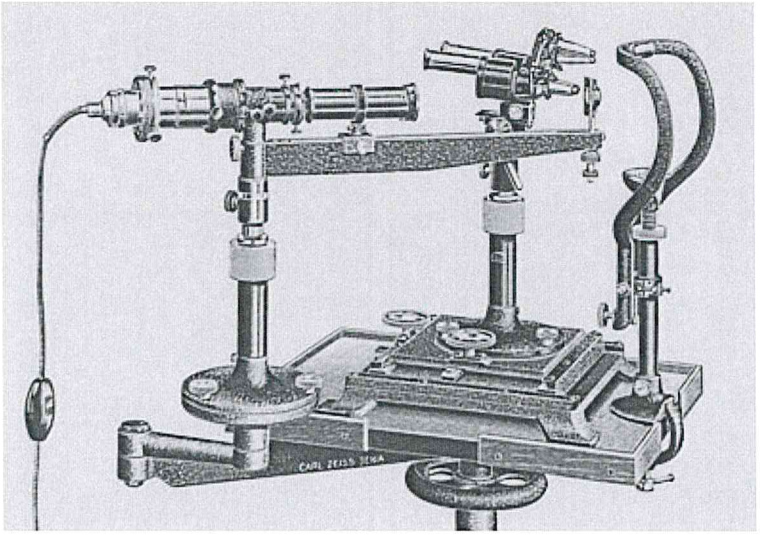

*Fig. 32*
*Slit lamp after Gullstrand with corneal microscope after Koeppe (1911)*

It seems that KOEPPE was the first to really recognise the value of the invention of GULLSTRAND. He was the author of the most important publications in GRAEFE's archive between 1916 and 1919. His research work culminated in the book "Mikroskopie des lebenden Auges" (1920; 2nd vol. 1922).

In 1920, KOEPPE also tried to use the slit lamp for examination of the posterior segments of the eye by introducing contact lens examination of the fundus and compared the technique with the more advanced methods of ophthalmoscopy. In co-operation with HENKER, he also complemented the GULLSTRAND slit lamp with a binocular corneal microscope to form a slit lamp instrument.

About 1926, the slit lamp instrument was redesigned again. The vertical arrangement of the slit projector (slit lamp) made it an easy to handle instrument. With this instrument ZEISS made a comparatively small, compact instrument – the slit lamp after COMBERG (1933). For the first time, the axis through the patient's eye was fixed as the common swivelling axis for both slit lamp and

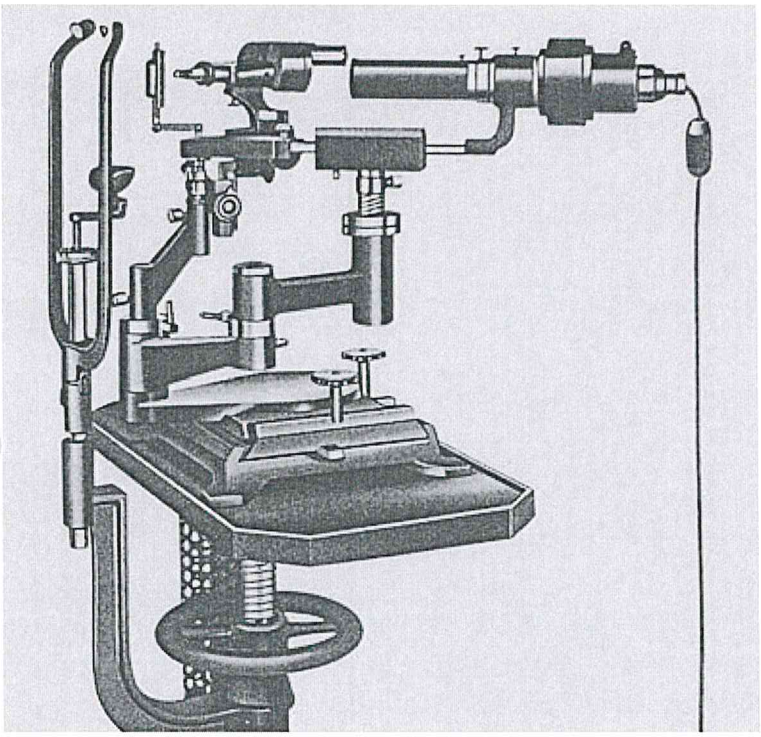

*Fig. 33*
*Bausch & Lomb slit lamp after Koeppe (1926)*

microscope – a fundamental principle that was adopted for every slit lamp instrument developed later. The instrument, however, did not yet have a co-ordinate cross-slide stage for instrument adjustment but only a laterally adjustable chin rest for the patient. The importance of focal illumination had not yet been fully recognised.

On this instrument, the advantages of the GULLSTRAND slit lamp were restricted by the fixed connection between microscope and illumination system.

In 1926, BAUSCH&LOMB built a slit lamp based on KOEPPE's investigations with some advanced features, but this instrument nevertheless did not gain acceptance by the market. It had a common swivel axis for the microscope and the illumination system below the patient's eye and a common horizontal adjusting facility with cross slide for both these subassemblies.

The vertical adjustment of illumination system and microscope had to be performed with the table spindle with the headrest remaining fixed. Here, although rather awkwardly, the coupling of the microscope and illumination system was achieved for the first time with regard to adjustment of the instrument in all three co-ordinates.

In 1927, ZEISS introduced the iris stereo camera developed by HARTINGER. This camera constituted a considerable step forward compared to the commonly used home-made instruments.

The documentation of findings at that time was still confined to drawings. It must be said, however, that the atlases and textbooks were dominated by masterly drawings by ophthalmologists or specially trained scientific artists (e.g. the slit lamp atlas by MEESMANN, 1927). Without the illustrations of the painter BREGENZER which are equally instructive even today, the standard work of VOGT "Lehrbuch und Atlas der Spaltlampenmikroskopie" (1931) would have been only a dry representation of precisely observed changes, requiring a lot of imagination by the reader.

In 1930, about 20 years after the introduction of the first slit lamp by GULLSTRAND, Rudolf THIEL presented the first optical section photographs ("photographed slit images") to the 48th Session of the Deutsche Ophthalmologische Gesellschaft. This was the beginning of slit lamp photography. For illumination, THIEL used an arc slit lamp customary at that time, the photographic apparatus consisting of a photomicrographic eyepiece and a ZEISS Biotar lens (f = 4 cm, 1 : 1.4 aperture). Using a tube socket, he obtained a camera extension of 20 cm, so that the image on the screen could be observed with a magnification of 3.5 to 4x. The exposure time was 1/25 s at a slit width of 0.5 mm. By narrowing the slit to 1 to 1.5 mm, the exposure time could be reduced to 1/50s.

Although the depth of field was very low, the photographs of the crystalline lens made visible fine

structures such as opacities with Cataracta coerula. With photography of the optical section THIEL hoped to develop an objective method for recording particularly lens opacities and their progression. This would provide information allowing him to contribute to the disputed question of medicinal treatment of the grey cataract.

