OCTAX LASERSHOT M™
OCTAX NAVILASE®
USER MANUAL

Recommended use of Laser Systems
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Vitrolife

For the sake of convenience the Octax LaserShot or Octax NaviLase will be referred to as LaserShot or NaviLase in this user manual.

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Intended Use for Octax LaserShot M and NaviLase

For use in assisted reproduction procedures to ablate or drill the zona pellucida of an oocyte or embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis. The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, blastocyst collapse prior to vitrification procedures and sperm viability testing.

Intended Purpose Octax LaserShot M and NaviLase

Octax LaserShot M and Octax NaviLase are laser systems dedicated to be used in clinical routine in the field of assissted reproductive technology (ART). The laser systems are part of assissted reproduction procedures to ablate or drill the zona pellucida of an oocyte or embryo to facilitate assisted hatching or recovery of cells (polar bodies or blastomeres or trophectoderm cells) for pre-implantation genetic diagnosis, respectively. The devices can also be used to collapse blastocyst stage embryos prior to vitrification and to identify viable spermatozoa among immotile spermatozoa.

Contraindications for Octax LaserShot M and NaviLase

At present there are no known cell-specific contraindications, i.e. there are no morphological or other cell indicators for oocytes, embryos ans sperm cells, that are contraindications for using the Octax LaserShot M and NaviLase System. Contraindications on the patient side regarding Assisted Hatching or biopsy of oocytes or embryos are left to the judgement of the physician and are related to the patient or the number of oocytes or embryos available. There are no patient-related contraindications for sperm viability testing. The Octax LaserShot M and NaviLase System does not have any influence on treatment related contraindications.

Side effects Octax LaserShot M and NaviLase System

When using the laser systems not according to their intended use, there is a risk of partial damage in the cytoplasm due to heat and degeneration of the cell treated. This is especially the case when the laser beam is directly focussed or applied to a cell. When using the NaviLase system in multi-pulse mode and intentional or unintentional movement of the oocyte or embryo treated during the application of the laser beam, there is a chance that the laser interacts with non-defined areas of the cells and damage to the cells. Laser energy which is absorbed by medium causes a temperature increase. When releasing twenty laser pulses at 10 ms pulse length using a 150 mW laser beam, a calculated energy of 30 mJ is transferred to the medium. In an isolated media droplet of 20 µl volume this amount of energy, evenly spread over the volume, would cause a temperature increase of 0.36°C. When using the laser systems for sperm viability testing, using the laser beam repeteadily and directly on the sperm head may damage the functionality of proteins located in the sperm head.

Intended user group

Healthcare professionals, typically medical technical assistants (MTA) or clinical embryologists. The user has to have at least basic experience in working in an IVF laboratory, especially with one or all of the procedures in which the use of a laser system is potentially indicated, e.g. ICSI, Assisted Hatching, Biopsy, Vitrification.

Intended patient target groups

Female and Male patients in the age group below a maternal age of 60 that have failed to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse and / or patients with a specific disease or genetic predisposition in the male or female that require ART in order to enable pre-implantation diagnosis of the chromosomal or genetic constitution of their oocytes or embryos.

Intended clinical benefits to patients

The intended clinical benefits apply to patients who undergo a treatment in the field of assisted reproduction with the aim to achieve a clinical pregnancy. Ablation or drilling of the zona pellucida of an oocyte or embryo facilitates assisted hatching of the embryo prior implantation and can benefit the clinical outcome by better implantation or live brith rate. In regard to the recovery of cells (polar bodies or blastomeres or trophectoderm cells) for pre-implantation genetic diagnosis, the benefit of the laser is to facilitate the procedure, whereby reducing the time of exposure of oocytes or embryos to unfavorable culture conditions. For blastocyst collapse prior vitrification the application of the laser supports better survival rates after vitrification / warming, which increases the total number of embryos available for consecutive transfers. The identification of viable spermatozoa among immotile spermatozoa by the laser technique has a beneficial effect on fertilization rates, which are connected to the clinical outcome.

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Contact and support **rear side**

DEFINITIONS



This symbol denotes important information regarding the correct treatment of cells and the proper use of the laser. Please read all warnings carefully before treating any embryos or oocytes to ensure safe application and optimal results.



This symbol denotes important cautions. Please read all precautions before treating any embryos or oocytes to ensure safe and optimal results.



This symbol denotes important additional information regarding the laser device and treatment of cells.

WARNINGS



ABOUT THIS MANUAL

The procedures described in this manual concern a particular device installed by Vitrolife GmbH authorized personnel at a designated location. The LaserShot M or NaviLase devices must be operated by trained personnel according to the instructions contained in this user manual.



LASER

The laser of the LaserShot M and the NaviLase system are classified as a class 1M laser. Class 1M lasers emit in the wavelength range from 302,5 nm to 4000 nm.

Laser Radiation, do not view directly with optical instruments.



EYE SAFETY OF THE OPERATOR

Eye safety of the operator is guaranteed under normal operation of the LaserShot M and NaviLase, and in a situation when user removable parts may be missing. However, do not disassemble or uninstall the LaserShot M or NaviLase system and watch the beam employing optics. Any installation / deinstallation of hard- and software, respectively, is strictly reserved to trained and certified service personnel authorized by Vitrolife GmbH.



To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



INTEGRITY OF THE ELECTRO-OPTICAL SYSTEM

Maintenance of microscope components, wrong handling of the microscope or strong displacement of the electro-optical system, e. g. by mechanical shock can result in an incorrect position of the beam splitter system, the magnifier lens, the camera, and the turret, respectlively. As a result of any of the above, aiming of the laser may no longer correspond to the crosshair position displayed at the video image and damage to embryos may occur if the laser is used in this condition. After maloperation of the microscope, repeat the *Laser aiming verification procedure or contact Technical Service.*



INCORRECT LASER AIMING

Failure to follow the laser aiming verification procedure could result in wrongly located openings and therefore may damage the treated oocyte or embryo.



MULTIPLE OR SMALL OPENINGS

Only a single opening should be made in the zona pellucida. Multiple openings or openings that are too small may prevent embryo hatching and/or lead to abnormal embryo development.



DEVELOPMENT STAGE

Laser assisted hatching should only be performed on 4-8 cell embryos. Effects of laser assisted hatching on embryos of later developmental stages (> 8 cell stage) are not known.



Only use the 25x laser lens when using LaserShot M or NaviLase. Use of other objectives for laser treatments may damage the embryo.



LONG-TERM FOLLOW UP

To date there are no known reports showing a greater occurrence rate of major or minor defects in children born after laser assisted hatching of embryos. Long-term follow-up data on children derived from embryos treated by laser assisted hatching does not yet exist. A follow-up study of 134 such babies found no increase in the major congenital malformations, chromosomal aberrations or minor congenital malformations between the laser assisted hatching treated group and all deliveries at their hospital. (Kanyo, K., Konc, J. “A follow-up study of children born after diode laser assisted hatching.” European Journal of Obstetrics and Gynecology. 110: 176-180 (2003)).



INSTALLATION AND MAINTENANCE

Installation and repair of the LaserShot M or NaviLase shall only be carried out by a person certified by Vitrolife. The LaserShot M must remain on the microscope and at the location where it was installed. If a LaserShot M or NaviLase is disconnected and/or moved without supervision by a person certified by Vitrolife the LaserShot M or NaviLase will no longer be approved for clinical use and the warranty may be voided.

If the LaserShot M , NaviLase or parts of it are modified, appropriate inspection and testing must be conducted by a Vitrolife certified person to ensure continued safe use.

A preventative maintenance of the laser is recommended every 12-18 months to ensure optimal performance of the laser.



ELECTROMAGNETIC COMPATIBILITY

The LaserShot M and Navilase have been tested and found to comply with IEC 60601-1 and with the limits for medical devices to the IEC 60601-1-2:2014/ EN 60601-1-2:2014 for electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, or if connected to material not certified by Vitrolife, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

Consult the manufacturer, their representative or dealer for help.

WARNING: The use of accessories and cables other than those supplied by Vitrolife, may result in increased emissions or decreased immunity of the ME equipment or ME system.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the LaserShot M , including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



CONNECTION TO EXTERNAL EQUIPMENT

To guarantee basic safety and compliance with elevant EC standard (i.e. EN 60601-1 – Part 1 for medical electrical equipment) and essential performance, this equipment must only be connected to computer equipment certified by Vitrolife, and connection must only be made using certified cables.



LIMITED WARRANTY

Vitrolife warrants exclusively to the Customer that for a period of 12 months from date of installation or 13 months from date of shipment, whichever comers first, the LaserShot M or NaviLase will be free from defects in material and workmanship under normal use. The Customer shall notify Vitrolife of any defect that occurs during this period immediately after having discovered the defect and in any case not later than 5 days thereafter.

The limited warranty shall terminate immediately if installation, maintenance, repair or relocation of the laser system is carried out by other than Vitrolife certified personnel.

- The limited warranty shall not apply to damage resulting from:

- Failure to perform routine maintenance in accordance with this User Manual;

- Accident, abuse, misuse, or misapplication of the device;

- Use and operation that does not comply with instructions provided in the User Manual;

- Normal wear and tear.



CONNECTORS

Do not disconnect the USB cable connector unless instructed to do so by qualified support personnel.



The recipient end user of the LaserShot M / NaviLase systems should not unpack and install it upon receipt. Unpacking, installation, setup and end-user training of LaserShot M / NaviLase systems must be carried out by appropriately qualified technical staff authorized by Vitrolife GmbH.



TE MODE: RESTRICTIONS IN USE

The TE mode must only be used by experienced users trained in doing trophectoderm biopsies. The laser puls(es) can assist the release of mechanically stretched intracellular bonds between trophectoderm cells for biopsy. The TE mode must never be applied to the zona pellucida.



REPEATED LASER SHOTS

Repeated laser shots to the same position of the embryo could result in an increased risk of embryo damage. In case of risk of applying repeated laser shots to the same position of the embryo the laser action can be immediately stalled by pressing the emergency stop button.



INFLUENCE OF TEMPERATURE ON DRILL OPENING SIZE

When using a heated stage during zona manipulation, make sure that it has been set to the correct temperature. Inappropriate temperature settings will lead to unexpected drill hole sizes. Lower temperatures result in smaller openings, while higher temperatures cause openings of excessive sizes that may lead to embryo damage.



The user of the laser system should report any serious incident that has occurred in relation to the device to Vitrolife and the competent authority of the Member State in which the user is established.

"Serious incident" means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.



Do not connect an additional multiple socket-outlet or extension cord to the medical equipment (ME) system.



Only connect items that have been specified as part of the ME system or specified as being compatible with the ME system.

PRECAUTIONS



INFLUENCE OF Z-POSITION OF THE OOCYTE/EMBRYO ON DRILL OPENING SIZE

Inappropriate Z-positioning will result in smaller drill holes and in reduced laser beam quality. It is recommended to keep the cell near the bottom of the culture dish during laser treatment.



To minimize the risk of damage to the oocyte or embryos, administer as few laser pulses as possible at the lowest energy levels possible to achieve the prescribed effect.



Direct the laser beam towards a section of the zona pellucida where the adjacent perivitelline space is widest or next to an area of fragmentation.



A holding pipette should be used during laser treatment to minimize the risk of embryo movement.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The below table contains the applicable information required for CISPR11 systems:

Guidance and manufacturer's declaration – Electromagnetic emissions
LaserShot M and NaviLase laser systems is intended for use in the electromagnetic environment specified below. The customer or the user of LaserShot M and NaviLase laser systems should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions EN/CISPR 11 Radiated and Conducted Emission	Class A Group 1	LaserShot M and NaviLase laser systems use RF energy only for their internal function. Therefore, their RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and professional healthcare facility environment (CISPR 11 class A). It it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might take mitigation measures, such as relocating or re-orienting the equipment.
Voltage fluctuations flicker emissions IEC 61000-3-3	Passed	

Electromagnetic Immunity

Guidance and manufacturer's declaration – Electromagnetic immunity

LaserShot M and NaviLase laser systems is intended for use in the electromagnetic environment specified below. The customer or the user of LaserShot M and NaviLase laser systems should assure that the used in such an environment

Immunity test	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	contact ± 8 kV air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient /burst IEC 61000-4-4	AC Mains +/- 2kV Signal +/- 1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	Line-to-line ± 0.5 kV, ± 1 kV Line-To-Earth ± 0,5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° and 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment If the user of LaserShot M and NaviLase laser systems requires continued operation during power mains interruptions, it is recommended that the incubator be powered from an uninterruptible power supply or battery. No degradation of the essential performance was observed and EUT remains safe during the test.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

The below two tables contain the applicable information required for a system other than those specified for use only in a shielded location and for systems that are not life supporting.

Guidance and manufacturer's declaration – Electromagnetic immunity

LaserShot M and NaviLase laser systems is intended for use in the electromagnetic environment specified below. The costumer or the user of LaserShot M and NaviLase laser systems should assure that it is used in such an environment

Immunity test	Compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	No degradation of the essential performance was observed and EUT remains safe during the test in normal operational mode and in alarm mode. Portable and mobile RF communications equipment should be used no closer to any part of LaserShot M and NaviLase laser systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000 4-3	3 V/m 80 MHz to 2.7 GHz	IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 28 V/m 450 MHz, ±5 kHz FM, 1 kHz sinus 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz 27 V/m 385 MHz, 50% PM at 18 Hz 9 V/m 710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz
NOTE 1 At 80 MHZ and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
2 Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LaserShot M and NaviLase laser systems incubator is used exceeds the applicable RF compliance level above, the LaserShot M and NaviLase laser systems incubator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the incubator. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

SYMBOL GLOSSARY

Symbol	Description	Symbol	Description
	Medical device manufacturer		Date of manufacture
 YYYY-MM	Medical device manufacturer Date of manufacture, Year-month		Consult instructions for use
SN	Serial number	REF	Catalogue number
CE 0123	Declaration of conformity according to MDR 2017/245 The identification number of the Notified Body is 0123	MD	Medical device
 Class 1M*	Caution, laser radiation Class 1M laser product		Temperature limit, °C
	Approval mark of SIQ Certifies that the device is complaint to EN 60601-1: 2006 And A11 :2011 And A12:2014		Caution, risk of electric shock
FWGB	Trademark of the manufacturer of laser power supply		Class II equipment
IP40	IP codes	ta 40	Rated – ambient temperature
	Direct current		Indoor use only

PART I: INTRODUCTION

This chapter provides an outline of the key features and applications of the LaserShot M/NaviLase system

Introduction

The laser systems for microsurgery utilized in the field of assisted reproductive technology (ART). The laser systems can be used to manipulate the zona pellucida of oocytes or embryos in order to assist hatching and to extract polar bodies or cells for subsequent genetic analysis.

Key Features of the LaserShot M / NaviLase System

The LaserShot M / NaviLase system is based on an infrared laser diode emitting at a wavelength of 1,48 µm which is coupled to an inverted microscope. The laser beam is directed along the microscope optical axis. The spatial arrangement of lenses and mirrors within the laser unit allows focusing of the laser beam to the image plane of the microscope objective. In addition to LaserShot M, NaviLase includes motion elements which allow the controlled movement of the laser beam to any position within the working field which is visible from the camera image. The microscope should be equipped with a heating stage to ensure optimal conditions for oocytes, zygotes and spermatozoa. The infrared 1,48 µm wavelength emitted by the laser diode is non-mutagenic and thus, it is ideally suited for the use in non-contact procedures in ART.

Working with LaserShot M/ NaviLase and EyeWare

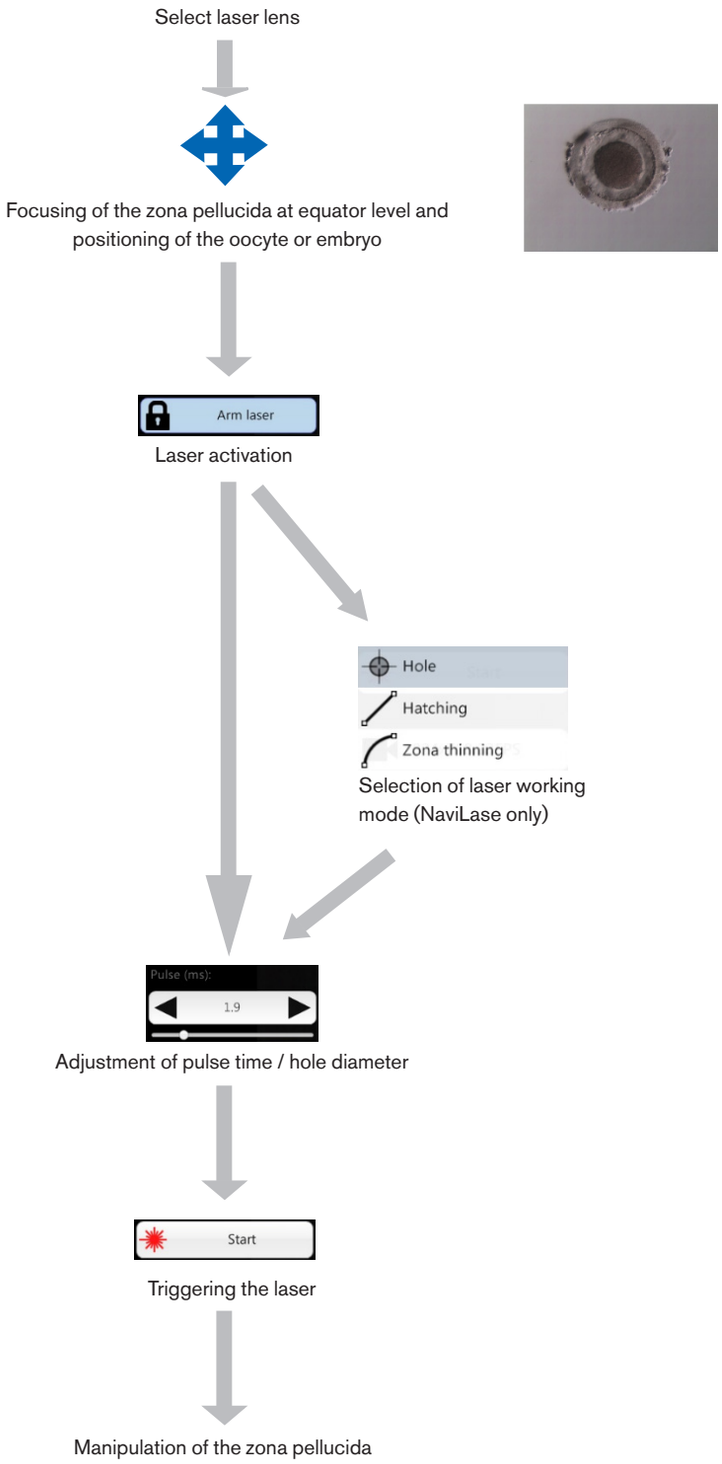
The LaserShot M / NaviLase system provides an advanced laser technology for ART featuring digital control and digital video / image processing combined with high optical and electro-mechanical quality. Controlled by the EyeWare imaging software the LaserShot M / NaviLase system can be intuitively used for the daily routine.