Shortly after this, the Argentinian PAVIA, who had worked particularly on fundus photography from 1929 also showed photographs of the optical section. Similarly he also used a slit lamp with an arc light source. With "ultrasensitive" photographic plates and very short exposure times he succeeded in presenting the Tyndall phenomenon in the anterior chamber and took a photograph of the individual layers of the crystalline lens.

Around 1930, LEITZ introduced a telescopic loupe on the market that was built on the principle of the GALILEAN telescope; improvements such as an increased working distance and wider field of view were included. The longer path needed was reduced by a prism system. This principle was used until recently.

For the focusing loupe that was initially hand held HENKER made a holding bracket in Jena. And for the loupe itself, ARRUGA had a fine adjustment mechanism made in 1925. The diaphragm tube located in between was recommended by KOEPPE to reduce scattered light. Later he mounted a disk with colour filters in front of this tube. In 1936, the colloidometer after RÖNNE was made as an accessory for comparative assessment of opacities of aqueous humour.

From 1933 onwards, further development of the slit lamp was stimulated in a decisive manner by GOLDMANN, his ideas being put into practice by HAAG-STREIT. Horizontal and vertical co-ordinate adjustment being performed with three control elements on the cross-slide stage. Here, too, the common swivel axis for microscope and illumination system was connected to the cross-slide stage, which allowed it to be brought to any part of the eye to be examined.

A further improved slit lamp made by the same company was launched on the market in 1938. On this instrument a control lever (joystick) was used for the first time to allow for horizontal movement. The instrument had no double articulated arm for the illumination system or other facilities for separate adjustment, which are considered superfluous today. It is one of GOLDMANN's merits to have discovered the importance of focal illumination in the examination of the ocular media, and as a result, stimulated improvements in the instrument and the simplification of its operation.

In relation to fundus examination by means of additional lenses, advancements were made by VALOIS and LEMOINE in 1933, and by HRUBY in 1941. Similarly the pyramid gonioscope after VAN BEULEN should be mentioned, and finally the three-mirror contact lens introduced by GOLDMANN in 1948.

In 1939, realising the importance of the close relationship between the depth of field and photographic representation, GOLDMANN introduced an instrument that allowed a sharp slit photograph to be taken of cornea and crystalline lens simultaneously. The instrument was based on a sequential method where the slit movement and a film advance were coupled mechanically. This method was developed to begin with for measuring purposes. With this instrument GOLDMANN and his pupils opened up the field of photographic measurements on the eye and in the following years expanded it further.

In 1940, HEINZ was the first to report on substandard cine film records of the optical section. Later (in 1951) JONKERS also turned to slit lamp cinematography. On the whole, however, this method did not gain wide acceptance.

After World War II the slit lamp after COMBERG was developed further by CARL ZEISS in Jena. On this instrument, the slit projector could be swivelled continuously across the front of the microscope.

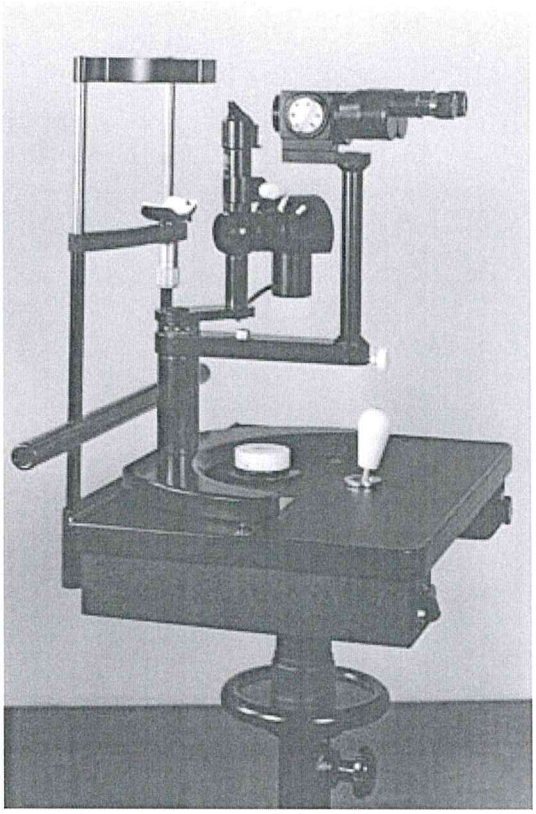

*Fig. 34*
*Zeiss slit lamp after H. Littmann (1950)*

Among the microscopes, first the PM XVI preparation microscope (1946 – 1949) and later the SM XX stereomicroscope with a Galilean magnification changer was used (from 1949/1950 onwards). Despite modern ZOOM optics, the principle of a magnification drum and a telescope system is still used for slit lamps and surgical microscopes.

In 1950, at ZEISS in Oberkochen the slit lamp was redesigned by LITTMANN. He also adopted the control mechanism after GOLDMANN and the vertical illumination path of rays bent through a prism according to COMBERG. During observation, the slit illumination system could be swivelled through in front of the microscope. Additionally the stereo telescope system with a common objective and Galilean magnification changer was used.

Following state-of-the-art photography, other methods followed in the photography of optical sections, firstly, black/white stereo photography, colour photography and later stereo colour photography.

In 1952, BELMONTE-GONZALEZ was the first author to report on experiments in biomicroscopic stereo photography. He placed a stereo camera (ICA 45/107 with Tessar lens of 1 : 4.5 and f = 6.5 cm) directly to the eyepieces of a microscope of a LITTMANN slit lamp. An additional light source served to illuminating the area surrounding the slit. The photographs were taken with a 16x magnification. At 1/5 to 1 s, the exposure times were comparatively long.

NORTON (1964) also coupled a twin-lens stereo camera to the eyepieces of a slit lamp. Later, LEE-ALLEN developed a similar system by coupling two cameras with the optical system of a slit lamp. The transparencies, that were obtained as single images had to be placed very accurately side by side however, to yield the stereoscopic effect.

In 1961, MATTHÄUS however preferred a beam splitting attachment in combination with a multi-purpose instrument manufactured by IHAGEE/Dresden. The set-up additionally had an annular flash and an SM XX slit lamp, on to which the camera was mounted in place of the microscope.

At the same time, various authors (PRINCE in 1965, LOISILLIER, SCHIFF-WERTHEIMER in 1957, DUGAGNI in 1957, STEPANIK in 1959, and OSSWALD in 1959) worked on replacing the incandescent lamp illumination with an electronic flash for photography.

In 1965, based on the slit lamp after LITTMANN, the Model 100/16 Slit Lamp was produced, followed by the Model 125/16 Slit Lamp in 1972. Both models only differ by their working distances of 100 mm and 125 mm.

With the development of the photo slit lamp the first instrument was launched onto the market in

1966. This instrument, being a normal slit lamp with an integrated flash lamp, enabled photographs of slit images to be taken both monoscopically and, by a simple switch, stereoscopically. The same objective was used for photography and observation. This instrument was further developed in 1970 with the introduction of the Model 69 Slit Lamp for routine examinations.

At the same time, a photo slit lamp model was introduced with which photography (monoscopic) was possible only via a camera adapter. On this instrument, stereo photographs could be only taken via an optical beam splitter accommodating 2 cameras.

In 1976, with the development of the Model 110 Slit Lamp and the 210/211 Photo Slit Lamps an innovation was introduced whereby each instrument was constructed from standard modules allowing for a wide variety of different configurations to be produced. At the same time the illumination systems were converted to halogen lamps, which deliver a considerably brighter light of near daylight quality.

The 10 SL Slit Lamp was also launched in 1976. This simple slit lamp, when fitted with an ophthalmometer attachment, resulted in the combination model 10 SL/O. This instrument was followed by the 30 SL Slit Lamp in 1977 and as the model 30 SL/M it became universally applicable in measurements of the eye. In 1977/1978 the 75 SL Slit Lamp was introduced, specially designed for clinical research and education and was further developed in 1987 to provide the Model 40 SL/P Photo Slit Lamp. In 1988, the Model 20 SL Slit Lamp was introduced to the professional world. This comfortable routine instrument considerably assisted in the daily work of the ophthalmologist.

From 1994 onwards, the new slit lamp range was launched by CARL ZEISS including the simple slit lamp SL 105, the routine slit lamp SL 120 and the universal slit lamp SL 160.

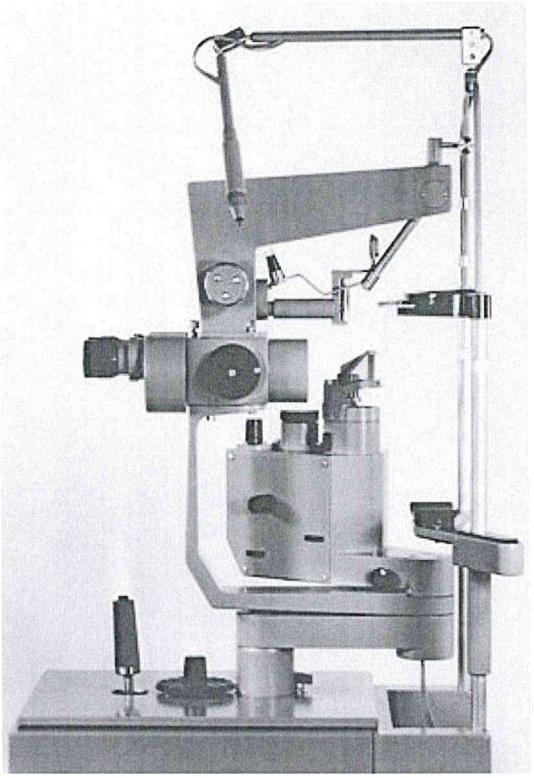

*Fig. 35*
*Model 69 Slit Lamp (1970)*

In 1996, this range was complemented by the SL 130 Slit Lamp that made the advantages of the new slit lamp optics accessible to users working in the field of laser treatment.

In 1999, CARL ZEISS introduced the SL 115 Classic Slit Lamp as ideal instrument for routine examinations and contact lens fitting.

The primary field of application of the slit lamp is the inspection of the anterior segments of the eye including crystalline lens and the anterior vitreous body and with a contact lens, deeper lying eye segments become visible, particularly the iridocorneal angle that cannot be seen via a direct optical path.

The development of the applanation tonometer for the measurement of the sitting patient's intraocular

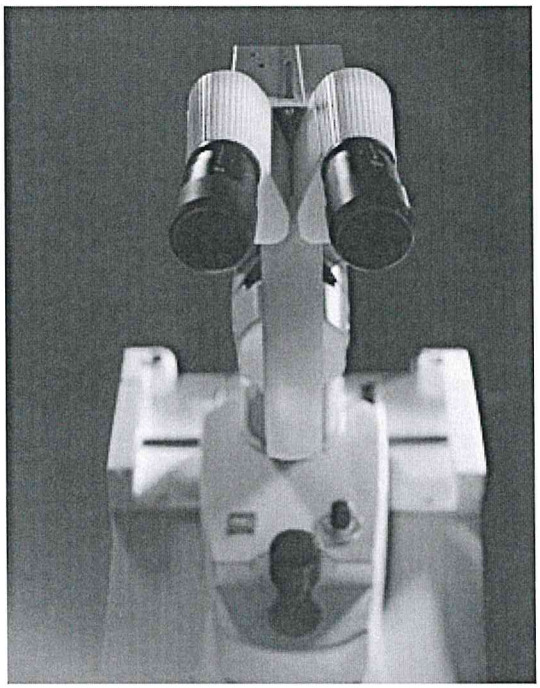

*Fig. 36*
*SL 115 Classic Slit Lamp (1999)*

pressure has extended the range of applications of a former pure observation instrument, the "slit lamp", into a measuring instrument. Further accessories for measuring cornea thickness and the distance between cornea and crystalline lens (anterior chamber depth) further extend this trend. A special attachment for the inspection of the corneal endothelium has made the slit lamp an even more indispensable tool than before. In 1918, VOGT was already able to see the corneal endothelium in vivo with a magnification of 40x by examining the surface structure of the reflecting layer, the so-called area of specular reflection.

Reticles are used for measurements on the anterior segment of the eye and for assessing tissue and cell structures. A special eyepiece serves for length and angle measurements. Ports for connecting co-observation tubes and TV cameras complete the range of accessories for education and research.

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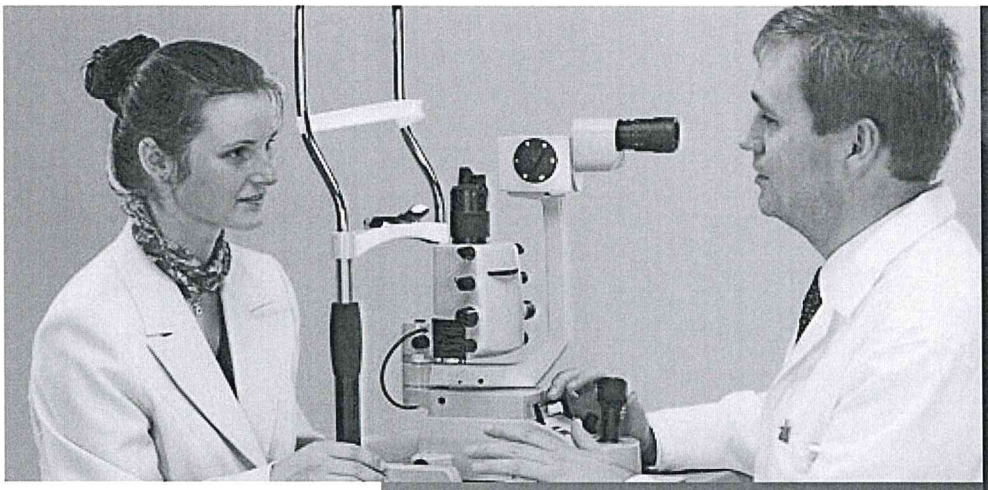

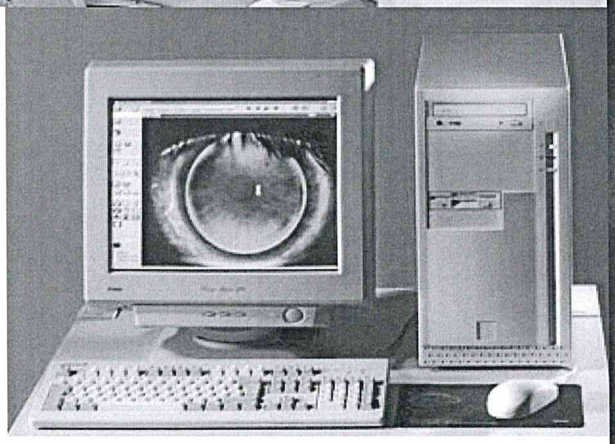

Publication No.: 000000-1152-35[illegible] in Germany. Printed on environment-friendly paper, bleached without the use of chlori[illegible] a.I III/01
Specifications subject to change.