Acquired by a high resolution digital camera a live video stream of the cells is displayed at the computer monitor. The video image is overlaid by an computer generated crosshair, which marks the aiming position of the laser beam. A laser pulse is triggered either by mouse or optionally by foot switch. The irradiation time of the laser is set within the user interface of the EyeWare software.

With EyeWare not only microscopic devices, microscopic imaging and measurements can easily be managed, but also documentation has been made very convenient. With the database module patient data and snapshots are stored and administrated. Connection to

an external database allows importing and exporting of datasets. A predefined report with any set of examination results can be printed after only a few mouse clicks. Datasets may be exported to PDF-files for e-mail forwarding and to RTF-files or to CSV-files for further text or spreadsheet program processing, respectively.

Working Principle

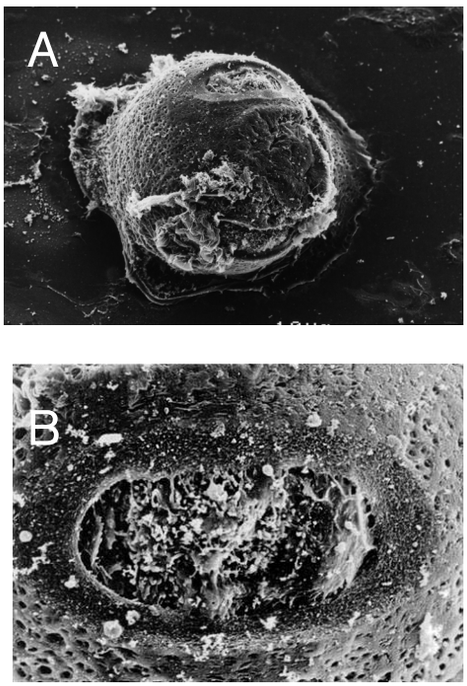


Manipulation of the Zona Pellucida using LaserShot M / NaviLase

The laser beam generated by the LaserShot M / NaviLase causes a tangential thinning or opening of the zona pellucida of oocytes and embryos by a highly localized photo thermal process which lyses the glycoprotein matrix.

Thereby, trench-like openings with even walls are generated (Fig. 1) which appear circularly shaped in a two-dimensional view. The size of the opening can be adapted to the respective procedure simply by varying the irradiation time of the laser. The reproducibility of the drilling effect is very high.

The LaserShot M / NaviLase system uses a laser that has no known potential mutagenicity as compared to, e. g. UV laser procedures. Furthermore, with the laser having a relatively low power in focus (100 mW - 250 mW) fundamental safety studies have been conducted. Until now no adverse effect of the described laser procedures has been documented. A follow-up study on 134 children born after laser assisted hatching (LAH) was performed and revealed no increase in the major congenital malformation rate, no increase in chromosomal aberrations and no difference in the minor congenital malformation rate.



Photos courtesy CHUV, Lausanne, Switzerland

Fig. 1: Scanning electron micrographs of a laser treated murine zygote at low magnification (A) and at higher magnification (B).

IMPORTANT

Inform the patient about contraindications and side effects of laser applications (see p. 3).

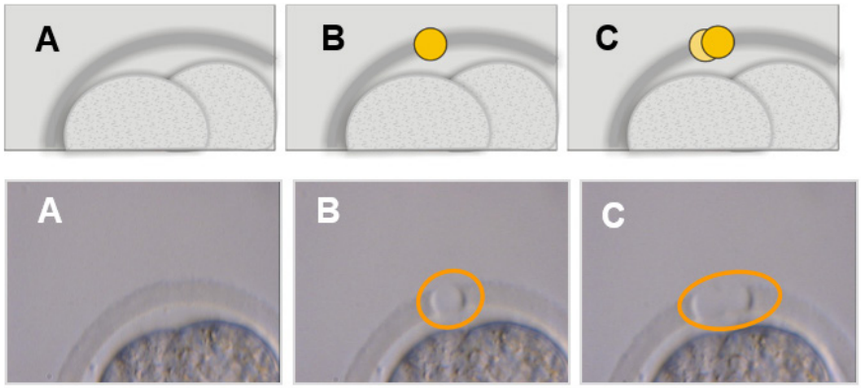
Application notes for LaserShot M and NaviLase

Assisted hatching (AH)

The aim of AH is to locally weaken the zona pellucida by creating a trench along the optical axis of the laser beam (see. Fig. 1, p.17) which appears as a hole when seen through an inverted microscope.

To minimize the risk of damage to blastomeres, users should administer as few laser pulses as possible at the shortest pulse lengths possible to achieve zona drilling or thinning effects. Only a single opening should be made in the zona pellucida. Multiple openings or those that are too small might prevent the embryo from hatching or lead to abnormal development. The laser beam should be directed towards a section of the zona pellucida where the adjacent perivitelline space is widest.

For AH, the drilled hole size should be approximately 1.5 times of the thickness of the zona pellucida. A minimal invasive strategy is to create an opening by means of 2 holes with a diameter of 20 µm, i.e. slightly larger than the zona thickness (typically 16-18 µm in human embryos). An overlap of approximately 50% will generate the desired hole size resulting in the formation of an oval shaped opening. (see figure C below.) Due to the 50% overlap, this approach is robust with respect to small variations in the actual zona thickness.



Pictures: University of Bonn

Alternatively, the outer layers of the zona pellucida may be ablated largely and across a wider area, but without breaching it. This process is commonly referred to as zona thinning. An area of 25-40% of the circumference of the zona pellucida should be thinned by contiguous laser shots generating holes of 15–20 µm in diameter with maximum 50% overlap. The overlapping laser shots should be positioned in a way to ablate about 50-70% of the initial zona pellucida thickness.

Note: AH is not recommended for routine use in all ART patients.

Blastomere biopsy (cleavage stage)

The aim of cleavage stage biopsy is to retrieve 1 or 2 blastomeres from a day three embryo for genetic analysis.
A pulse time should be selected to create an opening of about 20 µm. The embryo should be rotated and blastomere(s) selected for biopsy should be positioned using a holding capillary. The embryo should be held close to the bottom of the dish to maximize laser efficiency.

An oval shaped opening should be drilled using two or three overlapping laser pulses to open the zona pellucida for easy access of the single blastomere selected for biopsy. If two blastomeres were selected for biopsy, the opening should be made in between the two cells.

Trophectoderm (TE) cell biopsy

The aim of TE biopsy is to retrieve 2-10 TE cells as samples for genetic analysis. TE cells are separated from a blastocyst stage embryo without causing damage to the inner cell mass (ICM).



TE MODE: RESTRICTIONS IN USE

The TE mode must only be used by experienced users trained in doing trophectoderm biopsies. The laser puls(es) can assist the release of mechanically stretched intracellular bonds between trophectoderm cells for biopsy. The TE mode must never be applied to the zona pellucida.

15 to 20 hours prior to biopsy, AH is performed making a small hole in the zona pellucida of the embryo using 1-3 laser pulses. The opening should be placed at the opposite side of the ICM. Typically, 5-7 TE cells will have formed a hernia, protruding from the hole, at the time point of biopsy. This step is optional but will facilitate the biopsy procedure.

Under the inverted microscope, a holding pipette is used to position and firmly fix the blastocyst in a way that the herniating TE cells are facing the biopsy pipette. The blastocyst should be hold close to the bottom of the dish to maximize laser efficiency. The biopsy pipette should have an inner diameter of 20-30 µm.

The laser should be switched to TE mode.

For biopsy, 2-10 of the herniated TE cells should be aspirated into the biopsy pipette. Subsequently, the aspirated TE cells should be gently pulled away from the blastocyst to stretch and expose the intracellular junctions and minimize cell damage. Subsequently, two or three laser pulses are applied to the intracellular junctions of the cells to be separated. Pulling gently will completely break the intracellular junctions and the separated cells should be aspirated into the biopsy capillary carefully. They are finally placed at some distance from the embryo for subsequent transfer into a tube for genetic analysis.

If cells are to be biopsied from cryopreserved blastocysts, laser application should be performed after thawing, as soon as the ICM can be located and before the blastocyst has fully re-expanded. A hole of 15-20 µm should be created opposite from the ICM. Thawed blastocysts will have TE cells herniating out of the zona pellucida after 2 to 3 hours of re-expansion.

Blastocyst collapsing

Blastocyst collapsing is a common procedure to remove the fluid inside the blastocoel in order to improve the efficiency of cryo-protectants and increase the survival rate during vitrification and warming. The laser should be positioned to target the junction between two TE cells that are located well away from the ICM. The blastocyst collapse should be induced by applying one (and only one) single laser pulse of 0.5 -1.5 ms. It is not necessary to breach the zona for successful collapsing. Full collapse of the TE layer may take up to 10 minutes after applying the laser pulse. Occasionally, an embryo will not collapse even after time back in the incubator, but it will collapse during the vitrification procedure.
Collapsing may be performed on full, expanded, hatching and completely hatched blastocysts.

Sperm viability testing

When performing ICSI it is important to use viable sperm. However, in semen samples containing only immotile spermatozoa it is difficult to assess which sperm are viable or not. In such cases viability can be tested using the Octax laser. After a laser pulse has been fired at the end of the sperm tail, the tail will start curling or shrinking if the sperm is viable and can be used for micro injection.

1. Use the laser lens.
2. Collect a few immotile sperm with normal morphology and flexible tail (they should be free of debris).
3. Line up the collected sperm to be able to work in an economic way.
4. Apply 1-2 laser shots to the end of the tail of each sperm.
5. If the end of the tail starts curling or shrinking (= osmotic reaction to the opening of the plasma membrane) the sperm is viable and can be used for microinjection.

Useful hints:
It may take 5-10 s until the response to the laser pulse(s) becomes visible.
The laser pulse length needed for sperm viability testing may vary, depending on the individual microscope setup. Test for the appropriate pulse length, start with times around 2-4 ms.



DAILY ROUTINE

For maximal confidence, we recommend to confirm positioning and aiming of the crosshair and the correct opening size of the drilling on a daily basis before treating any patient embryo (please refer to the section Getting started or Quick Guide).



TECHNICAL SUPPORT

If you need assistance at any time, please contact Technical Service. For contact details please refer to the section Customer Service.

Setting up LaserShot M / NaviLase

The recipient end user of the device should not install the device upon receipt. Unpacking, installation, setup and end-user training of LaserShot M / NaviLase systems must be carried out by appropriately qualified technical staff authorized by Vitrolife GmbH.



EYE SAFETY OF THE OPERATOR

Eye safety of the operator is guaranteed under normal operation of the LaserShot M / NaviLase, and in a situation when user removable parts may be missing. However, do not disassemble or uninstall the LaserShot M / NaviLase system. Any installation/ deinstallation of hard- and software, respectively, is strictly reserved to trained and certified service personnel authorized by Vitrolife GmbH.



INTEGRITY OF THE ELECTRO-OPTICAL SYSTEM

Maintenance of microscope components, wrong handling of the microscope or strong displacement of the electro-optical system, e. g. by mechanical shock can result in an incorrect position of the beam splitter system, the magnifier lens, the camera, and the turret, respectively. As a result of any of the above, aiming of the laser may no longer correspond to the crosshair position displayed at the video image and damage to embryos may occur if the laser is used in this condition.



LASER

The laser of the LaserShot M / NaviLase system is classified as a class 1M laser. Class 1M lasers emit in the wavelength range from 302,5 nm to 4000 nm and are safe under normal operation, but may be hazardous if the user employs optics within the beam.



TECHNICAL SUPPORT

If you need assistance at any time, please contact Technical Service. For contact details please refer to the section Customer Service.

System Components

Figure 2 shows the LaserShot M / NaviLase system mounted to an inverted microscope, consisting of:

- the NaviLase Motion Module (NaviLase only)
- the Laser Module
- the Mirror block
- the Laser Lens
- the Eye USB 2.0 camera

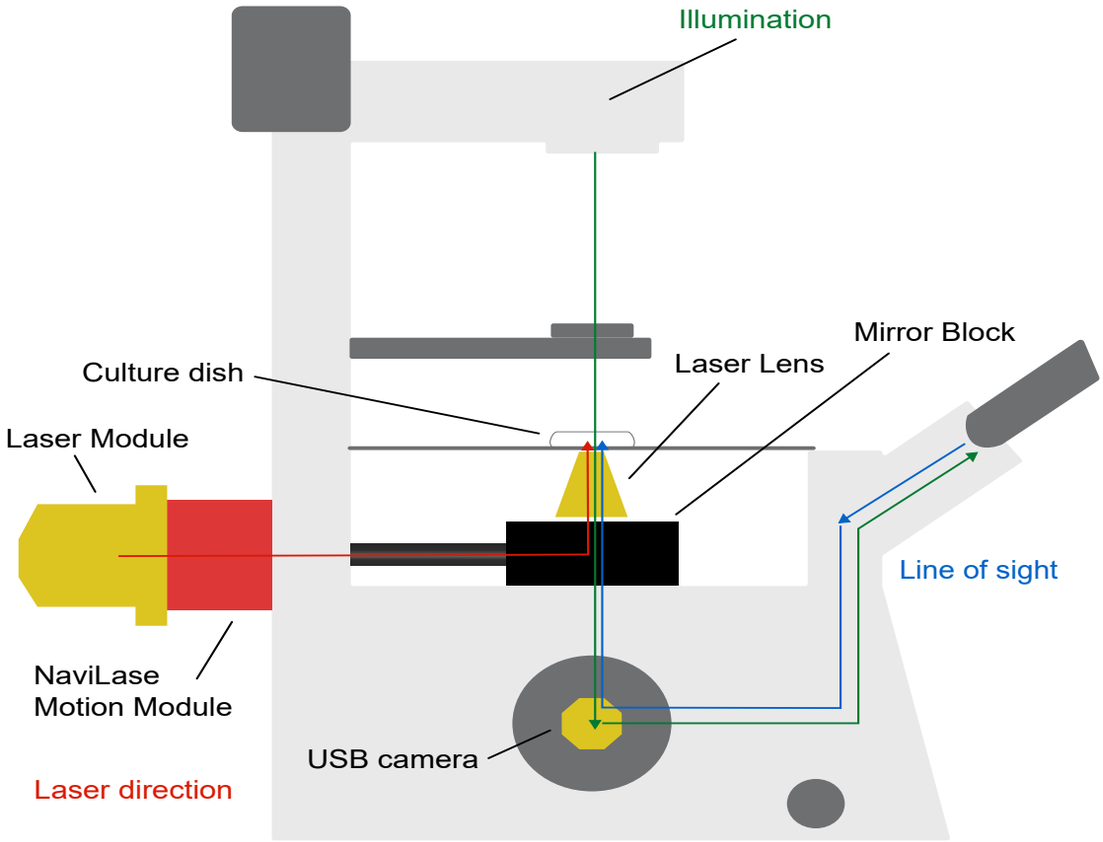


Fig. 2: Laser system components mounted onto an inverted microscope (example: Nikon Ti-2). Motion Module exclusively for NaviLase.

Inverted microscopes have to have a CE declaration according to IVD 98/79/EC as a minimum requirement. The following inverted microscopes are approved to be used with laser systems (this list raises no claim for completeness):

Olympus Corporation	IX 51	S8F-3
	IX 53	P1F
	IX 71	S8F-3, S1F-3
	IX 73	P1F, P2F
	IX 81	F-3
	IX 83	P1ZF, P2ZF
Leica Microsystems	DMI 3000	B and with fluorescence light path
	DMI 4000	B and with fluorescence light path
	DMI 6000	B and with fluorescence light path
	DMi8	with fluorescence light path
Nikon Corporation	Ti	S, U, E
	TE-2000	S, U, E
	Ti2	A, E
Carl Zeiss Microimaging	Axio Observer	A1, D1, Z1
	Axio Observer	3, 5, 7
	Axiovert	200

Inverted Microscopes that do not comply at least with IVD 98/79/EC or MDD 93/42/EWG are not approved to be used with the MDR 2017/745 versions of Laser systems

The LaserShot M and NaviLase can be supplied in different set-ups also covering the following accessories

Product name	REF
Target Pointer for laser systems	19310/4150
Breadboard for installing laser systems to Olympus IX53/73/83	19310/0141

A scheme of the complete LaserShot M / NaviLase system including the computer running the EyeWare software for visualizing the image from the Eye USB 2.0 digital camera and controlling the NaviLase by its motion control elements is depicted in below.