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# Motorized instrument table
# MT01, MT02


Medinstrus



## Motorized Instrument table MT02

### Technical information

| | |
|---|---|
| Height | Min 65 cm<br>Max 105 cm<br>Elevating – 40 cm |
| Elevating speed | 25 mm/s |
| Lifting capacity | 100 kg |
| Weight | 38 kg |
| Height adjustment mechanism | Electrical |
| Height adjustment control | UP/DOWN switch |
| Power supply | ~115/230V 50/60Hz |



## Motorized Instrument table MT01

### Technical information

| | |
|---|---|
| Height | Min 63 cm<br>Max 103 cm<br>Elevating – 40 cm |
| Elevating speed | 30 mm/s |
| Lifting capacity | 50 kg |
| Weight | 18 kg |
| Height adjustment mechanism | Electrical |
| Height adjustment control | UP/DOWN switch |
| Power supply | ~115/230V 50/60Hz |

Aukščio reguliavimo mechanizmas
Elektrinis

**UAB „Medinstrus"**
Krucių g. 9, Krucių k.
LT-89327 Mažeikių r.
Lithuania

**Tel:** +370 443 25451
**Fax:** +370 443 25455
**E-mail:** info@medinstrus.lt
**Web:** www.medinstrus.lt

IAET Ref.

1

# EU Declaration of Conformity

*in accordance with Regulation (EU) 2017/745 on Medical Devices*

2 ***Manufacturer: Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany***

3 *Authorised representative: n/a*

4 ***Single Registration Number: DE-MF-000007732***

5 We, the manufacturer, herewith declare under our sole responsibility that the following Medical Device(s) meet(s) the Requirements of the European Regulation (EU) 2017/745.

| | | |
|---|---|---|
| 6 | **Product identification** | Slit Lamp |
| 7 | **Medical Device Name / Trade Name** | **SL 115 Classic** |
| 8 | **Models/Reference** | SL 115 Classic |
| 9 | **Part Number(s)** | n/a |
| 10 | **Accessories** | IT 760.i, IT 1060.i, SL Imaging Solution, AT 020 |
| 11 | **Medical Device Class** | Class I |
| 12 | **Conformity Assessment Procedure** | Annex II and III of Regulation (EU) 2017/745 |
| 13 | **Scope of Application** | This Declaration of Conformity is valid for all products manufactured until 2022-03-07 |
| 14 | **UMDNS classification** | 12-281 |
| 15 | **GMDN Code** | 35148 |
| 16 | **Basic UDI-DI** | 4049471_SL0001_YV |
| 17 | **Notified Body** | n/a |
| 18 | **Certificate Number** | n/a |
| 19 | **The device is also in conformance with** | Directive 2011/65 EU (RoHS) |

20 Any Modification to the Product not authorized by the manufacturer will invalidate this Declaration.

i.V. Dr. Christian Muenster
Head of CoCe Jena

i.V. Dr. Hans-Joachim Miesner
Director Regulatory Affairs
and Clinical Affairs Active Devices

**Jena, 2021-07-08**
Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52,
07745 Jena, Germany

# Translation Matrix - EU Declaration of Conformity

(Language according to IATE abbreviation)