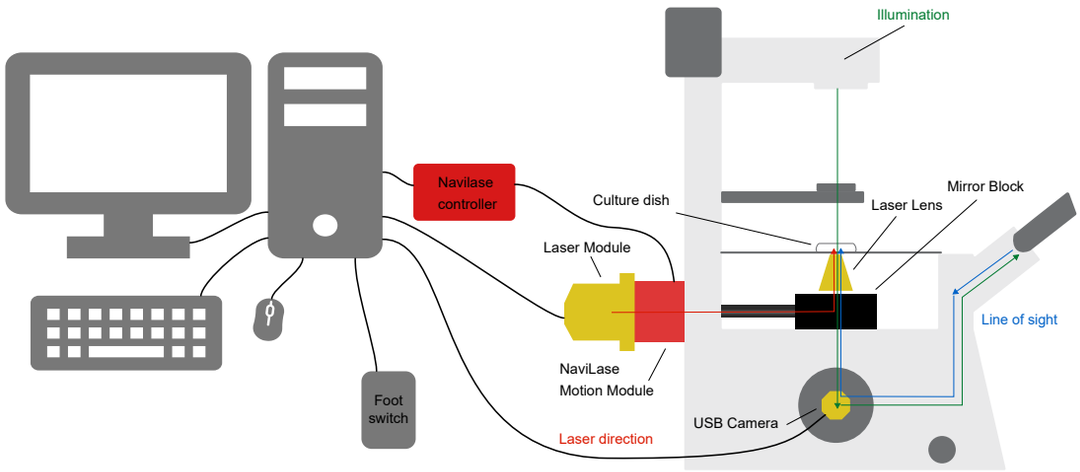


Fig. 3: Diagram of the complete LaserShot M / NaviLase system including computer, Eye USB 2.0 digital camera, Laser Lens and LaserShot M / NaviLase components Figure does not show installation package.



CONNECTORS

Do not disconnect the USB cable connector unless instructed to do so by qualified support personnel.



CONNECTION TO EXTERNAL EQUIPMENT

To guarantee basic safety and compliance with elevant EC standard (i.e. EN 60601-1 - Part 1 for medical electrical equipment) and essential performance, this equipment must only be connected to computer equipment certified by Vitrolife, and connection must only be made using certified cables.



One EyeWare license running on a dedicated PC is intended to control one laser system.

The Laser Systems

The schematic illustration in Figure 3 depicts the optical path of the visible light (green line) and the optical path of the LaserShot M / NaviLase laser beam (red line). Emitted from the laser module the beam can get diverted on demand by the NaviLase motion module. At the beam splitter located below the nosepiece the laser light is deflected from a horizontal to a vertical orientation and focused to the culture dish by the laser lens. Thus, the laser beam points perpendicularly upwards. The visible illumination light path proceeds perpendicularly downwards. After passing through the beam splitter of the laser, the visible light is diverted and intersected into two paths by microscope optics. Some part of the visible light gets directed towards the camera port whereas the remaining part of the light points towards the eyepiece. This design ensures the safe use of the laser even when looking through the eyepieces (blue line) whilst a laser pulse is released.

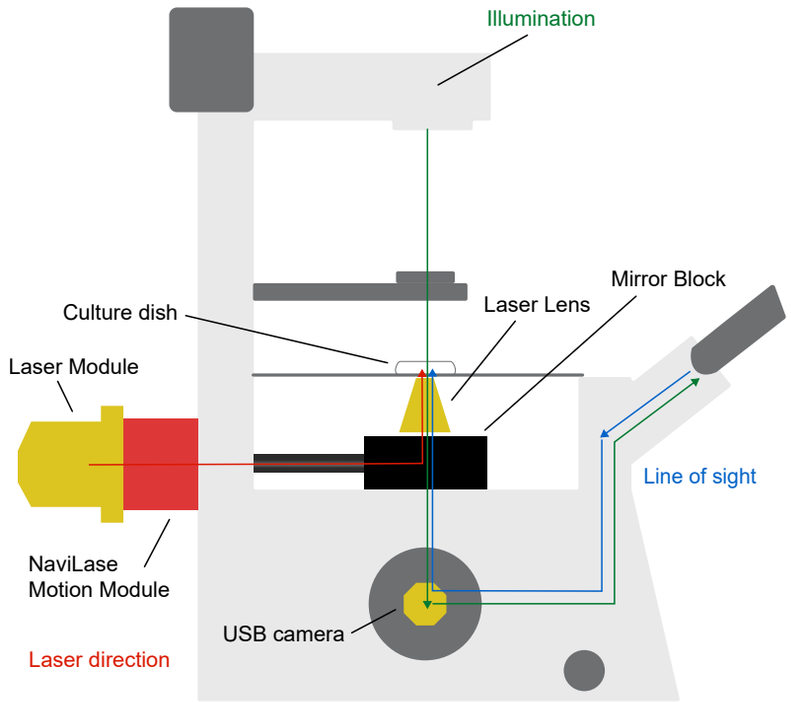


Fig. 4: Schematic view of an inverted microscope equipped with the LaserShot M / NaviLase system

WARNING

EYE SAFETY OF THE OPERATOR

Eye safety of the operator is guaranteed under normal operation of the LaserShot M / NaviLase, and in a situation when user removable parts may be missing. However, do not disassemble or uninstall the LaserShot M / NaviLase system. Any installation / deinstallation of hard - and software, respectively, is strictly reserved to trained and certified service personnel authorized by Vitrolife GmbH.

On the laser module two status indicator LEDs and an USB connector are located, as shown in Figure 4. The status indicator LEDs provide information about the status of the device in addition to any messages/warnings displayed by EyeWare when controlling the LaserShot M / NaviLase system. The significance of the status indicator LEDs is as follows:

•• (flashing) device USB initialization (during computer boot sequence, after device plugin)

•• laser powered up, laser in standby position

•• laser in unlocked position after activation through EyeWare

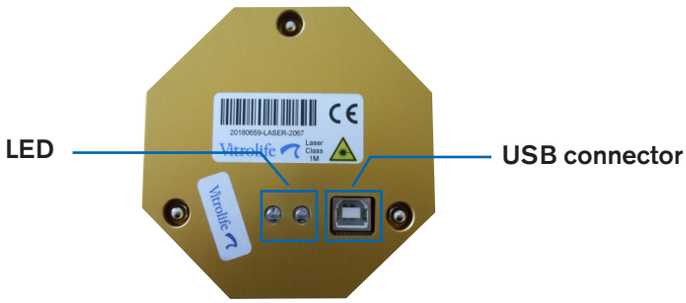


Fig. 5: laser module with detailed view of status LEDs and USB connector



LED

For normal operation, the status indicator LEDs do not provide any additional information. Please communicate the status of these LEDs when contacting Technical Support in case you are suspecting a problem with your LaserShot M / NaviLase system.

PART II: WORKING WITH LASERSHOT M / NAVILASE

This chapter provides basic information about operation and control of the LaserShot M and NaviLase device in conjunction with the EyeWare software.

Control of the Laser by EyeWare Software

The EyeWare software provides the user interface for targeting, controlling and activating laser pulses in LaserShot M and NaviLase system in combination with an Eye USB2 high-resolution camera. Software applications also cover image acquisition and storage, measurements and documentation. EyeWare is a SQL server based multi-purpose imaging and archival software, which uses encryption for saved patient data.

Cybersecurity requirements for EyeWare and the PC running EyeWare:

- The EyeWare software shall only be installed using manufacturer-approved installation media or released installation packages.
- The EyeWare software shall only be installed on a PC with the current minimum installation requirements (see there, next page) for secure and reliable operation. The operating system should be maintained according to the validated configuration and the responsible organization's IT security procedures for secure and reliable operation. Unsupported changes to system settings, permissions, or installed software should be avoided.
- Updates and patches shall only be installed using manufacturer-approved installation packages or service media. Unofficial, modified, or untrusted update packages shall not be used.
  Installation packages should be verified according to the manufacturer's instructions. If an integrity check or signature verification fails, installation shall be stopped and the package shall be treated as untrusted.
- EyeWare software does not provide a function to connect to the internet and does not require internet access for intended clinical operation. If the PC running EyeWare contains Ethernet, Wi-Fi, or other network interfaces, these interfaces are not required by EyeWare for intended operation and should remain disabled, disconnected, or restricted where feasible - except for updating operating system and for service tasks of the Octax laser system. Block unneeded ports through the firewall, as appropriate.
- Access to the computer and EyeWare application should be restricted to authorized users using unique user accounts. Administrative privileges should be limited to authorized service or IT personnel.
- Enable Bitlocker and store the recovery key in a safe place.
- Enable display logon screen on screen saver resume.
- User credentials should be protected against unauthorized disclosure. Shared or uncontrolled use of administrator credentials are to be avoided.
- Users should not install unsupported software, modify system permissions, change configuration files, alter registry settings, or change the operating environment in a way that may affect secure or reliable operation.

- Before disposal, transfer, or decommissioning of the computer or storage media, patient-related and procedure-related data should be removed or protected according to applicable data protection procedures.

Recommended cybersecurity practices for PCs running EyeWare software:

Find the recommended cyber security practices in detail the “Vitrolife privacy and security guide”.



CYBERSECURITY

Residual cybersecurity risks remain possible mainly through local user access, operating system vulnerabilities, removable media, unauthorized installation packages, malware, or unintended changes to the validated system configuration. These risks are reduced by authenticated access to the operating system and application, verification of connected device serial numbers, verification of calibration and configuration data during application start-up, trusted installation/update mechanisms, application logging, encryption of patient data at rest, and cybersecurity-related labelling. Please follow the secure installation and maintenance requirements to control the residual risk as far as possible.

Installation Requirements

For proper operation of the EyeWare software, a computer system complying with the following minimum specifications is recommended:

- Intel processor (Intel Core i5, Intel Core Ultra or better)
- 8 GB RAM minimum, 16 GB RAM recommended
- SSD with 500 GB capacity minimum, 1 TB recommended
- BIOS-option to disable C-States Control
- USB keyboard and USB mouse (see cybersecurity above)
- 7 USB-A ports minimum
- Operating System Windows 11, 64 bit
- TFT screen with full HD resolution (1920x1080)

System Components

EyeWare software comes on a USB flash.



Fig. 7: EyeWare software USB flash (symbol image, Pixabay)

The EyeWare software provides the user interface for targeting, controlling and activating laser pulses. In the following sections, many different aspects of EyeWare are described with special focus on features which are relevant for laser control, image capture and processing.

Setting up EyeWare Software

As an integral part of the LaserShot M / NaviLase system, EyeWare software has to be installed in combination with the hardware of LaserShot M / NaviLase system itself.



The recipient end user of the LaserShot M / NaviLase systems should not unpack and install it upon receipt. Unpacking, installation, setup and end-user training of LaserShot M / NaviLase systems must be carried out by appropriately qualified technical staff authorised by Vitrolife GmbH.

Calibration setup

Calibration of objectives and the intermediate magnification is done during the setup of the laser system. Verification or modification of the pre-set calibration can be done at any time. Any modification of the calibration settings require restart of EyeWare.

Open the “calibration setup” dialogue at the FILE menu and select brand of microscope at first.

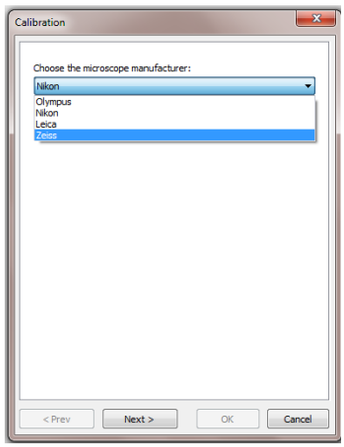


Fig. 8: EyeWare calibration setup dialogue

Specify whether or not the microscope is equipped with magnifier. If there is a magnifier define the magnification ratio.

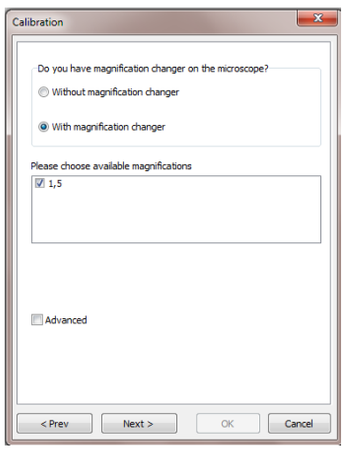


Fig. 9: EyeWare calibration setup dialogue

Specify manufacturer of the lens and its magnification for each individual nose head position. For any nose head position not hosting any lens uncheck the box "in use". After definition of all 6 positions is done, confirm the settings and restart EyeWare in order to apply the new settings.

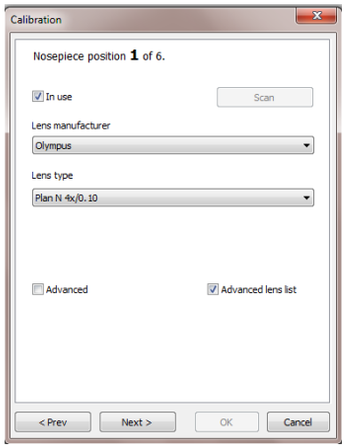


Fig. 10: EyeWare calibration setup dialogue

Main concept and workflow

The main concept of EyeWare is the transfer of data between different sections of the software. A typical workflow consists of the following steps:

1. Activate the live video display by accessing the **Video page**.

2. Find the target object at the live video display by adjusting the microscope.

3. Take a **Snapshot** by pressing the <F10> key. This automatically saves images to Quick File.

4. In order to select for the images which should be permanently stored, navigate to the **Quick File** page.

5. Double-clicking to the selected image opens the **Image page.**

6. Add some **Measurements.**

7. Return to the Video page. When changing the page, the **Storage Wizard** prompts to save data to the database. Complete the wizard in order to save data; then the Video page is displayed again.

Return to step 1 and repeat as often as necessary.

8. Finally, navigate to the **Database page** select patient and examination, switch to the **Report page**, preview and print the examination report.

In order to recall previously saved information, navigate to the Database page or to the Quick File Page.

All aspects **highlighted** are explained in more detail in the following.

Structure of EyeWare

The EyeWare software consists of several program sections each appearing as separate pages at the EyeWare main window. See Figure 11 for the different elements of the main window (menu bar, main toolbar, pages and status bar).

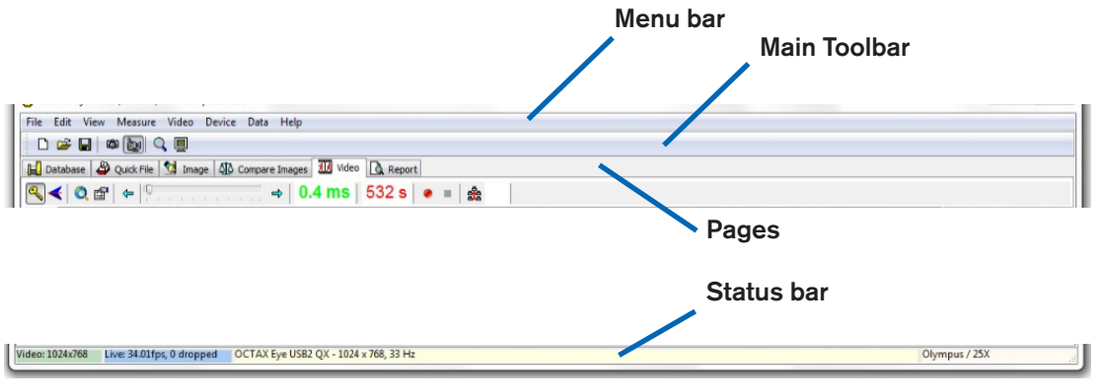


Fig. 11: Elements of the EyeWare main window

Menu Bar

The main menu of EyeWare is structured according to Windows standard, containing:

1. The File Menu: Navigate to Open / Save Image, Print, Change Report Template, Export, Send as Email Attachment, and Program Settings dialogs.

2. The Edit Menu: Contains standard Windows functions including Cut / Copy / Paste / Delete operations. Additionally, Insert Measure can be selected.

3. The View Menu: Activate / deactivate the display of Standard and Data Toolbars and Status Bar.

4. The Measure Menu: Navigate between Type of Measure Line and the Measurement Customisation dialog.

5. The Video Menu: This Menu is active when the Video page is in use. It allows navigating between Snapshots, Quick Snapshots, Full Screen display mode, video sources and Camera Setup.

6. The Device Menu: This menu allows managing the LaserShot M / NaviLase device or additional devices connected.

7. The Data Menu allows navigation and editing. Within the Database and Quick File page this function allows navigation in, and editing of the active category and images, respectively.

8. The Help Menu: Provides Information about the current version of EyeWare installed and allows generating and saving Support Request Data.

Main Toolbar

The main toolbar contains the most important commands, such as image file management, video snapshot and the standard clipboard buttons.

Pages

The software is organized into six pages, representing areas of the program. By changing between pages, certain actions are triggered.

1. The **Database** page: Management of data, containing patient data and examination records.

2. The **Quick File** page: Image storage for transient use in an image gallery.

3. The **Image page**: Processing of individual images including measurements and measurement labels. Any changes can be saved to the Database, the Quick File or export as Bitmap or JPEG file.

4. The **Compare Images** page: Possibility to compare up to 4 images

5. The **Video** page: Live video display, control of supported devices such as LaserShot M / NaviLase, optical calibration settings, and image gallery

6. The Report page: Preview of examination report, print report or save to PDF .

Status Bar

The status bar shows useful information about the status of the program, including the current video camera resolution, refresh rate, the number of measurements performed, current calibration and database information.

Video Page with Laser Targeting Feature

On the Video page, EyeWare displays a live video stream acquired by the Eye USB2.0 digital video camera. Depending on the use of the laser either in the classical 'static' mode or in the dynamic 'moveable' mode, two different appearances of the graphical user interface are available: the classical 'Windows'-like view and the full screen view.

The classical view of the Video page acts as a control interface for the LaserShot M system and the static mode of the NaviLase system. For laser targeting, control and activation, the Video page has to be opened. Figure 12 illustrates the essential elements of the Video page, including the Laser Toolbar and the Crosshair.

The Video page provides the basis for snapshots from the live video display. The status bar provides information about the camera resolution, the amount of images captured per second (fps) and the current calibration settings.

Appearance of the Crosshair

The video image can be overlaid by a Crosshair which indicates the target area of the laser beam. A combination of up to two crosshairs and three circles can be selected. The circles represent diameters of 10 µm to 40 µm of the microscopic image shown on the monitor. In order to activate or change the appearance of the Crosshair, select Video – Overlay – Crosshair. The preferred appearance can be selected from the drop-down menu (Fig. 13).