| | | | |
|---|---|---|---|
| **bg** | 1) ЕС декларация за съответствие според регламент (ЕС) 2017/745 относно медицинските изделия | 9) Артикулен(и) № | 17) Нотифициран орган |
| | 2) Производител | 10) Принадлежности | 18) Номер на сертификата |
| | 3) Упълномощен представител | 11) Клас на медицинското изделие | 19) Уредът също така съответства на |
| | 4) Единен регистрационен номер | 12) Процедура за оценяване на съответствието | 20) Всички модификации по продукта, които не са упълномощени от производителя, ще направят настоящата декларация |
| | 5) Ние, производителят, с настоящото декларираме на своя собствена отговорност, че следното(ите) медицинско(и) изделие(я) отговаря(т) на изискванията на европейския Регламент (ЕС) 2017/745. | 13) Обхват | |
| | 6) Етикет на продукта | 14) UMDNS класификация | |
| | 7) Име на медицинското изделие/търговско наименование | 15) GMDN код | |
| | 8) Модели/Референция | 16) Базов UDI-DI | |
| **cs** | 1) EU prohlášení o shodě podle nařízení (EU) 2017/745 o zdravotnických prostředcích | 9) Číslo(a) artiklu | 17) Oznámený subjekt |
| | 2) Výrobce | 10) Příslušenství | 18) Číslo certifikátu |
| | 3) Zplnomocněný zástupce | 11) Třída zdravotnického prostředku | 19) Zařízení je rovněž ve shodě s |
| | 4) Jedinè registrační číslo | 12) Postup posuzování shody | 20) Jakákoli úprava produktu, která není autorizována výrobcem, zneplatní toto prohlášení. |
| | 5) My, výrobce, tímto prohlašujeme na svou výhradní odpovědnost, že následující zdravotnické prostředky splňují požadavky evropského nařízení (EU) 2017/745. | 13) Oblast působnosti | |
| | 6) Označení prostředku | 14) Klasifikace UMDNS | |
| | 7) Název zdravotnického prostředku / obchodní název | 15) Kód GMDN | |
| | 8) Modely / odkaz | 16) Základní UDI-DI | |
| **da** | 1) EU-overensstemmelseserklæring iht. forordningen (EU) 2017/745 om medicinsk udstyr | 9) Artikelnummer/-numre | 17) Bemyndiget organ |
| | 2) Producent | 10) Tilbehør | 18) Certifikatnummer |
| | 3) Autoriseret repræsentant | 11) Medicinsk udstyrsklasse | 19) Udstyret er ligeledes konform med |
| | 4) Enkelt registreringsnummer | 12) Overensstemmelsesvurderingsprocedure | 20) Enhver ændring af produktet, som ikke er godkendt af producenten, vil gøre denne erklæring ugyldig. |
| | 5) Vi som producent erklærer hermed på eget ansvar, at følgende medicinske udstyr er i overensstemmelse med kravene i EU's forordning (EU) 2017/745. | 13) Anvendelsesområde | |
| | 6) Produktidentifikation | 14) UMDNS-klassificering | |
| | 7) Det medicinske udstyrs navn / handelsnavn | 15) GMDN-kode | |
| | 8) Modeller / reference | 16) Grundlæggende UDI-DI | |
| **de** | 1) EU-Konformitätserklärung entsprechend Verordnung (EU) 2017/745 über Medizinprodukte | 9) Artikelnummer(n) | 17) Benannte Stelle |
| | 2) Hersteller | 10) Zubehör | 18) Zertifikatsnummer |
| | 3) Bevollmächtigter | 11) Medizinprodukteklasse | 19) Das Gerät ist ebenso konform mit |
| | 4) Einmalige Registrierungsnummer | 12) Konformitätsbewertungsverfahren | 20) Alle Änderungen am Produkt, die nicht vom Hersteller autorisiert sind, bewirken das Erlöschen dieser Erklärung. |
| | 5) Wir, der Hersteller, erklären unter unserer alleinigen Verantwortung, dass das/die nachfolgend bezeichnete(n) Medizinprodukt(e) den Anforderungen der Verordnung (EU) 2017/745 entspricht. | 13) Geltungsbereich | |
| | 6) Produktkennzeichnung | 14) UMDNS Klassifizierung | |
| | 7) Name des Medizinproduktes / Handelsname | 15) GMDN Code | |
| | 8) Modelle / Referenz | 16) Basic UDI-DI | |
| **en** | 1) EU Declaration of Conformity in accordance with Regulation (EU) 2017/745 on Medical Devices | 9) Part Number(s) | 17) Notified Body |
| | 2) Manufacturer | 10) Accessories | 18) Certificate Number |
| | 3) Authorised representative | 11) Medical Device Class | 19) The device is also in conformance with |
| | 4) Single Registration Number | 12) Conformity Assessment Procedure | 20) Any Modification to the Product not authorized by the manufacturer will invalidate this Declaration. |
| | 5) We, the manufacturer, herewith declare under our sole responsibility that the following Medical Device(s) meet(s) the Requirements of the European Regulation (EU) 2017/745. | 13) Scope of Application | |
| | 6) Product identification | 14) UMDNS classification | |
| | 7) Medical Device Name / Trade Name | 15) GMDN Code | |
| | 8) Models/Reference | 16) Basic UDI-DI | |
| **et** | 1) EL vastavusdeklaratsioon meditsiiniseadmete määruse (EL) 2017/745 kohaselt | 9) Tootenumber(-numbrid) | 17) Teavitatud asutused |
| | 2) Tootja | 10) Abiseadmed | 18) Sertifitseerimisnumber |
| | 3) Volitatud esindaja | 11) Meditsiiniseadme klass | 19) Seade vastab ka |
| | 4) Unikaalne registreerimisnumber | 12) Vastavushindamismenetlus | 20) Mis tahes modifikatsioonid seadmel, mida tootja ei ole heaks kiitnud, muudavad selle deklaratsiooni kehtetuks. |
| | 5) Meie kinnitame tootjana oma ainuvastutusel, et järgnev meditsiiniseade on kooskõlas Euroopa määruse (EL) 2017/745 nõuetega. | 13) Kohaldamisala | |
| | 6) Toote märgistus | 14) UMDNS-klassifikatsioon | |
| | 7) Meditsiiniseadme nimi / kaubanimi | 15) GMDN Code | |
| | 8) Mudelid/viitenr | 16) Põhi-UDI-DI | |
| **fi** | 1) EU-vaatimustenmukaisuusvakuutus lääkinnällisistä laitteista annetun asetuksen (EU) 2017/745 mukaisesti | 9) Tuotenumero(t) | 17) Ilmoitettu laitos |
| | 2) Valmistaja | 10) Lisävarusteet | 18) Sertifikaatin numero |
| | 3) Valtuutettu edustaja | 11) Lääkinnällisten laitteiden luokka | 19) Laitteen muu vaatimustenmukaisuus: |
| | 4) Yksilöllinen rekisterinumero | 12) Vaatimustenmukaisuuden arviointimenetelmä | 20) Tuotteeseen ilman valmistajan valtuutusta tehdyt muutokset mitätöivät tämän vakuutuksen. |
| | 5) Valmistaja ilmoittaa yksinomaisella vastuullaan, että seuraava lääkinnällinen laite on (seuraavat lääkinnälliset laitteet ovat) eurooppalaisen asetuksen (EU) 2017/745 vaatimusten mukainen (mukaisia). | 13) Soveltamisala | |
| | 6) Tuotetunniste | 14) UMDNS-luokitus | |
| | 7) Lääkinnällisen laitteen nimi / kauppanimi | 15) GMDN-koodi | |
| | 8) Mallit / viite | 16) Yksilöllinen UDI-DI-tunniste | |

# Translation Matrix - EU Declaration of Conformity

(Language according to IATE abbreviation)