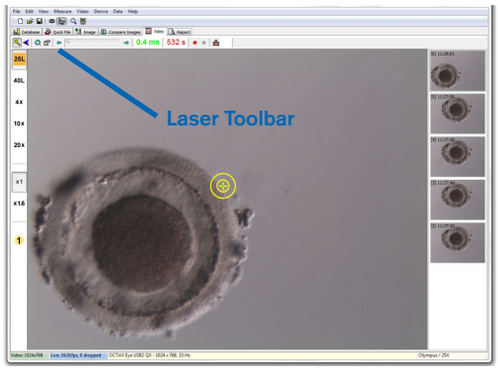


Fig. 12: EyeWare Video page with Laser Toolbar and laser targeting Crosshair

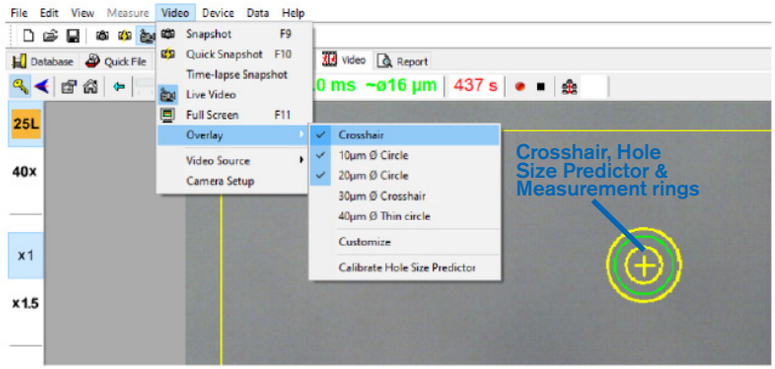


Fig. 13: Selection of the Crosshair mode at the Video pagewindow

Hole Size Predictor

The laser Hole Size Predictor is displayed as a green circle which is part of the electronic target overlay. The circle diameter of Hole Size Predictor serves as a convenient means of reliably indicating the expected hole size in correlation to the selected pulse time. It interactively changes its diameter depending on the pulse time selected (Fig. 13). Vice versa the Hole Size Predictor allows adjusting the pulse time in accordance to the required hole size.

Calibration of the Hole Size Predictor

After installation of the laser system or after introducing changes to the current microscope setup (e.g. heated microscope stage), the Hole Size Predictor has to be calibrated to reliably predict the hole size for the current microscope setup. The calibration procedure is based on the actual diameter of a hole which was drilled at defined settings (see in bold below).

The diameter of the Hole Size Predictor can be calibrated in a range between -70% and +200% in steps of 5% relative to the current value (Fig. 14).

Follow the steps below to calibrate the diameter of the Hole Size Predictor:

1. Select the live video page, full-screen mode (F11), in the EyeWare software.

2. Place a warmed dish (37°C / 98,6°F) containing a cell which will not be used for any further treatment on the heated microscope stage, e.g. an oocyte which failed to fertilize.

The cell should be positioned at the bottom of the dish.

3. Locate the cell through the laser lens and focus on the zona pellucida.

4. Unlock the laser, using the corresponding software button.

5. Select “Hole” as working mode from the menu if using NaviLase.

6. Using the computer mouse and “drag & drop”, direct the circle indicating the laser target to an area on the zona pellucida (NaviLase).

7. When using LaserShot M, align the zona pellucida with the laser target using the cross moving table of the microscope.

8. Using the ms scale, adjust the laser pulse length in a way that the diameter of the circle indicating the position and diameter of the laser holes corresponds to the zona pellucida thickness.

9. Release the laser by clicking the button or by pressing the footswitch while avoiding any vibrations of the microscope.

10. Observe the diameter of the drilled hole: if overlapping with the green circle of the Hole size predictor, no further action is needed.

11. In case the diameter of the drilled hole does not match with the diameter of the green circle, procede with the next step for calibration:

12. Select Video - Overlay – Calibrate Hole Size Predictor from the menu and adjust the indicated hole size by clicking the arrows on the right side to overlap with the actual diameter of the drilled hole (Fig. 14).

13. Click ok to save the change.

14. To verify calibration, drill a new hole in another area of the zona pellucida and observe the diameter of the drilled hole and green circle.

The Hole Size Predictor is now calibrated to predict the diameter of drilled holes according to the selected pulse lengths (at 37°C / 98.6°F, laser lens, zona at the bottom of the dish, current microscope setup).

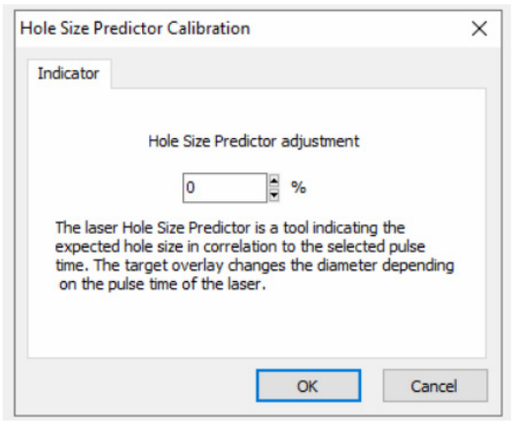


Fig. 14: Calibration of the Hole Size Predictor at the Video page

CAUTION

INFLUENCE OF Z-POSITION OF THE OOCYTE/EMBRYO ON DRILL OPENING SIZE

Inappropriate Z-positioning will result in smaller drill holes and in reduced laser beam quality. It is recommended to keep the cell near the bottom of the culture dish during laser treatment.

Alignment of the Crosshair

In order to match the position of the Crosshair with the center of drilled hole, select Video - Overlay – Customize from the menu and correct the position of the crosshair in XY-orientation by scrolling the sliders.

Alternatively, one slider may be highlighted by clicking and the Crosshair may be moved to the proper position by use of the cursors of the keyboard. This allows for a more precise control (Fig. 15). Another possibility to position the electronic target would be to move it to its exact position by keeping the <CTRL> key pressed whilst dragging it with the mouse.

Please note that the electronic Crosshairs can only be repositioned as long as the laser stays in its home position (NaviLase only).

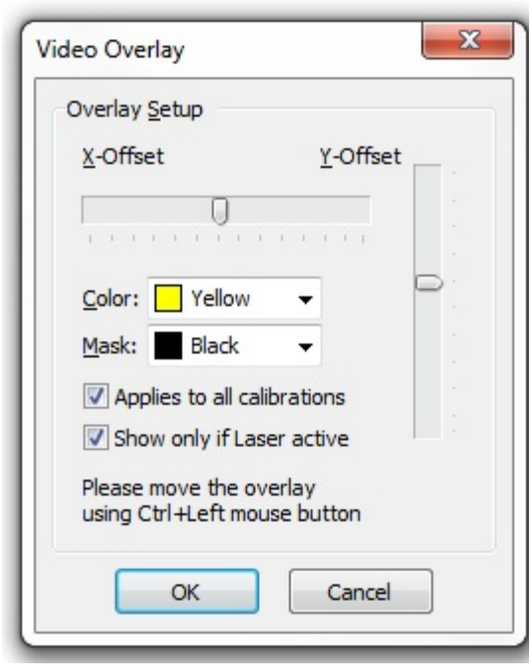


Fig. 15: Control of Crosshair position

The Video Toolbar



The Video toolbar provides the elements of the user interface for controlling the laser Pressing the Key button turns the laser into active mode.



Clicking the Laser release button triggers a laser pulse. Alternatively the laser can be triggered by pressing the laser release button of the computer mouse or optionally by an external foot switch.



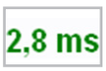
The homing function for NaviLase resets the position of the movable laser beam to the home position of the fixed laser. LaserShot M is invariably in home position.



The laser is secured by a timeout after 600 s of inactivity of operation and will switch automatically to an inactive mode.



The laser irradiation time can be adjusted with the slider. Additionally, both arrow icons next to the slider are available to increase or decrease the duration time in steps of 0.1-0.2 ms. A more precise adjustment of the laser duration time can be accomplished by using the arrow keys of the computer keyboard.



The current laser irradiation time is displayed in green color.



Whilst displaying a live video stream, pressing the video capture icon starts recording of a video sequence. There is no limitation in number and length of video files by EyeWare software. Extended length of video capture (hours) may cause problems with saving and is not intended. After finishing the sequence by clicking the stop button the software starts the storage wizard. Video files will be saved and can be recalled from the Database page in the section Video clips.



Information about the status of the laser is displayed in the Laser Properties dialog (Fig. 16), which can be activated by clicking the icon. The information is useful in case of contacting Technical Support.

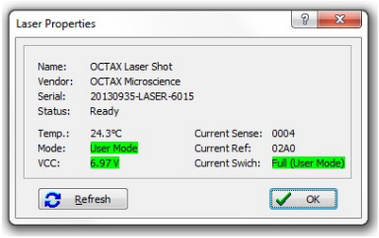


Fig. 16: Laser Properties dialog (Laser properties data shown are exemplary)



Access customization of the strength of the selected video filter. For description of the available filter channels see chapter “Calibration side bar” below.
Note that this icon/feature is only available in case the USB-camera from iDS is connected.

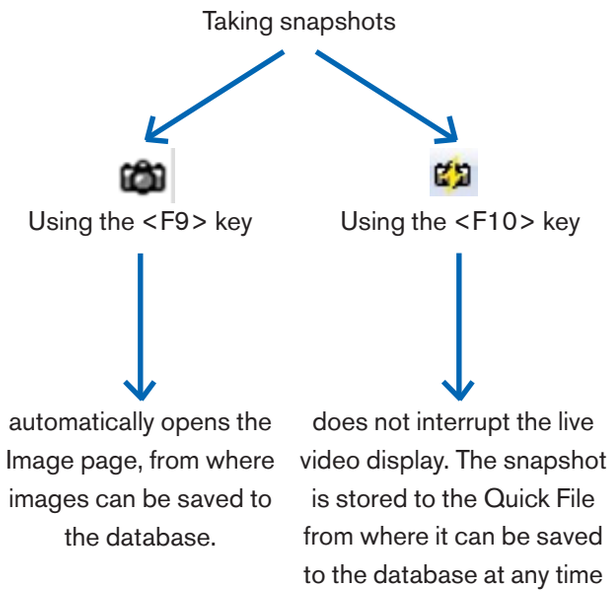
Triggering the Laser

After switching the laser into active mode and selecting the irradiation time, LaserShot M / NaviLase can be triggered by clicking , by pressing the laser release button of the computer mouse or optionally with an external foot switch.

Taking Snapshots

A snapshot of the live video image can be taken by clicking the camera button at the main toolbar, in the Video menu or by pressing the <F9> key. This will automatically open the Image page. Now some Measurements can be added. For saving the image select the button or return to the Video page. When changing page, the Storage Wizard prompts to save image data to the database.

Taking a snapshot of the life video image without interrupting the video display is accomplished by pressing the <F10> key. The snapshot image will be stored to the Quick File from where it can be saved to the database by clicking the batch transfer button



Calibration side bar

For quick recalling a pre-defined calibration set due to changing the objective or intermediate magnification, select the corresponding button within the left sidebar of the EyeWare window (Fig. 17).

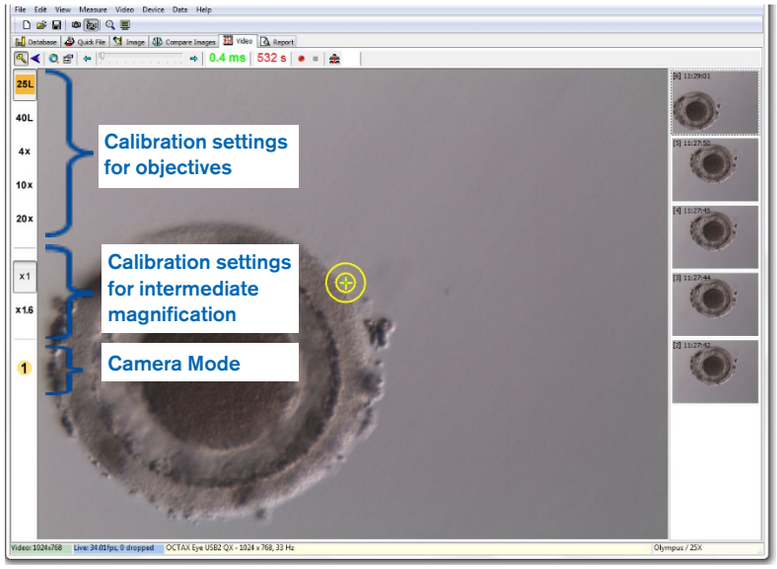


Fig. 17: Display of calibration settings for objectives, for the intermediate magnification, and the camera mode within the left sidebar

Access of video filters for live contrast enhancement and/or display of two sizes of the field of view on screen – only available in case the USB-camera from iDS is connected:

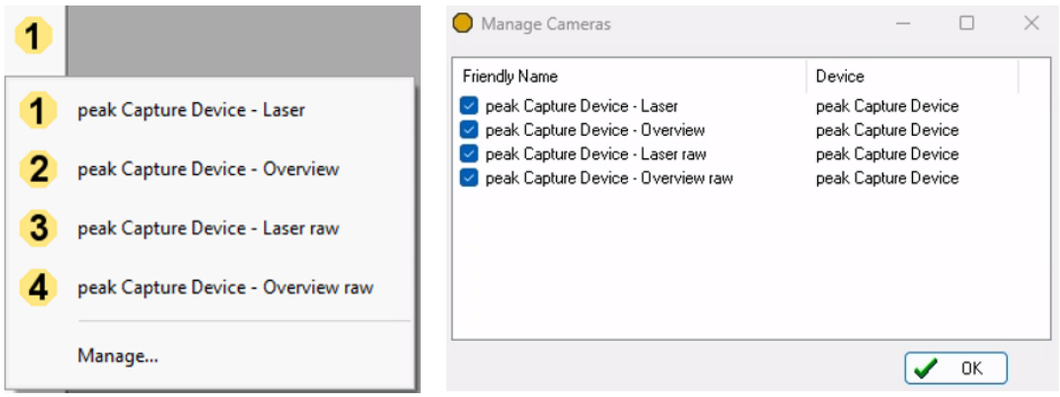
- Press on the yellow number in the calibration side bar (Fig. 17,“Camera mode”).
- A dropdown menu opens for “peak Capture Device”:

  1 – Laser: live contrast enhancement
  working field of NaviLase zoomed to size of the screen

  2 – Overview: live contrast enhancement
  display of the full camera chip, working field of NaviLase looks small

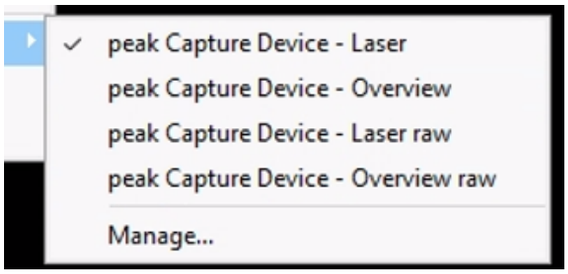
  3 – Laser raw: no contrast enhancement
  working field of NaviLase zoomed to size of the screen

  4 – Overview raw: no contrast enhancement
  working field of NaviLase looks small

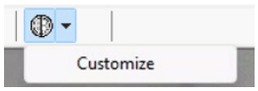


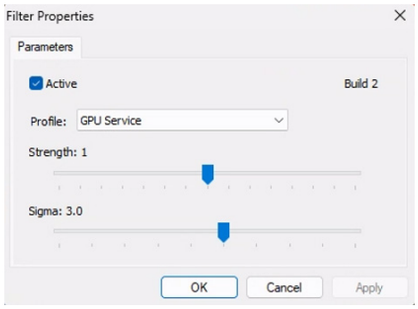
Click on a line to select a mode; click on “Manage…” to select/deselect modes from display in the Calibration bar in the Manage Cameras window.

Alternatively, the camera modes can be accessed and managed via the menu Video -> Video Source:



The strength of the contrast enhancement filter is set to default for all channels.
To change the settings, click on the icon video filter and Customize to open the window Filter Properties. After changing the value(s), click Apply and OK to save changes.





Active calibration settings are displayed by a colored button corresponding with the color code of the lens. Likewise, the camera settings in use are indicated by an active button within the left sidebar and displayed at the status bar.

Note: The calibration values are saved with each image, both in the Database and in the Quick File. Each time an image is recalled from either location, there will be a notification to restore the calibration setting that is compatible with the recalled image (Fig.18).

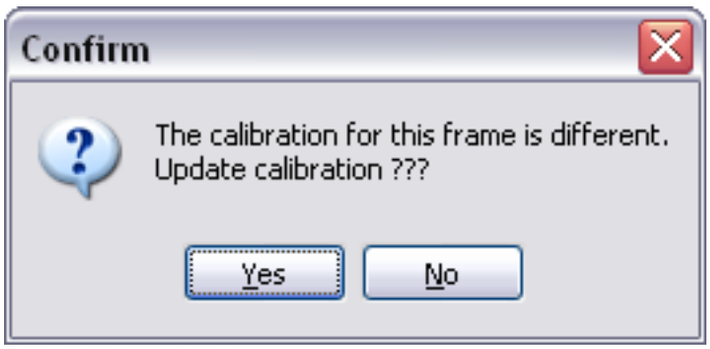


Fig. 18: Confirm dialog box

When switching back to the live video stream, the calibration settings which are indicated on the left sidebar become active again.



The recipient end user of the LaserShot M /NaviLase systems should not unpack and install it upon receipt. Unpacking, installation, setup and end-user training of LaserShot M systems must be carried out by appropriately qualified technical staff authorised by Vitrolife GmbH.

Image gallery sidebar

Any image being taken by using the quick snapshot function by pressing the <F10> key will be displayed in the right sidebar on the Video image page (Fig. 19). The image gallery sidebar provides instant display and easy navigation between acquired images which have been stored to Quick File.

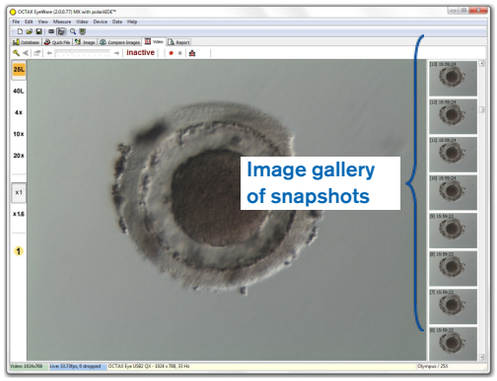


Fig. 19: Video page with image gallery sidebar

The Full Screen Mode: LaserShot M and dynamic operation of NaviLase

The dynamic features of NaviLase are only available in the full screen mode of the EyeWare (Fig. 20). Also LaserShot M can be controlled here. The full screen mode can be accessed by pressing the <F11> key. Pressing the <F11> key again allows returning to the classical view for the operation of NaviLase in the static mode.