| | | | |
|---|---|---|---|
| **fr** | 1) Déclaration de conformité UE en respect du règlement (UE) 2017/745 relatif aux dispositifs médicaux | 9) Numéro(s) d'article | 17) Organisme notifié |
| | 2) Fabricant | 10) Accessoires | 18) Numéro du certificat |
| | 3) Mandataire | 11) Classe du dispositif médical | 19) L'appareil est également conforme à |
| | 4) Numéro d'enregistrement unique | 12) Procédure d'évaluation de la conformité | 20) Toute modification apportée au dispositif et non autorisée par le fabricant invalidera la présente déclaration. |
| | 5) Nous, le fabricant, déclarons par la présente sous notre seule responsabilité que le(s) dispositif(s) médical/ux suivant(s) satisfait/satisfont les exigences du règlement européen (UE) 2017/745. | 13) Champ d'application | |
| | 6) Étiquetage du produit | 14) Classification UMDNS | |
| | 7) Nom du dispositif médical / Nom commercial | 15) Code GMDN | |
| | 8) Modèle / Référence | 16) IUD-ID de base | |
| **el** | 1) Δήλωση συμμόρφωσης ΕΕ σύμφωνα με τον κανονισμό (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα | 9) Κωδικός(οί) προϊόντος | 17) Κοινοποιημένος οργανισμός |
| | 2) Κατασκευαστής | 10) Εξαρτήματα | 18) Αριθμός πιστοποιητικού |
| | 3) Εξουσιοδοτημένος αντιπρόσωπος | 11) Κατηγορία ιατροτεχνολογικού προϊόντος | 19) Η συσκευή συμμορφώνεται επίσης με |
| | 4) Ενιαίος αριθμός καταχώρισης | 12) Διαδικασία εκτίμησης της συμμόρφωσης | 20) Οποιαδήποτε τροποποίηση στο προϊόν που δεν έχει εγκριθεί από τον κατασκευαστή καθιστά άκυρη την παρούσα δήλωση. |
| | 5) Εμείς, η κατασκευαστική εταιρεία, δηλώνουμε δια του παρόντος με αποκλειστική μας ευθύνη ότι το ακόλουθο ιατροτεχνολογικό προϊόν πληροί τις απαιτήσεις του Ευρωπαϊκού Κανονισμού (ΕΕ) 2017/745. | 13) Πεδίο εφαρμογής | |
| | 6) Επισήμανση προϊόντος | 14) Ταξινόμηση UMDNS | |
| | 7) Ονομα ιατροτεχνολογικού προϊόντος/εμπορική ονομασία | 15) Κωδικός GMDN | |
| | 8) Μοντέλο/Αναφορά | 16) Βασικό UDI-DI | |
| **es** | 1) Declaración de conformidad según el Reglamento (UE) 2017/745 sobre los productos sanitarios | 9) Número(s) de artículo(s) | 17) Organismo notificado |
| | 2) Fabricante | 10) Accesorios | 18) Número de certificado |
| | 3) Representante autorizado | 11) Clase de producto sanitario | 19) El dispositivo también cumple |
| | 4) Número de registro único | 12) Procedimientos de evaluación de la conformidad | 20) Cualquier modificación del producto no autorizada por parte del fabricante anulará esta declaración. |
| | 5) Nosotros, el fabricante, declaramos bajo nuestra responsabilidad que los siguientes productos sanitarios cumplen los requisitos del Reglamento europeo (UE) 2017/745 | 13) Ámbito de aplicación | |
| | 6) Identificación del producto | 14) Clasificación UMDNS | |
| | 7) Nombre del producto sanitario/nombre comercial | 15) Código GMDN | |
| | 8) Modelo/referencia | 16) UDI-DI básico | |
| **ga** | 1) Dearbhú Comhréireachta AE de réir Rialachán (AE) 2017/745 maidir le Feisti Leighis | 9) Uimhir (uimhreacha) na míre | 17) Comhlacht a dtugtar fógra dó |
| | 2) Monaróir | 10) Oirlúintí | 18) Uimhir an deimhnithe |
| | 3) Ionadaí údaraithe | 11) Aicme an fheiste leighis | 19) Clolonn an feiste chomh maith le |
| | 4) Uimhir aonair chlárúcháin | 12) Nós imeachta um measúnú comhréireachta | 20) Má dhéantar aon Mhionathrú ar an Táirge gan údarú ón déantóir, beidh an Dearbhú seo neamhbhailí. |
| | 5) Leis seo, dearbhaímid, an déantóir, faoin bhfreagracht atá againn amháin, go gcomhlíonann an Fheiste/na Feisti Leighis a leanas Riachtanais an Rialacháin Eorpach (AE) 2017/745. | 13) Raon feidhme | |
| | 6) Lipéad an táirge | 14) Aicmiú UMDNS | |
| | 7) Ainm an bhfeiste leighis / Trádainm | 15) Cód GMDN | |
| | 8) Leaganacha / Tagairt | 16) UDI-DI bunúsach | |
| **hr** | 1) Izjava o sukladnosti EU-a sukladno Odredbi (EU) 2017/745 o medicinskim proizvodima | 9) Broj artik(a)la | 17) Prijavljeno tijelo |
| | 2) Proizvođač | 10) Pribor | 18) Broj certifikata |
| | 3) Ovlašteni zastupnik | 11) Razred medicinskih proizvoda | 19) Uređaj je također sukladan s |
| | 4) Jedinstven registarski broj | 12) Postupci ocjenjivanja sukladnosti | 20) Svakom izmjenom proizvoda koju nije odobrio proizvođač poništit će se ova izjava. |
| | 5) Mi, proizvođač, ovime izjavljujemo pod vlastitom odgovornošću da sljedeći medicinski proizvod(i) ispunjava(ju) zahtjeve Uredbe (EU) 2017/745. | 13) Područje primjene | |
| | 6) Oznaka proizvoda | 14) UMDNS klasifikacija | |
| | 7) Naziv medicinskog proizvoda / trgovačko ime | 15) GMDN šifra | |
| | 8) Model / upućivanje | 16) Osnovni UDI-DI | |
| **hu** | 1) EU-megfelelőségi nyilatkozat az Európai Parlament és a Tanács (EU) orvostechnikai eszközökről szóló 2017/745 rendelete szerint | 9) Cikkszám(ok) | 17) Bejelentett szervezet |
| | 2) Gyártó | 10) Tartozék | 18) Tanúsítvány száma |
| | 3) Meghatalmazott képviselő | 11) Orvostechnikai eszköz osztálya | 19) Az eszköz a következőknek is megfelel: |
| | 4) Egyedi regisztrációs szám | 12) Megfelelőségértékelési eljárás | 20) A terméken a gyártó által nem engedélyezett módosítások érvénytelenítik a jelen nyilatkozatot. |
| | 5) Alulírott gyártó, ezúton kizárólagos felelősségünk tudatában kijelentjük, hogy az alábbi orvostechnikai eszköz(ök) megfelel(nek) a 2017/745. sz. EU-rendelet előírásainak. | 13) Hatály | |
| | 6) Termék címkéje | 14) UMDNS osztályba sorolás | |
| | 7) Az orvostechnikai eszköz neve / kereskedelmi név | 15) GMDN kód | |
| | 8) Modell / hivatkozási szám | 16) Alapvető UDI-DI | |
| **it** | 1) Dichiarazione di conformità UE ai sensi al regolamento (UE) 2017/745 relativo ai dispositivi medici | 9) Codice/i articolo | 17) Organismo notificato |
| | 2) Produttore | 10) Accessori | 18) Numero di certificazione |
| | 3) Mandatario | 11) Classe dispositivo medico | 19) Il dispositivo è conforme anche a |
| | 4) Numero di registrazione unico | 12) Procedura di valutazione della conformità | 20) Qualsiasi modifica apportata al prodotto senza l'autorizzazione del produttore invalida la presente Dichiarazione. |
| | 5) Con la presente, si dichiara in qualità di produttore e sotto la propria esclusiva responsabilità che il/i seguente/i dispositivo/i medico/i soddisfa/soddisfano i requisiti del Regolamento Europeo (UE) 2017/745. | 13) Applicabilità | |
| | 6) Etichettatura del prodotto | 14) Classificazione UMDNS | |
| | 7) Nome del dispositivo medico/Denominazione commerciale | 15) Codice GMDN | |
| | 8) Modello/Riferimento | 16) UDI-DI di base | |

# Translation Matrix - EU Declaration of Conformity

(Language according to IATE abbreviation)