The left sidebar of the full screen view contains control elements for taking snapshots and capturing videos. By activating the button "Arm laser" all relevant elements for the control of the LaserShot M or dynamic NaviLase laser function can be accessed ,i.e. adjusting the pulse time, selecting the working mode of the laser (NaviLase only), and triggering the (first) laser pulse(s).

All control elements for the camera mode and the appropriate calibration settings for the objective and intermediate calibration in use are located within the left sidebar.

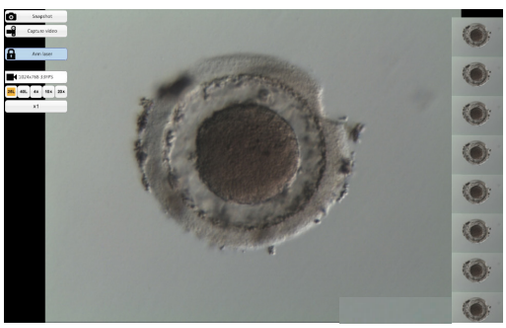


Fig. 20: Full screen mode for NaviLase dynamic operation

Taking Snapshots

Snapshot images acquired by either clicking the "Snapshot" button or by pressing the <F10> key are displayed within the image gallery. Individual Snapshot images within the gallery can be enlarged by moving the mouse cursor across the image of interest (Fig. 21).

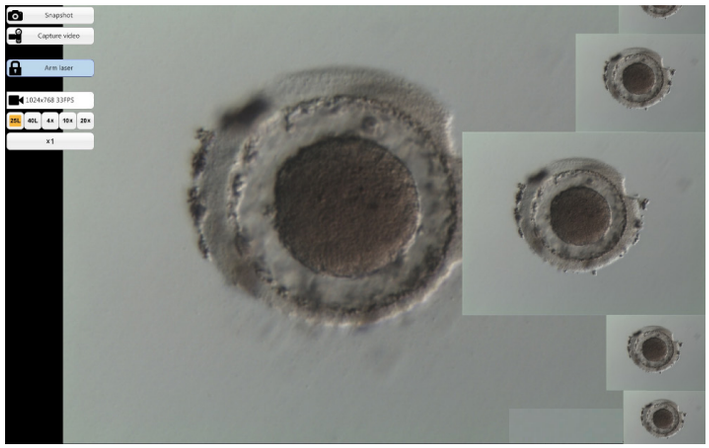


Fig. 21: Full screen mode with image gallery sidebar zoom function

Arm Laser

Clicking to  activates the LaserShot M or NaviLase laser and provides access to the respective control elements.

Clicking "Start"  initiates the laser action

NaviLase control elements for dynamic operation (not available for LaserShot M)

All control elements required for the dynamic operation of NaviLase (Fig. 22) can be accessed after activating the "Arm laser" field.

As a first step, the laser working mode has to be selected. Moving the mouse cursor across the field ‘Hole’ activates a drop down menu. Available working modes are the positioning of a hole, of a straight line or of a curved line to anywhere within the working area.

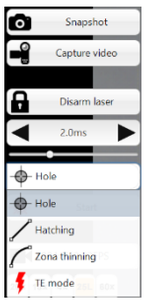


Fig. 22: Selection of laser dynamic working modes

Hole (NaviLase dynamic operation)

After selecting "Hole" as the designated operation mode, the electronic laser target gets activated. It indicates the current position of the laser impact and the expected hole size, depending of the selected pulse time. By using the drag & drop function of the mouse the electronic target can be moved to the intended position within the working field (Fig. 23). Adjustment of the expected hole size can be done by modifying the “Pulse time” either by moving the slider, clicking to the arrows or turning the mouse wheel.

Clicking "Start" 

initiates the laser action and converts this field into an emergency stop 

button which may be used stall the laser action at any time.

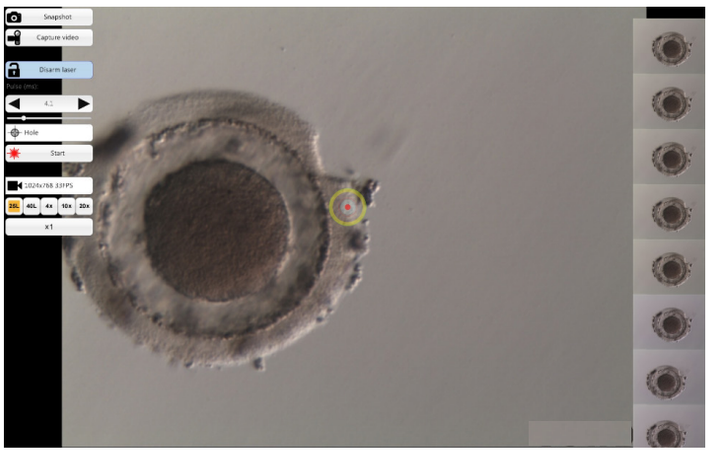
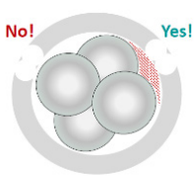


Fig. 23: NaviLase operational mode for drilling single holes at a position of choice



PVS (PERIVITELLINE SPACE) MAX. RULE

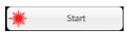
For maximum safety and minimal invasive reasons, always select the spot to perform the laser drilling where the distance between cell membrane and zona pellucida is the largest



Hatching (NaviLase dynamic operation)

The "Hatching" mode offers the possibility to apply a defined number of laser pulses along a straight line. It is ideal for drilling small openings, either for assisted hatching or for biopsies

After selecting "Hatching" as the designated operation mode, the electronic laser target gets activated. It shows the current position of the laser impact (indicated by a red dot in the center) and the expected hole size including a short line. By dragging & dropping the red starting spot of the line the electronic target line can be moved to the intended position within the working field (Fig. 24). The length of the line is defined by the distance between the blue starting and the yellow stopping spot. The distance can be adjusted by dragging each of the spots to their confining positions. Adjustment of the expected hole size can be done by modifying the “Pulse time” either by moving the respective slider, clicking to the arrows or turning the mouse wheel. The number of pulses per line is limited to 60. A maximum overlap of 50% between adjacent circles is allowed.

Clicking "Start" 

initiates the laser action and converts this field into an emergency stop button 

which may be used stall the laser action at any time.

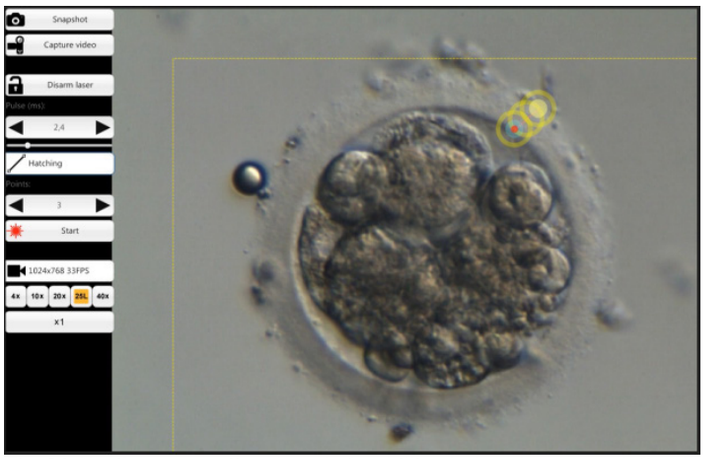


Fig. 24: NaviLase operational mode for drilling holes along a predefined straight line

Zona thinning (NaviLase dynamic operation)

The "Zona thinning" mode offers the possibility to apply a defined number of laser pulses along a curved line.

After selecting "Zona thinning" as the designated operation mode, the electronic laser target gets activated. It shows the current position of the laser impact (indicated by a red dot in the center) and the expected hole size including a curved line. By dragging & dropping the blue starting spot of the line the electronic target line can be moved to the intended position within the working field (Fig. 25). The length of the line is defined by the distance between the starting and the yellow stopping spot. The distance can be adjusted by dragging each of the spots to their confining positions. The radius of the curved line can be adjusted to the perimeter of the zona pellucida by moving the pink spot to the appropriate position. Adjustment of the expected hole size can be done by modifying the "Pulse time" either by moving the respective slider or by clicking to the arrows.

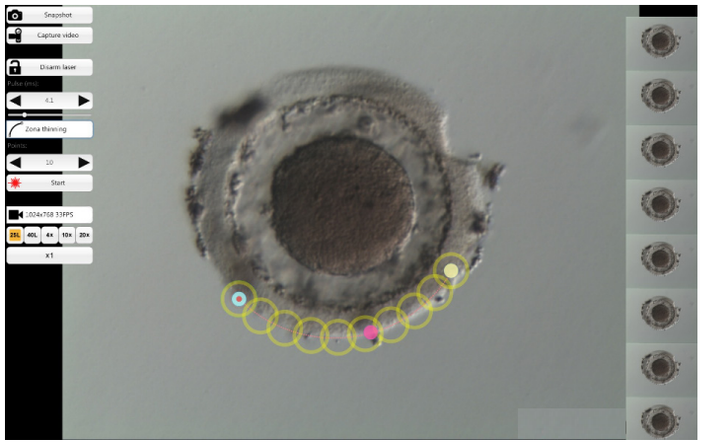


Fig. 25: NaviLase operational mode for drilling holes along a predefined curved line

The degree of overlapping between adjacent circles and hence the shape of the line produced by the laser can be determined by adjusting the number of pulses whilst keeping the pulse time (the hole size) at a defined value (Fig. 26). The number of pulses per curve is limited to 60. A maximum overlap of 50% between adjacent circles is allowed.

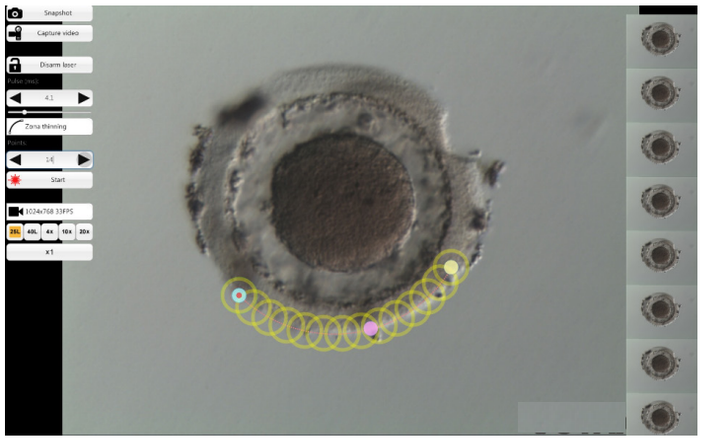
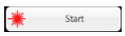


Fig. 26: NaviLase operational mode for drilling holes along a predefined curved line with high degree of overlapping of individual shots

Clicking "Start"  initiates the laser action and converts this field into an emergency stop button  which may be used stall the laser action at any time.

TE mode (NaviLase dynamic operation)

The "TE" (trophectoderm) mode offers the possibility to apply a preselected number of one to three laser pulses along a straight, vertical line. It is used to support a trained operator during trophectoderm biopsy for the step of releasing intracellular bonds between mechanically stretched trophectoderm cells.



TE MODE: RESTRICTIONS IN USE

The TE mode must only be used by experienced users trained in doing trophectoderm biopsies. The laser puls(es) can assist the release of mechanically stretched intracellular bonds between trophectoderm cells for biopsy. The TE mode must never be applied to the zona pellucida.

After selecting "TE mode" as the designated operation mode, the electronic laser target gets activated. It shows the current position of the laser impact (indicated by a red dot in the center) and a line along which the preselected number of shots will be applied.

The number of shots applied in TE mode can be pre-selected in the classical view of EyeWare as shown in Fig. 27. From the menu select Device -> NaviLase ->-TE mode to select 1, 2, or 3 shots.

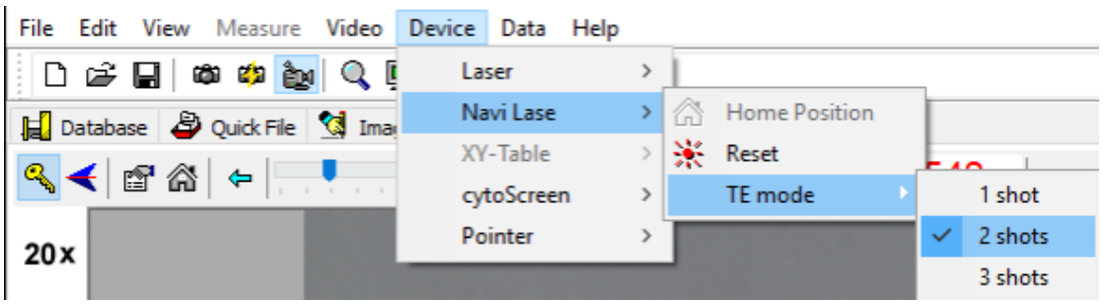


Fig. 27: NaviLase preselection of laser pulses in TE mode

For operation in full screen mode, the electronic target line can be moved to the intended position within the working field by dragging & dropping the red starting spot of the line (Fig. 28). Adjustment of the laser impact can be done by modifying the "Pulse time" either by moving the respective slider, clicking to the arrows or turning the mouse wheel.

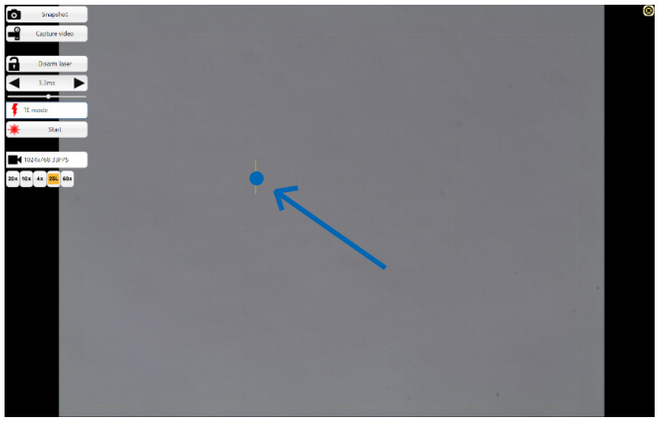


Fig. 28: NaviLase target line in TE mode (see arrow).

Clicking "Start"  initiates the laser action and converts this field into an emergency stop button  which may be used stall the laser action at any time.

TE mode using LaserShot M

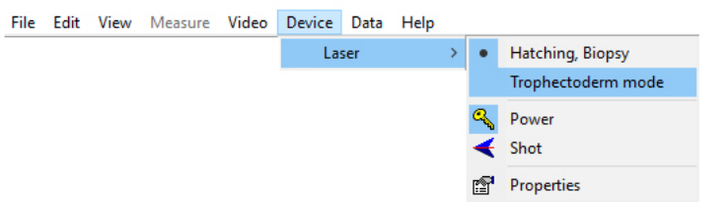
The "TE" (trophectoderm) mode offers the possibility to apply a preselected number of one to three laser pulses along a straight, vertical line. It is used to support a trained operator during trophectoderm biopsy for the step of releasing intracellular bonds between mechanically streched trophectoderm cells.



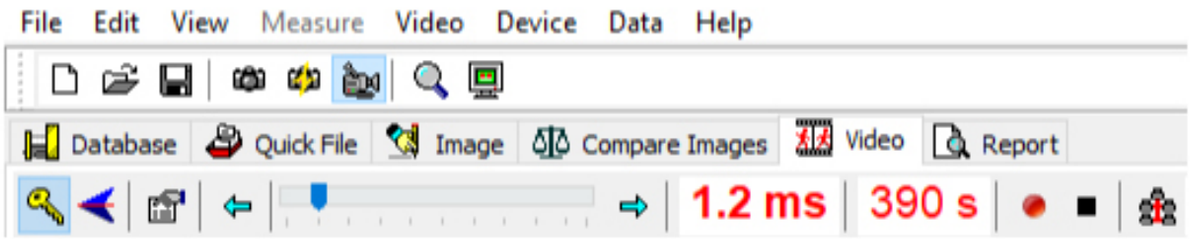
TE MODE: RESTRICTIONS IN USE

The TE mode must only be used by experienced users trained in doing trophectoderm biopsies. The laser pulse can assist the release of mechanically stretched intracellular bonds between trophectoderm cells for biopsy. The TE mode must never be applied to the zona pellucida.

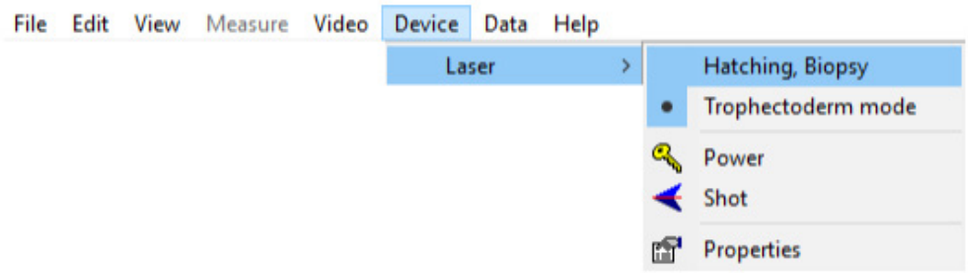
To select the TE mode in the classical view of EyeWare:
Select Device -> Laser -> Trophectoderm mode from the menu



After selecting "Trophectoderm mode" as the designated operation mode, the display of laser pulse length changes from green to red color. This is to indicate that TE mode is active and the last pulse length used in TE mode has been saved and is displayed. The Hole Size Predictor (circle) is inactivated automatically. The laser target is indicated by a crosshair.

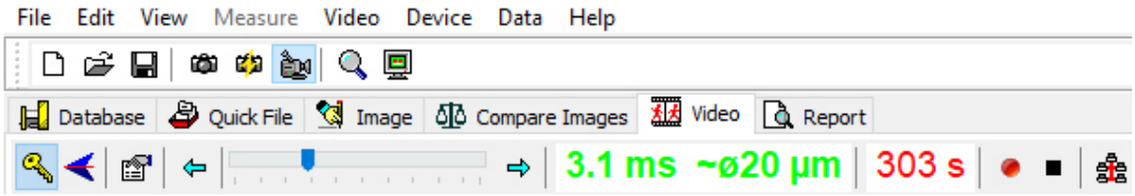


Use the laser to support in TE biopsy as recommended in Indications for Use (pp. 19)
After finishing TE cell treatment, switch back to hatching/blastomere biopsy mode:
Select Device -> Laser -> Hatching, Biopsy from the menu.



Alternatively, the laser is reset to hatching mode automatically after switching the laser off and on again using the key symbol from the laser tool bar.

Check that the display of laser pulse length is displayed in green color to indicate hatching mode. The last pulse length used in hatching mode has been saved is displayed. The Hole Size Predictor is reactivated automatically.



WARNING

REPEATED LASER SHOTS

Repeated Laser shots to the same position of the embryo could result in an increased risk of embryo damage. In case of risk of applying repeated Laser shots to the same position of the embryo the laser action can be immediately stalled by pressing the emergency stop button.

Quick File Page for Rapid and Temporary Storage of Images

The Quick File provides a clipboard-like storage of images without associated measurements. It can be useful for quickly saving an image without following the complete procedure of the Storage Wizard. For recalling an image from Quick File and displaying it at the Image page, e.g. for reviewing measurements or saving to a file or to the database, highlight the desired image and double-click it.

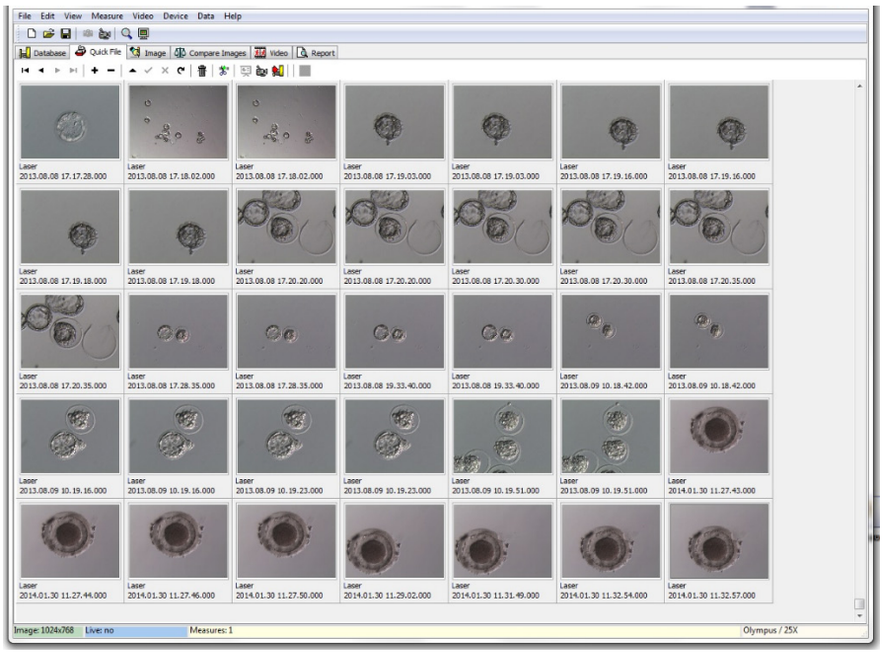


Fig. 29: Quick File page

There is no limitation in number of images saved to Quick File. However, a large number of images makes it more difficult to identify a specific one. When using the Quick File, it is recommended to empty the Quick File gallery after completing the storage of all images which are intended to be saved (Fig. 29) at the end of the day.

The Quick File Toolbar

The Quick File toolbar mainly includes the functions similar to the functions of the Database toolbar. For information regarding a specific button move the mouse cursor over any button to get a short description of its function or consult the chapter Database Page. Additional functions are:

Delete Function 

For deleting selected items of the Quick File click on the trash can icon. Keep the [shift] and/or [CTRL] key pressed and select all desired images.

Batch Transfer to the Database 

Using the database batch transfer button, more than one image can be transferred to the database at the same time with the Storage Wizard. More than one image can be selected by keeping the [shift] or [Ctrl] key pressed and highlight all desired images. After the transfer of all selected images to the database has been completed, a dialog box prompts to select whether or not stored images should be deleted from Quick File.

Compare Images Page

The Compare Images page provides the possibility to display and compare up to four selected images. In order to transfer images to the Compare Images page, select images from Quick File by right-clicking and assign the corresponding position this particular image is thought to have on the Compare images page (Positions A,B, C, or D) (Fig. 30). EyeWare does not evaluate the images selected for comparison.

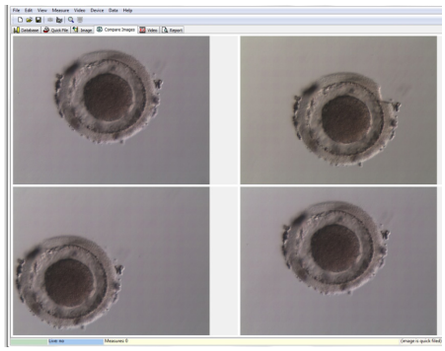


Fig. 30: Compare Images page

Image Page with Measurement Feature

The Image page is mainly used to assign measurements to newly acquired snapshots

(Fig.31). Additionally, existing images can be loaded from either the database (double click to the respective image at the Database page) or from files (select File > Open Image) and displayed. Changes can be saved either to the database by the use of the Storage Wizard (select ✔ or change page) or to file (selecting File > Save Image). The measurement function allows the determination of the cell diameter, the hole diameter and the thickness of the zona pellucida.

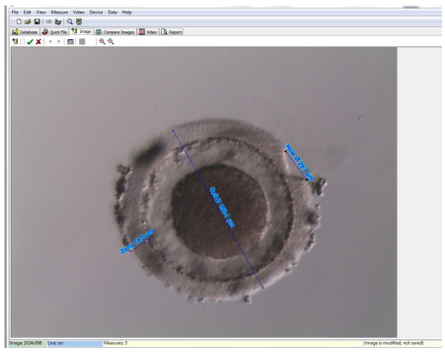


Fig. 31: Image page with measurements

Measurement Toolbar

For information regarding a specific button move the mouse cursor over any button to get a short description of its function.

Measurement Function

By using the measurement function new measurements can be applied. In order to determine the size of an object, click to the position where the line should start and hold the mouse button down until the end point is reached. The length of the drawn line is displayed in µm. The measurement function can either be activated by clicking the measurement button or by pressing the <Ins> key.

After selecting the drawn measurement line by clicking, it can be edited with different operations, like cut / copy / paste / delete, resizing, moving etc. The type of measurement can be modified from the Measure menu.

Calibration of EyeWare is required for carrying out measurements. Calibration depends on the microscope set-up and is set at "calibration setup…". Please make sure to select the proper calibration settings before applying any measurements.

Apply changes to the database

Clicking  saves any modifications to the database, which then are displayed at the measurement category of the database page.

Clicking  cancels changes and reverts the image to the last version stored.

Navigation

Using the arrows allows scrolling through the gallery of images of a patient in a selected examination or through the gallery of images at the Quick File page, depending on the location from which the image has been accessed.

Type of Measure Line

The type of measure line can be modified in the *Measure* menu. Either a predefined label (cell diameter, cell total diameter, hole diameter, zona pellucida thickness) can be selected (Fig. 32) or a new type of measure can be created using the measure customization dialog.

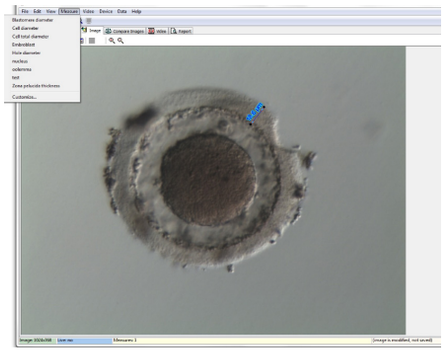


Fig. 32: Defining the type of measure in the Measure Menu

Measure Customisation Dialog

A new Measurement application can be created and a list of defined measurements can be set up (Fig. 33).

A new Measurement application is created by clicking New App, then the measurements are defined as follows:

- its name - for the printed report
- its short label - for the measure lines displayed on the image
- its long label - for the display in the menu

If a measurement is identified with diameter "TRUE" the program will calculate area and volume, assuming the object is spherical. Adding the "&"-character to the long label allows creating keyboard shortcuts, by defining the character following the “&” as the shortcut key. For example: &Cell Diameter will define "C" as shortcut in the measure menu (Cell Diameter).

The copy (Ctrl C) and paste (Ctrl V) short-cuts can be used to copy the Ø - symbol.

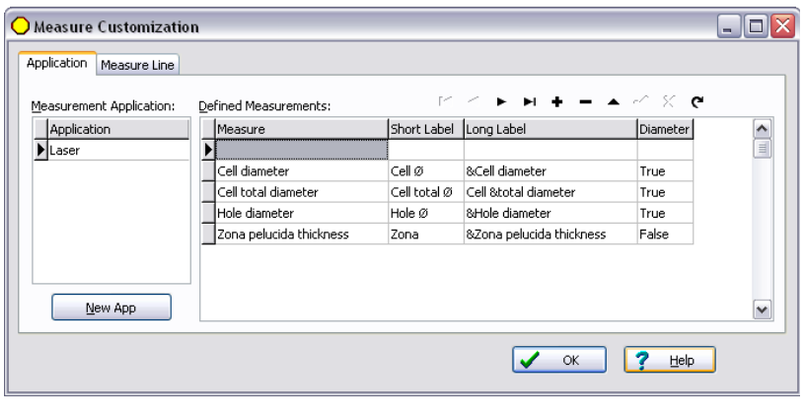


Fig. 33: Measure customisation dialog, measure application setup

Measure Line

For the individual appearance of the measure lines their color, arrow color, arrow fill color, shadows and text font can be configured (Fig. 34).

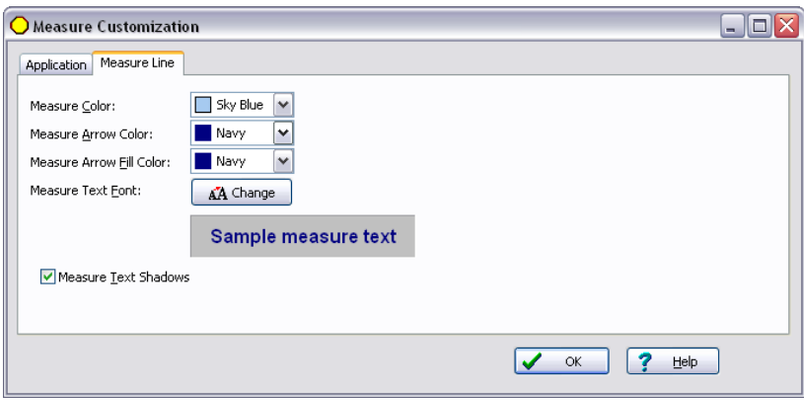


Fig. 34: Measure customisation dialog, measure line properties

Storage Wizard for Associating Images with Patients

For simplifying the process of storing a new image to the database of EyeWare, the Storage Wizard guides through the steps necessary to save an image. Please note every image intended to be kept has to be saved to the database.

1. Deciding where to save the image

It can be chosen between storing the image temporarily to Quick File or associating the image with a patient, respectively.

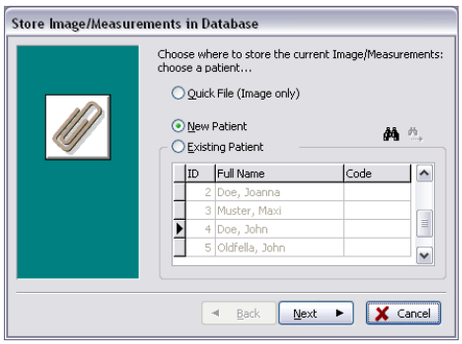


Fig. 35: dialog saving images

In case an image is supposed to be associated with a patient data set either choose New patient to generate a new patient data set (please proceed to step 2), or select an Existing patient from the list. In case of a large patient population, use the search function, by clicking . Now search for ID, Last Name, First Name, Birthday or Code (proceed to step 3).

2. Adding a new patient

When adding a new patient file, the database allows entering a limited amount of information about the patient.

- Last Name
- First Name
- Birthday
- Code

For the field ‘Code’ either the ID number of the main patient tracking database or any other unique identifier can be chosen. Patient data (last and first names, birthday) will be encrypted upon saving to the database and is protected against reading without using the EyeWare database function for cybersecurity reasons.

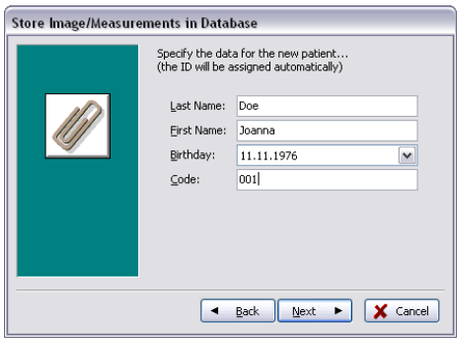


Fig. 36: dialog saving images

3. Selecting the examination

With each image of a patient, an examination is associated. The examinations are used to organize the images of the respective patient. One patient can have different examinations and one examination can contain different images.

For a new examination, choose New Examination. Otherwise, select an existing examination and directly proceed to step 5. Whenever saving an image to a new patient, no examinations will initially exist. Therefore, a new examination needs to be added according to step 4.

4. Adding a new examination

An examination is mainly determined by the date at which it is carried out. In addition, the name of the examiner and the examining lab can be added in order to keep track of all relevant examination data.

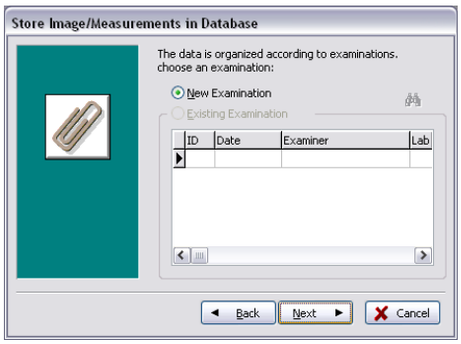


Fig. 37: dialog saving images

5. Finish

An examination is mainly determined by the date at which it is carried out. In addition, the name of the examiner and the examining lab can be added in order to keep track of all relevant examination data.

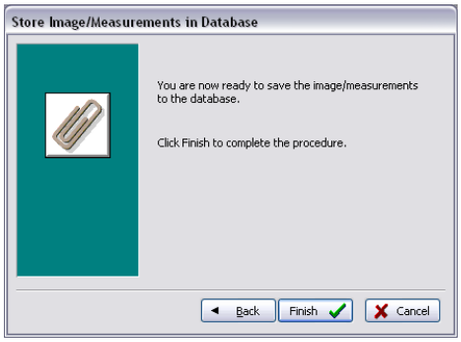


Fig. 38: dialog saving images

The Database Page for Managing Data Sets

The Database page allows recalling and managing data sets, based on patient data and examination records. Navigation through patient data sets and examination data sets can be accomplished by using the respective navigation bar for each of the sections. (Fig. 39).

The database of EyeWare is structured for routine medical use. For this intent a patient list is at the root of the database. For each patient the respective examinations are assigned. Each examination may contain one or more images or videos associated with one or more measurements (Fig. 40).

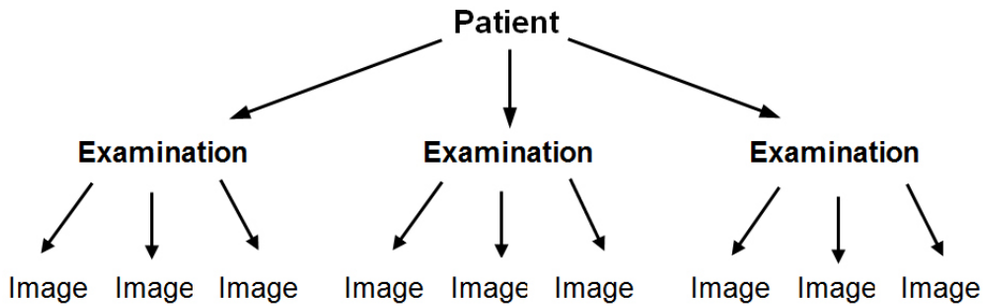


Fig. 39: Structure of the database

When a snapshot is saved to the database by use of the Storage Wizard, it is associated with both patient and examination data. The wizard also allows the entry of new patient/ examination data.

In some circumstances, as in a non-patient related operation, it may be desirable to shortcut the Storage Wizard and to quickly save the image to Quick File. Please note that when using Quick File, no measurements are saved.

For recalling an image from the Database page and loading it to the Image page (e.g. for reviewing measures or saving to a file), double-click any image of the active examination.

With every image stored a comment may be associated. Click  to open the multiline editor. The software automatically timestamps every image at the time point of saving it to the database.

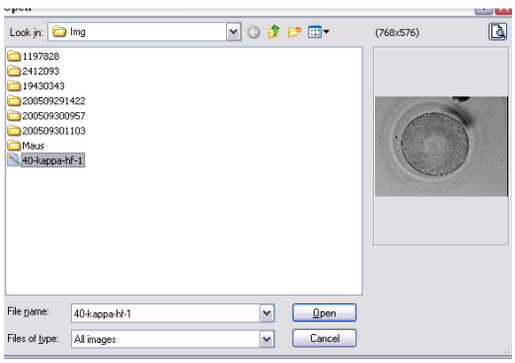


Fig. 40: Database page

The DatabaseToolbar

For information regarding a specific button move the mouse cursor over any button to get a short description of its function:

Data Navigation

Clicking the arrows allows scrolling through the highlighted category or directly getting to the first or last object.

Insert / Delete Function

The active object may be inserted or deleted.

Data Revision (edit, post, cancel, refresh)

After selection of a category a specific dataset can be edited. Subsequently, modifications can either be accepted or deleted. Clicking the refresh button will update the dataset.

Search Function

The search function offers the selection of different search criteria depending on the active category denoted by a bold title (Patient , Examinations , Images or Measurements).