| | | | |
|---|---|---|---|
| lv | 1) ES atbilstības deklarācija saskaņā ar Regulu (ES) 2017/745 par medicīnas ierīcēm | 9) Artikula numurs / artikulu numuri | 17) Paziņotā struktūra |
| | 2) Ražotājs | 10) Piederumi | 18) Sertifikāta numurs |
| | 3) Pilnvarotais pārstāvis | 11) Medicīnas ierīču klase | 19) Ierīce atbilst arī |
| | 4) Vienotais reģistrācijas numurs | 12) Atbilstības novērtēšanas procedūras | 20) Jebkuras produkta izmaiņas, ko nav apstiprinājis ražotājs, atceļ šo deklarāciju. |
| | 5) Mēs, ražotājs, ar šo apliecinām un uzņemamies atbildību, ka tālāk minētā(-s) Medicīniskā(-s) ierīce(-s) atbilst Eiropas Regulas (ES) 2017/745 prasībām. | 13) Iecelšanas tvērums | |
| | 6) Izstrādājuma etiķete | 14) UMDNS klasifikācija | |
| | 7) Medicīnas ierīces nosaukums / tirdzniecības nosaukums | 15) GMDN kods | |
| | 8) Modeļi / atsauce | 16) Pamata UDI-DI | |
| lt | 1) ES atitikties deklaracija pagal Reglamentą (ES) Nr. 2017/745 dėl medicinos priemonių | 9) Gaminio numeris (-iai) | 17) Notifikuotoji įstaiga |
| | 2) Gamintojas | 10) Priedai | 18) Sertifikato numeris |
| | 3) Įgaliotasis atstovas | 11) Medicinos priemonės klasė | 19) Prietaisas taip pat atitinka |
| | 4) Unikalusis registracijos numeris | 12) Atbilstības novērtēšanas procedūras | 20) Bet koks gaminio modifikavimas, kuriam gamintojas nedavė leidimo, panaikina šios deklaracijos galiojimą. |
| | 5) Mes, kaip gamintojas, atsakingai pareiškiame, kad ši (-ios) medicinos priemonė (-ės) atitinka Europos Reglamento (ES) 2017/745 reikalavimus. | 13) Darbības joma | |
| | 6) Gaminio žymena | 14) UMDNS klasifikavimas | |
| | 7) Medicinos priemonės pavadinimas / Prekybinis pavadinimas | 15) GMDN kodas | |
| | 8) Modeliai / Nuoroda | 16) Bazinis UDI-DI | |
| mt | 1) Dikjarazzjoni ta' Konformità tal-UE skont ir-Regolament (UE) 2017/745 dwar Apparati Mediċi | 9) Numru(i) tal-Parti | 17) Korp Notifikat |
| | 2) Manifattur | 10) Aċċessorji | 18) Numru taċ-Ċertifikat |
| | 3) Rappreżentant awtorizzat | 11) Klassi tal-Apparat Mediku | 19) L-apparat huwa wkoll konformi ma' |
| | 4) Numru ta' Reġistrazzjoni Uniku | 12) Proċeduri ta' valutazzjoni tal-konformità | 20) Kwalunkwe Modifika fil-Prodott mhux awtorizzata mill-manifattur tinvalida din id-Dikjarazzjoni. |
| | 5) Aħna, il-manifattur, b'dan niddikjaraw taħt ir-responsabbiltà unika tagħna li l-Apparat(i) Mediku(ċi) li ġej(jin) jissodisfa(w) ir-Rekwiżiti tar-Regolament Ewropew (UE) 2017/745. | 13) Kamp ta' Applikazzjoni | |
| | 6) Tikketta tal-prodott | 14) Klassifikazzjoni UMDNS | |
| | 7) Isem tal-Apparat Mediku / Isem Kummerċjali | 15) Kodiċi GMDN | |
| | 8) Mudelli / Referenza | 16) UDI-DI Bażiku | |
| nl | 1) EU-conformiteitsverklaring overeenkomstig Verordening (EU) 2017/745 betreffende medische hulpmiddelen | 9) Artikelnummer(s) | 17) Aangemelde instantie |
| | 2) Fabrikant | 10) Toebehoren | 18) Certificaatnummer |
| | 3) Gemachtigde | 11) Klasse van medische hulpmiddelen | 19) Het apparaat is eveneens conform |
| | 4) Uniek registratienummer | 12) Conformiteitsbeoordelingsprocedure | 20) Elke wijziging aan dit product die niet door de fabrikant is goedgekeurd, maakt deze verklaring ongeldig. |
| | 5) Wij, de fabrikant, verklaren hierbij geheel onder eigen verantwoordelijkheid dat het volgende medische hulpmiddel voldoet aan de vereisten van de Europese Verordening (EU) 2017/745. | 13) Werkingssfeer | |
| | 6) Etiket van het hulpmiddel | 14) UMDNS-classificatie | |
| | 7) Naam van het medische hulpmiddel/handelsnaam | 15) GMDN-code | |
| | 8) Modellen/referentie | 16) Basic UDI-DI | |
| no | 1) EU-samsvarserklæring i samsvar med forordning (EU) 2017/745 om medisinsk utstyr | 9) Delenummer | 17) Varslet organ |
| | 2) Produsent | 10) Tilbehør | 18) Sertifikatnummer |
| | 3) Autorisert representant | 11) Medisinsk utstyrsklasse | 19) Utstyret er også i samsvar med |
| | 4) Enkelt registreringsnummer | 12) Prosedyre for samsvarsevaluering | 20) Enhver endring på produktet som ikke er autorisert av produsenten, vil gjøre denne erklæringen ugyldig. |
| | 5) Vi, produsenten, erklærer med dette på eget ansvar at det følgende medisinske utstyret oppfyller kravene i den europeiske forordningen (EU) 2017/745. | 13) Bruksområde | |
| | 6) Produktidentifikasjon | 14) UMDNS-klassifisering | |
| | 7) Navn/handelsnavn på det medisinske utstyret | 15) GMDN-kode | |
| | 8) Modeller/referanse | 16) Basic UDI-DI | |
| pl | 1) Deklaracja zgodności UE zgodnie z rozporządzeniem (UE) 2017/745 o wyrobach medycznych | 9) Numer(y) artykułu | 17) Jednostka notyfikowana |
| | 2) Producent | 10) Wyposażenie | 18) Numer certyfikatu |
| | 3) Upoważniony przedstawiciel | 11) Klasa wyrobu medycznego | 19) Urządzenie jest więc zgodne z |
| | 4) Niepowtarzalny numer rejestracyjny | 12) Procedura oceny zgodności | 20) Wszelkie modyfikacje produktu nieautoryzowane przez producenta powodują unieważnienie niniejszej deklaracji. |
| | 5) My, producent, niniejszym oświadczamy, na naszą wyłączną odpowiedzialność, że poniższy wyrób medyczny spełnia wymagania rozporządzenia europejskiego (UE) 2017/745. | 13) Zakres stosowania | |
| | 6) Oznakowanie produktu | 14) Klasyfikacja UMDNS | |
| | 7) Nazwa wyrobu medycznego / nazwa handlowa | 15) Kod GMDN | |
| | 8) Modele / Odniesienie | 16) Basic UDI-DI | |
| pt | 1) Declaração de conformidade UE de acordo com o regulamento (UE) 2017/745 relativo aos dispositivos médicos | 9) Número(s) de artigo | 17) Organismo notificado |
| | 2) Fabricante | 10) Acessórios | 18) Número de certificado |
| | 3) Mandatário | 11) Classe do dispositivo médico | 19) O dispositivo também está em conformidade com |
| | 4) Número único de registo | 12) Procedimiento de avaliação de conformidade | 20) Qualquer modificação ao produto não autorizada pelo fabricante invalidará esta declaração. |
| | 5) Nós, o fabricante, declaramos pelo presente, sob responsabilidade exclusiva, de que o(s) seguinte(s) dispositivo(s) médico(s) cumpre(m) os requisitos da regulamento (UE) 2017/745. | 13) Âmbito de aplicação | |
| | 6) Rótulo do dispositivo | 14) Classificação UMDNS | |
| | 7) Nome do dispositivo médico / Nome comercial | 15) Código GMDN | |
| | 8) Modelo / Referência | 16) UDI-DI básico | |

# Translation Matrix - EU Declaration of Conformity

(Language according to IATE abbreviation)

| | | | |
|---|---|---|---|
| ro | 1) Declarație de conformitate UE, pe baza Regulamentului (UE) 2017/745 privind dispozitivele medicale | 9) Număr/Numere de articol | 17) Organismul notificat |
| | 2) Producător | 10) Accesorii | 18) Număr certificat |
| | 3) Reprezentant autorizat | 11) Clasa de dispozitive medicale | 19) Dispozitivul este conform și cu |
| | 4) Număr unic de înregistrare | 12) Procedurile de evaluare a conformității | 20) Orice modificare adusă produsului și neautorizată de producător va anula valabilitatea prezentei declarații. |
| | 5) Noi, producătorul, declarăm în acest document pe propria răspundere că dispozitivul(ele) medical(e) respectă cerințele Regulamentului European (UE) 2017/745. | 13) Domeniul de aplicare | |
| | 6) Eticheta dispozitivului | 14) Clasificare UMDNS | |
| | 7) Numele dispozitivului medical / Denumirea comercială | 15) Cod GMDN | |
| | 8) Model / Referință | 16) UDI-DI de bază | |
| sv | 1) EU-försäkran om överensstämmelse enligt förordningen (EU) 2017/745 om medicintekniska produkter | 9) Artikelnummer | 17) Anmält organ |
| | 2) Tillverkare | 10) Tillbehör | 18) Certifikatnummer |
| | 3) Auktoriserad representant | 11) Klass av medicinteknisk produkt | 19) Instrumentet överensstämmer även med |
| | 4) Engångsregistreringsnummer | 12) Process för bedömning av överensstämmelse | 20) Samtliga modifieringar på produkten som inte har godkänts av tillverkaren kommer att ogiltigförklara denna försäkran. |
| | 5) Vi, tillverkaren, försäkrar härmed efter eget ansvar att följande medicintekniska produkt(er) uppfyller kraven i förordning (EU) 2017/745. | 13) Tillämpningsområde | |
| | 6) Produktidentifiering | 14) UMDNS-klassificering | |
| | 7) Namn på den medicintekniska produkten/handelsnamn | 15) GMDN-kod | |
| | 8) Modell/referens | 16) Grundläggande UDI-DI | |
| sk | 1) EÚ vyhlásenie o zhode podľa nariadenia (EÚ) 2017/745 o zdravotníckych pomôckach | 9) Číslo(a) výrobku | 17) Notifikovaná osoba |
| | 2) Výrobca | 10) Príslušenstvo | 18) Číslo certifikátu |
| | 3) Splnomocnený zástupca | 11) Trieda zdravotníckej pomôcky | 19) Prístroj je taktiež v zhode s |
| | 4) Jedinė registračné číslo | 12) Postup posudzovania zhody | 20) Po akejkoľvek úprave tohto produktu bez oprávnenia výrobcu bude toto vyhlásenie neplatné. |
| | 5) My, výrobca, týmto prehlasujeme na svoju vlastnú zodpovednosť, že nasledujúca/-e zdravotnícka/-e pomôcka/-y spĺňa/jú požiadavky európskeho nariadenia (EÚ) 2017/745. | 13) Rozsah pôsobnosti | |
| | 6) Označenie pomôcky | 14) Klasifikácia UMDNS | |
| | 7) Názov zdravotníckej pomôcky/obchodné meno | 15) Kód GMDN | |
| | 8) Modely/referenčný prvok | 16) Základný UDI-DI | |
| sl | 1) Izjava EU o skladnosti, ustrezna Uredbi (EU) 2017/745 o medicinskih pripomočkih | 9) Številka(e) artikla | 17) Priglašeni organ |
| | 2) Proizvajalec | 10) Dodatna oprema | 18) Številka certifikata |
| | 3) Pooblaščeni predstavnik | 11) Razred medicinskega pripomočka | 19) Naprava je prav tako skladna s/z |
| | 4) Enotna registrska številk | 12) Postopki ugotavljanja skladnosti | 20) Kakršne koli spremembe izdelka, ki jih ne odobri proizvajalec, izničijo to izjavo. |
| | 5) Mi, proizvajalec, ob izključni odgovornosti izjavljamo, da naslednji medicinski pripomoček/pripomočki ustreza/ustrezajo zahtevam Uredbe (EU) 2017/745. | 13) Področje uporabe | |
| | 6) Oznaka pripomočka | 14) Klasifikacija UMDNS | |
| | 7) Naziv medicinskega pripomočka/trgovsko ime | 15) Koda GMDN | |
| | 8) Modeli/referenca | 16) Osnovni UDI-DI | |
| tr | 1) Tıbbi Cihazlarla ilgili (AB) 2017/745 Yönetmeliği uyarınca AB Uygunluk Beyanı | 9) Parça Numarası(numaraları) | 17) Onaylanmış Kuruluş |
| | 2) Üretici | 10) Aksesuarlar | 18) Sertifika Numarası |
| | 3) Yetkili temsilci | 11) Tıbbi Cihaz Sınıfı | 19) Ayrıca bu cihaz şu standartlara uygundur: |
| | 4) Tek Kayıt Numarası | 12) Uygunluk Değerlendirme Prosedürü | 20) Ürün üzerinde üreticinin izni olmadan gerçekleştirilen herhangi bir Değişiklik bu Beyanı geçersiz kılar. |
| | 5) Üretici olarak, işbu belge ile yegane sorumluluk bize ait olmak üzere, aşağıda belirtilen Tıbbi Cihazın (AB) 2017/745 sayılı Avrupa Yönetmeliği'nin gerekliliklerini karşıladığını beyan ederiz. | 13) Uygulama Kapsamı | |
| | 6) Ürün tanımı | 14) UMDNS sınıflandırması | |
| | 7) Tıbbi Cihazın Adı / Ticari Adı | 15) GMDN Kodu | |
| | 8) Modeller/Referans | 16) Temel UDI-DI | |

**UAB "Medinstrus"**

# CE Atitikties Deklaracija

Mes, UAB "Medinstrus", įsikūrusi Krucių g. 9, Krucių k. LT-89327 Mažeikių r., Lietuva, tel. 00 370 443 25451, faks. 00 370 443 25455

DEKLARUOJAME savo atsakomybe, kad gaminys:

| | |
|---|---|
| Gaminio tipas: | **Oftalmologinis staliukas su elektriniu aukščio reguliavimo mechanizmu** |
| Modelis: | **MT01; MT02** |

atitinka sekančių Europos sąjungos direktyvų esminius saugumo rekalavimus:

**ŽEMOS ĮTAMPOS direktyva 2014/35/EU**

**ELEKTROMAGNETINIS SUDERINAMUMAS direktyva 2014/30/EU**

pritaikant standartus:

| | |
|---|---|
| **Safety** | **EN 60601-1:2006, EN 60601-1:2006/A1:2013** |
| **EMC** | **EN 55011:2009, EN 55011:2009/A1:2010** |
| | **EN 61000-3-2:2006, EN 61000-3-2:2014** |

Mažeikiai, 2018m. birželio 18d.

Vitalis Balčytis
Direktorius