First the search category has to be selected by clicking to the respective icon. Then the search term to be looked for has to be entered. Clicking will start the search (Fig. 41).

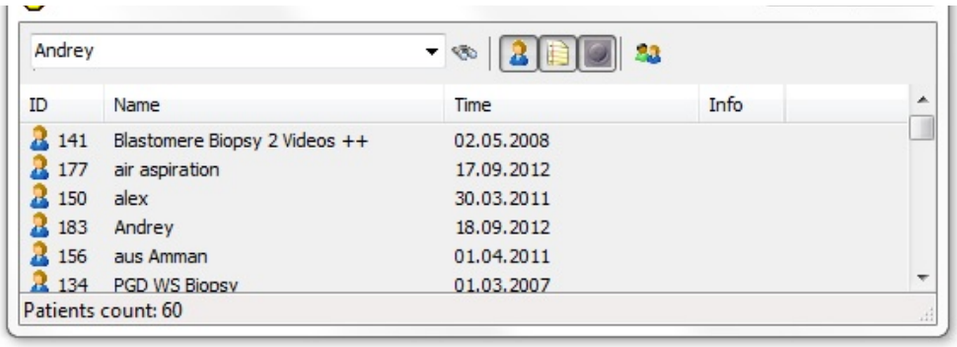
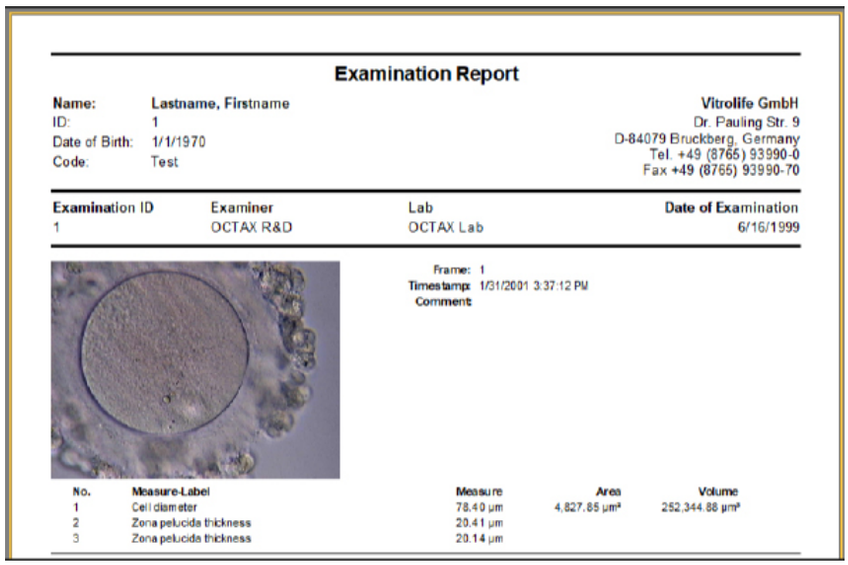


Fig. 41: Database search function

The icon for the search function is also shown in the Storage Wizard at step 1 and 3. Search function at step 1 corresponds with "Find in [patient]", step 3 with "Find in [examination]".

Report Page for Printing Examination Results

EyeWare allows to quickly printing out any set of examination results. The available report layouts are predefined. On the Report page, a preview of the examination report selected in the Database page is displayed below. This report will be printed as shown in the preview when the print command is issued after confirming the Print Dialog.



Examination Report

Name: **Lastname, Firstname**
ID: 1
Date of Birth: 1/1/1970
Code: Test

Vitrolife GmbH
Dr. Pauling Str. 9
D-84079 Bruckberg, Germany
Tel. +49 (8765) 93990-0
Fax +49 (8765) 93990-70

Examination ID	Examiner	Lab	Date of Examination
1	OCTAX R&D	OCTAX Lab	6/16/1999

Frame: 1
Timestamp: 1/31/2001 3:37:12 PM
Comment:

No.	Measure-Label	Measure	Area	Volume
1	Cell diameter	78.40 µm	4,827.85 µm²	252,344.88 µm³
2	Zona pelucida thickness	20.41 µm		
3	Zona pelucida thickness	20.14 µm		

Available Report Layouts

Four different pre-designed reports are available. For changing the type of report layout you may select the desired page design at *File - Report - Template* from the menu.

Export of reports

The report may be exported as PDF, RTF, DOCX or HTML file. The address shown in the upper right of the report can be customized through *File > Settings > User Data.*

The Report Page Toolbar

For information regarding a specific button move the mouse cursor over any button to get a short description of its function.

Navigation Function 

In case of a multipage report, navigation is possible by use of the arrow buttons.

Zoom Function 

Zooms the preview to display the whole page, to 100% or to maximal width respectively.

Full Screen 

Displays the report at full screen mode. At the upper most position of the screen, the report toolbar is shown upon moving the mouse to this area, allowing navigating between pages. To switch to normal view, press the <ESC> key or click on the door symbol in the toolbar.



TECHNICAL SUPPORT

If you need assistance at any time, please contact Technical Service. For contact details please refer to the section Customer Service.

Getting Started

Prior to the first use of the LaserShot M or NaviLase system or

- each time the whole microscope setup has been moved
- if the LaserShot M / NaviLase system was not used for a period of time
- after microscope maintenance
- after other major events, which could have induced movements and strong vibrations to the whole microscope and laser system

The position of the laser impact should be confirmed and the laser irradiation time should be determined to ensure safe treatment of oocytes and embryos.

Starting EyeWare Software

Start the EyeWare software by double clicking the icon item on the computer desktop. Confirm the message and in order to initialize the live video display, select Video page.

Laser Aiming Verification Procedure

Take a cell which will not be used for any further treatment, e.g. an oocyte which failed to fertilize. The cell doesn't need to be intact, except for its zona pellucida. Starting the EyeWare software and selecting the Video page initiates the live video screen. Activate the laser by clicking . Select a cell and switch to the dedicated laser optics. The laser impact area is located in the center of the field of view and is indicated by a crosshair. (In case the crosshair modus is inactive or in order to change the design of the electronic target, select Video – Overlay – Crosshair and the preferred design in the menu.) Move the zona pellucida of the spare cell into the crosshair area and trigger a single laser pulse by clicking , pressing the laser release button of the computer mouse, or optionally by using an external foot trigger.

The Crosshair on the screen should be located straight at the center of the opening to be created by the laser (Fig. 42). If this is not the case, the position of the crosshair has to be moved to the exact position within the laser drilled opening.

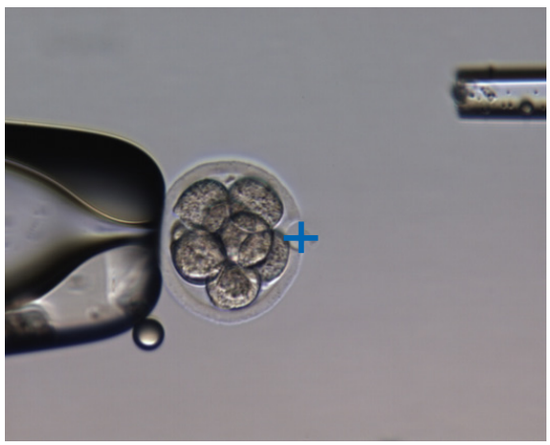


Fig. 42: Properly aligned electronic laser target

In order to match the position of the crosshair with the center of drilled hole, select *Video - Overlay – Customize* from the menu and correct the position of the crosshair in XY-orientation by scrolling the sliders.

After checking / aligning the crosshair in NaviLase home position, verify target position also in NaviLase dynamic mode as follows: position the spare cell in a corner of the NaviLase working area, move the laser target to the zona and trigger a single laser pulse. Verify position of the target indicator. It should be at the center of the drilled opening. If this was not the case, document deviation by taking a snapshot. Repeat above steps after moving the spare cell to the remaining three corners one after the other.



Caution: In case that the target indicator did not match with the center of the drilled opening in one or more cases, stop using NaviLase in dynamic mode. Contact customer service and provide the snapshots of the deviation(s). Only use NaviLase in verified home position until the error will be fixed.



INTEGRITY OF THE ELECTRO-OPTICAL SYSTEM

Wrong handling of the microscope or strong displacement of the electro-optical system, e. g. by mechanical shock can result in an incorrect position of the beam splitter system, magnifier lens position, camera, and the turret position, respectively. As a result of any of the above, aiming of the laser may no longer correspond to the crosshair position displayed at the video image and damage to embryos may occur if the laser is used in this condition.



INCORRECT LASER AIMING

Failure to follow the laser aiming verification procedure could result in wrongly located openings and therefore may damage the treated oocyte or embryo.



REPEATED LASER SHOTS

Repeated laser shots to the same position of the embryo could result in an increased risk of embryo damage. In case of risk of applying repeated laser shots to the same position of the embryo the laser action can be immediately stalled by pressing the emergency stop button.

Relationship between irradiation time and opening size

According to the drilling strategy, a single laser pulse must generate a hole of appropriate size. The relationship between laser irradiation time and opening size is influenced by various factors such as the type of microscope, the kind of heated microscope stage (glass or metal), the type of heating system, the temperature, the culture dish, the culture medium, and finally the thickness, type and hardness of the zona pellucida.

The sole controllable parameter determining the opening size is the laser irradiation time. The laser energy is a function of the laser power and the irradiation time. Since the laser power is fixed, variation of the laser irradiation time will adjust the total laser energy, by which a drilled hole is introduced into the zona pellucida,

Due to the variability between laser irradiation time and the obtained drill hole size, the appropriate irradiation time for creating a hole of defined size cannot be precisely predicted or transferred from one laboratory to another. Instead, it has to be determined by a brief experiment on a spare cell for each individual microscope setup. This procedure finally results in a reliable electronic hole size indication displayed by the LaserShot M / NaviLase Hole Size Predictor .

How to determine the “default pulse length setting” and verify the calibration of the Hole Size Predictor

The electronic overlay (green circle) of the Hole Size Predictor interactively indicates the expected opening diameter when selecting or changing a laser pulse length. Before starting to use the laser, verify the calibration of the Hole Size Predictor by following the steps below. Doing so, you can make yourself familiar with the “default pulse length setting” on your microscope. That is the pulse length which will generate an opening diameter of zona pellucida thickness (e.g. as will be used for assisted hatching or zona thinning):

1. Select the live video page, full-screen mode (F11), in the EyeWare software

2. Place a warmed dish (37°C / 98,6°F) containing a cell which will not be used for any further treatment on the heated microscope stage, e.g. an oocyte which failed to fertilize. The cell should be located at the bottom of the dish.

3. Locate the cell through the laser lens and focus on the zona pellucida.

4. Unlock the laser, using the corresponding software button.

5. Select “Hole” as working mode from the menu if using NaviLase.

6. Using the computer mouse and “drag & drop”, direct the circle indicating the laser target to an area on the zona pellucida (NaviLase).

When using LaserShot M, align the zona pellucida with the laser target circle using the cross moving table of the microscope.

7. Using the ms scale, adjust the laser pulse length in a way that the diameter of the green circle indicating the position and diameter of the laser holes corresponds to the zona pellucida thickness.

8. Release the laser by clicking the button or by pressing the footswitch while avoiding any vibrations of the microscope.

9. Verify that the diameter of the newly created hole is identical with the diameter of the circle indicating the position and diameter of the laser holes.

In case you observe a difference of the two diameters, re-check if all the following settings applied: temperature of the dish and microscope stage was 37°C / 98.6° F, the laser lens was used, the zona was located at the bottom of the dish.

Also read the following chapters about the influence of temperature and Z-positioning of the zona pellucida on the size of the drilled hole.

If the above treatment conditions were correct, see chapter Calibration of the Hole Size Predictor and perform a recalibration.

Important Notes on Laser Irradiation Time

Temperature

Conforming to good laboratory practice, the microscope to which the LaserShot M / NaviLase system is installed should be equipped with a heating stage that ensures temperature maintenance of the cells and the culture medium to 37°C during the entire procedure.

The relationship between irradiation time and opening size is temperature dependent. Choosing inappropriate temperature settings or forgetting to switch on the temperature controller will cause unexpected opening sizes.



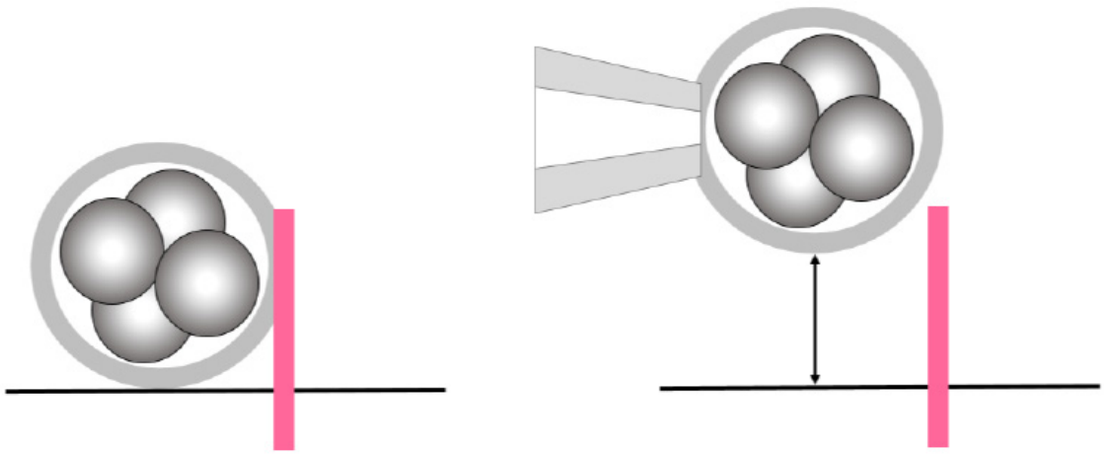
INFLUENCE OF TEMPERATURE ON DRILL OPENING SIZE

When using a heated stage during zona manipulation, make sure that it has been set to the correct temperature. Inappropriate temperature settings will lead to unexpected drill hole sizes. Lower temperatures result in smaller openings, while higher temperatures cause openings of excessive sizes that may lead to embryo damage.

Vertical (Z)-Positioning

Using a holding pipette to ensure the positioning of the embryo during laser treatment can be an advantage, but also introduces an additional parameter that needs the user's attention. For optimal results, the vertical (Z)-position of the holding pipette should always be as such, that the cell remains near the bottom of the culture dish during laser drilling.

The correlation between irradiation time and opening size is dependent on the vertical position (Z-direction) of the cell in relation to the bottom of the culture dish. Increasing the distance between the cell and the bottom of the culture dish will lead to increased absorption of the laser energy by the culture medium. Hence, wrong Z-positioning will result in unexpected opening sizes.





INFLUENCE OF Z-POSITION OF THE OOCYTE/EMBRYO ON DRILL OPENING SIZE

Inappropriate Z-positioning will result in smaller drill holes and in reduced laser beam quality. It is recommended to keep the cell near the bottom of the culture dish during laser treatment.

Variation of the Laser Drilling Position and Strength

After strong displacement of the whole electro-optical system, e.g. a mechanical shock, the quality of the drilled hole has to be checked when using the parameters which had been adjusted previously (irradiation time and aiming of the laser). The laser drilled holes and openings will be of good quality if the laser impact is located near the center of the live video image on the monitor. This position may deviate slightly from the center of the monitor screen depending on the monitor used and combination of lenses.

Closing Eyeware Software

Close the EyeWare software by selecting File > Exit from the main menu or by clicking 



INTEGRITY OF THE ELECTRO-OPTICAL SYSTEM

Wrong handling of the microscope or strong displacement of the electro-optical system, e. g. by mechanical shock can result in an incorrect position of the beam splitter system, magnifier lens position, camera, and the turret position, respectively. As a result of any of the above, aiming of the laser may no longer correspond to the crosshair position displayed at the video image and damage to embryos may occur if the laser is used in this condition.



DOUBTS ABOUT THE SUITABILITY OF THE LASER

In case of doubt about the suitability of the laser to create good quality openings do not continue to use the laser as there may be an increased risk of embryo damage. Please have your system checked by authorized support personnel or contact Technical Service. For contact details please refer to the section *Customer Service.*

PART III: ADDITIONAL INFORMATION

Advanced Functions of EyeWare, Advanced Database Functions, Program Settings and Camera Settings are listed in this chapter. Furthermore information about Maintenance, Troubleshooting and Customer Service is provided.

Advanced Image Handling Functions

Open Image and Save Image Dialog

EyeWare allows import of images and saving images to file. Supported file formats are Windows Bitmap files (*.bmp) and JPEG (*.jpg or *.jpeg). The Open Image and Save Image dialogs (Fig. 43, 44) are standard Windows functions.

Open Image 
A preview of the selected image is displayed in the Open Image dialog. A zoomed preview can be displayed by clicking the magnifier icon.

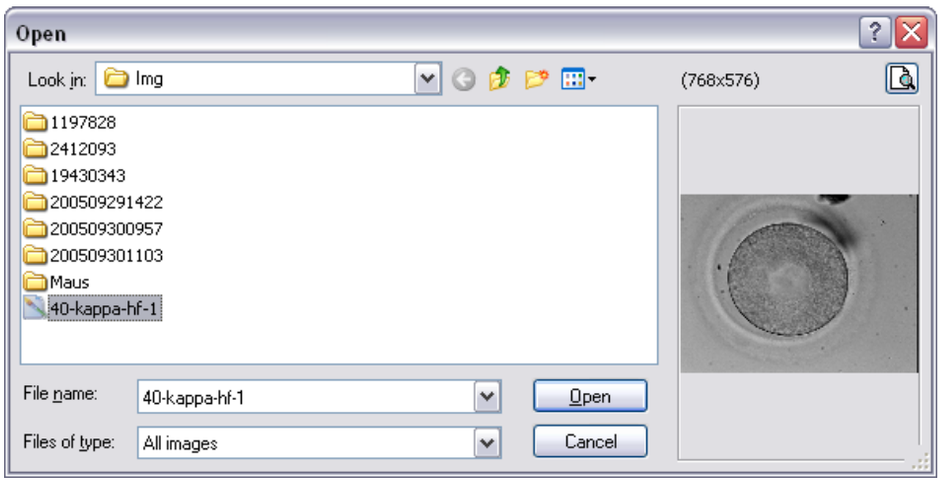


Fig. 43: dialog opening images

Save Image

Click and highlight an image at the **Database** or **Quick File** page and select Save Image.

Save with Measurements

Images to which measurements have been added can be stored together with the measure lines from the **Image page.**

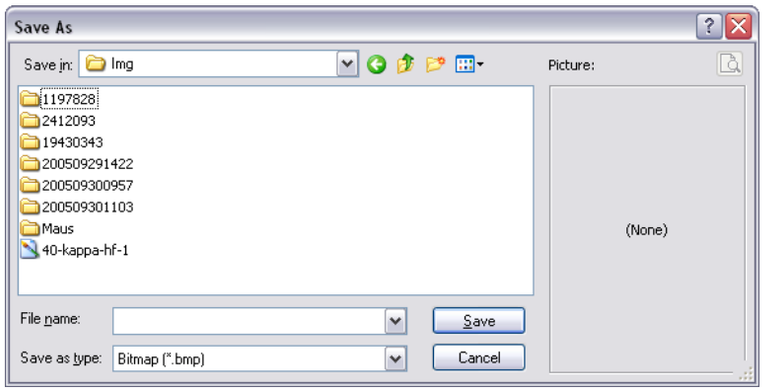


Fig. 44: Open Image and Save Image Dialog

Print

For printing a report from EyeWare, the printer must be chosen first. Be sure you have a printer installed and configured for this feature to function properly. Contact your system administrator if necessary.

The Print Dialog (Fig. 45) is a standard Windows dialog. For more information, refer to the Windows Help feature.

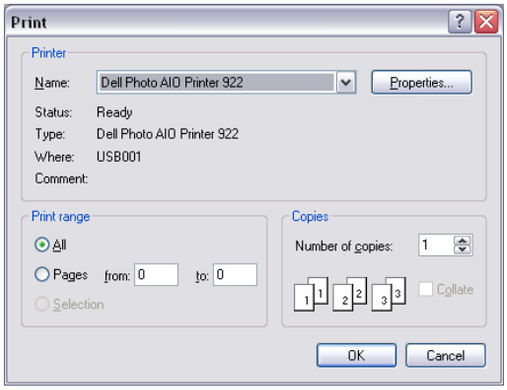


Fig. 45: Print Dialog

Program Settings

Several aspects of EyeWare are customizable. This allows the user to adapt some functions of the software according to specific needs. The Program Settings dialog allows modifying the following functions:

User Data

In this area, the end user contact information can be entered. There are up to 6 lines to be filled in with information such as name and address, telephone numbers, e-mail address etc. (Fig. 46).

Several language options are available.

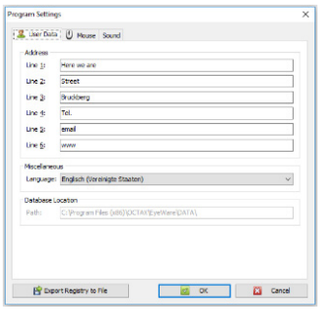


Fig. 46: Program Settings Dialog for User data entry

Mouse

This dialog allows configuring the properties of the computer mouse. While mouse pointer is located at the Test Area any click of one of the mouse buttons will reveal which mouse button corresponds to which button number. Tick the checkbox to select the mouse button that triggers the laser pulse. Additionally, a mouse button for taking a quick snapshot can be selected (Fig. 47).

Furthermore, a key from the keyboard can be selected to trigger the laser.

The footswitch for triggering the laser has to be activated using the shot key function F12.

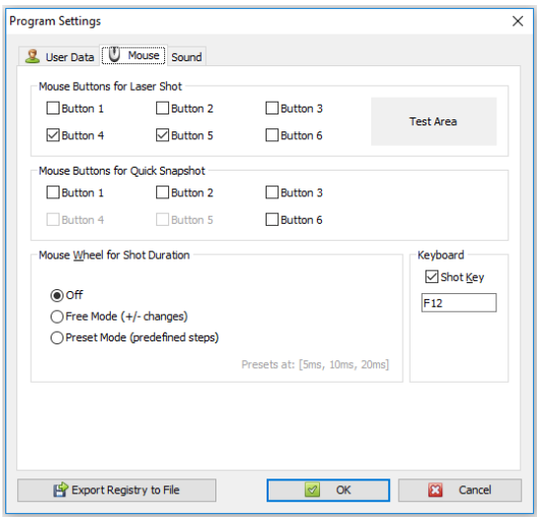


Fig. 47: Program Settings Dialog for mouse properties

Backup all Settings to REG-file
All settings of EyeWare can be saved to a backup file in the EyeWare system folder. Automatically, a file name is generated containing the computer name, date and time of storage (Fig. 48).

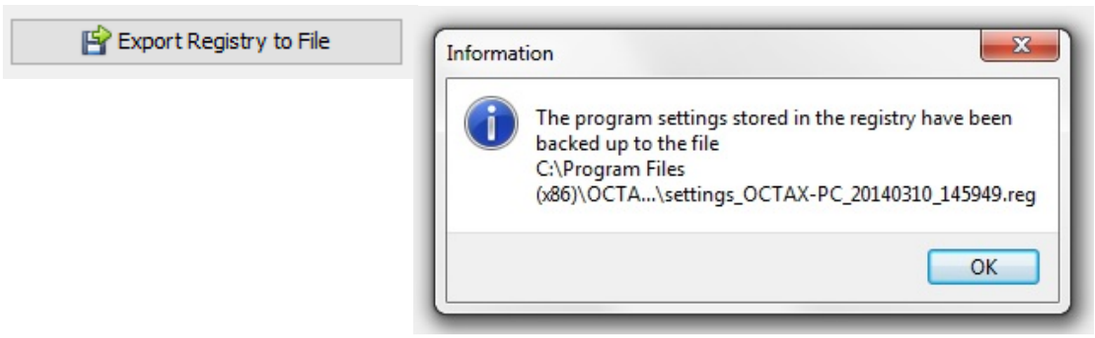


Fig. 48: Program settings are stored to the EyeWare system folder

In order to restore previous settings, select the appropriate file from Windows Explorer, double click and confirm the entry of the stored information into the registry. Now your previous settings are restored, including the settings of this dialog, and can be checked in the Program Settings dialog.

Camera Settings

The NaviLase system comes with an Eye USB2.0 camera. Exemplary, Fig. 49A, B show the camera properties of an Eye USB2.0 camera (1280x1024, 15 Hz). Usually, exposure, gamma and white balance should be set to automatic, whereas brightness and contrast can be adjusted manually.



Fig. 49A: Camera Properties dialog of an Eye USB2.0 camera

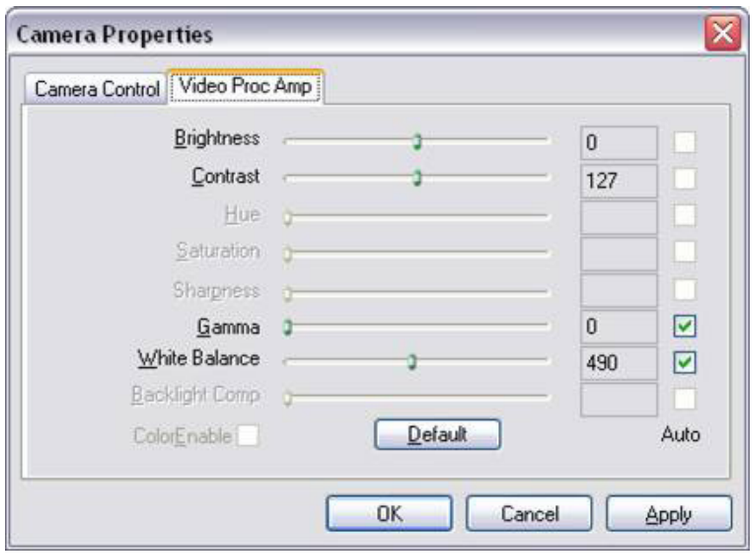


Fig. 49B: Camera Properties dialog of an Eye USB2.0 camera

Generating Support Request Data

EyeWare facilitates technical support. Open the menu Help and click Info… and then click Support Request (Fig. 50) and select the information that should be included to the support request. Alternatively use default settings. Always enter senders address details and s short description of the problem (Fig. 51).

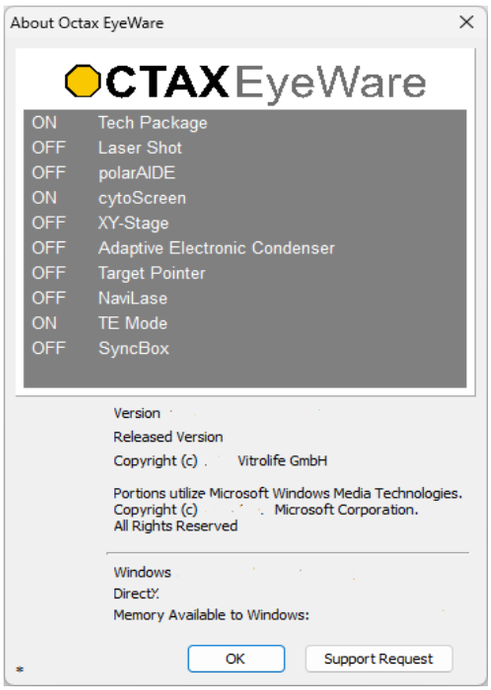


Fig. 50: Support Request

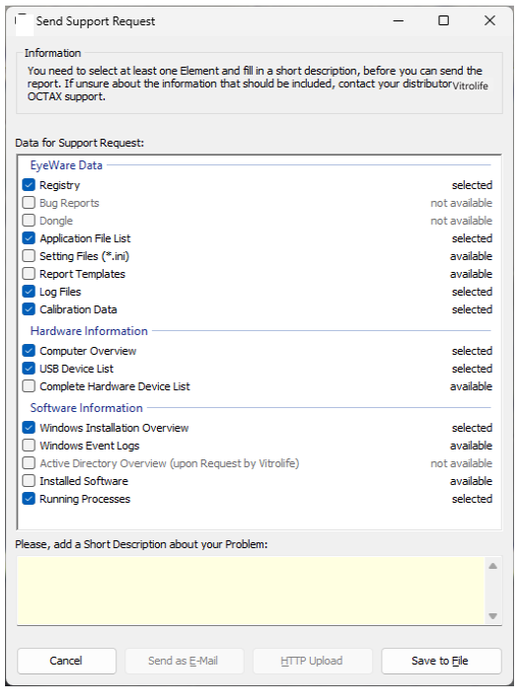


Fig. 51: Support Request Options

▪ Save to file: Select where to save the System Data and wait until data are copied. Attach the file to an e-mail to Vitrolife GmbH. For contact details please refer to the technical service section.



PLEASE NOTE

Without any administrator rights some of the system data are not available for enclosure to the support request file. For including these data please contact your system administrator if applicable.

Maintenance

The LaserShot M system exhibits superior mechanical and optical precision, which makes realignment unnecessary during routine use.

LaserShot M and NaviLase are maintenance free systems. For the static LaserShot M there are no parts to be replaced in specific intervals or movable parts prone to disturbances. The Octax laser systems have a lifetime of five years from installation date.

A preventative maintenance of the laser is recommended every 12-18 months to ensure optimal performance of the laser.

System updates will be provided within short response times by technical staff of Vitrolife GmbH, Germany. For contact details please refer to Customer Service.

Make sure not to touch any optical components, i.e. the mirror block and the laser objective lens, respectively.

Cleaning and Disinfection

Lasers and their components are not in contact with human oocytes or embryos when applied according to the intended use and will not be contaminated during treatment when used according to the instructions for use. Contamination can only occur in terms of slight dust accumulation through ambient air or accidental contamination of the laser lens with media or oil for embryo culture. The lasers can therefore be considered as non-critical devices with respect to reprocessing. Point-of-use processing after every treatment as well as high level cleaning, disinfection, or sterilization procedures are not required. Cleaning and low level disinfection can be handled in one step as described below.



Never remove any of the laser components from the microscope for cleaning! Never change their position or orientation or apply pressure!



Never spray any of the laser components with disinfectants or any other cleaning agent! Never use abrasive cleaning agents!

Clean the surfaces of the laser components whenever dust has accumulated. Cleaning of optical components outside the preventive maintenance intervals is only required after accidental contamination of the laser lens with media or oil for embryo culture or after exceptional dust deposition. If done according to the instructions below, cleaning and disinfection (regardless of its frequency) will not impact the lifetime of the lasers.

1. Cleaning and disinfection of metal and plastic surfaces of LaserShot M and NaviLase components. Moisten a lint-free cleaning tissue with a non-volatile, quaternary ammonium based disinfectant, ready to use for cell culture environment. The tissue should be slightly dampened, not wet. Wipe the surfaces of the laser components and let the disinfectant dry.

2. Cleaning and disinfection of optical components of LaserShot M and NaviLase (front lens of the 25 x laser objective, dichroic mirror): **Clean only if the laser lens has been contaminated with oil or media** for embryo culture, use a lint-free tissue or lens cleaning paper to absorb any visible liquid first. Subsequently, moisten a lint-free tissue or lens cleaning paper with small volumes of 70 % isopropyl alcohol. Make sure cleaning is done at the end of the working day, in well ventilated environment and when all embryo culture dishes are stored in incubators in order to avoid exposure of embryos to isopropyl. The cleaning tissue should be disposed outside the IVF laboratory. Carefully wipe the front lens of the laser objective or the dichroic mirror. **Do not touch with your fingers nor apply too much pressure.** The mirror should only be wiped unidirectional.
Let the cleaning agent dry off and visually inspect the optical surfaces for the absence of any remaining contaminants or traces of dried cleaning agent.

Troubleshooting Guide

In case some technical problems occur during operation of LaserShot M/ NaviLase please check possible causes of defects according to the list below before contacting the technical support.

Problem	Possible Cause	Recommendation
Misalignment Misalignment in "home" or "target pointer" position: crosshair on the screen is not located straight in the center of the opening you created	▪ whole setup has been moved ▪ LaserShot M / NaviLase was not used for some time ▪ microscope maintenance ▪ major events which could have introduced movements and strong vibrations to the microscope and laser system	1. Restart EyeWare, 2. Check the laser alignment in “home” or “target pointer” position 3. Correct overlay settings
	Golden laser objective is not in correct position	a. ensure objective is correct and right in place (clamped)
	1,5x/1,6x magnifier is not in correct position	b. Additional magnification is off (1x) and is clamped
	Light path selector lever is not in correct position	c. Beam splitter is in correct position and clamped
	Camera or c-mount is loose	d. Camera is tightly fixed (do not move it, only check)
		4. If the problem persists and misalignment is below 2 cm on the screen, move the overlay as described in the section Laser Aiming Verification Procedure
Misalignment in other locations crosshair on the screen is not located straight in the center of the opening you created		1. Restart EyeWare 2. Check the alignment in “home” or “target pointer” position 3. If the problem persists, contact Technical Support

unexpectedly small drilling sizes drilled opening is suddenly smaller as intended	glass stage yes/no culture media in use	laser irradiation time has to be adjusted as described in the section Laser irradiation time determination for appropriately sized openings
	excessive z-position	for optimal results, the vertical (Z)-position of the holding pipette should always be such that the cell remains near the bottom of the culture dish during laser drilling.
	temperature too low	increase temperature of culture cells and medium to 37°C
	PolarAIDE slider (not included in laser system) placed in the beam path (depending on type of microscope and position of the PolarAIDE slider)	Pull PolarAIDE slider out of the light beam path
drilled openings are gradually getting smaller while irradiation time remains constant	optics of the laser are getting dusty	call the technical service
Crosshair not displayed or unexpected appearance of crosshair	▪ crosshair modus is inactive ▪ appearance of crosshair has been modified	select video – overlay – crosshair and the preferred design from the menu.
Laser cannot be activated (key icon or “Arm laser”)	Laser not initialized correctly	**Check LEDs on golden laser module.** If red: 1. close EyeWare 2. disconnect USB cable from laser module 3. reconnect after 5 s 4. restart EyeWare
NaviLase does not move		**Check LEDs on NaviLase controller box.** If red: 1. close EyeWare 2. disconnect silver USB cable and black “5V” cable from controller box 3. reconnect both after 5 s 4. restart EyeWare

Troubleshooting guide:

Observation	Root cause	Effect	Check / action / solution
Laser does not hit intended target: laser has no effect or the laser effect appears to be far away from the target	Selected microscope extra magnification differs from setting in EyeWare software	Settings do not match calibrated laser alignment	Align settings in EyeWare with the settings on the microscope
	Objective in use differs from selection in EyeWare		Turn in the 25x laser objective on the microscope and select 25x in EyeWare
Laser effect is weak or laser has no effect	Z-position of the embryo is too high above the bottom of the dish	Laser light is absorbed by the medium before reaching the zona pellucida or the TE cells	Lower holding pipette; check that the embryo touches the bottom of the dish
	Treatment of a very large blastocyst		Increase pulse time
	Z-position of the embryo is too high above the bottom of the dish and cannot be lowered to touch the bottom		Check if the angle of the holding pipette prevents lowering the embryo to the bottom of the dish
	The target site of the embryo was not focused correctly	Laser light was not fully focused on intended target site	Adjust focus
	The contrast setting of the microscope is inappropriate to make holes visible	Laser holes cannot be seen	Improve condenser contrast setting
Hole diameter is smaller than expected	Lower temperature in the dish	The laser was calibrated for a higher temperature than present in the dish	Take care for stable and controlled temperature in the dish; check temperature of the heated stage in a test dish, e.g. using VitroTemp
	Change of heating stage	The new heating stage absorbs more laser energy than the previous (when the laser was calibrated)	Perform calibration of the Hole Size Predictor with the new heating stage
	Dust / dirt on optical components in the path of the laser light	Less laser light than intended reaches the target cell	Order laser service

Observation	Root cause	Effect	Check / action / solution
Laser seems to miss pulses when triggered	Triggering the laser very fast and repeatedly	A safety delay prevents that a laser pulse is released directly after a previous pulse	Reduce frequency of triggering to about 3 pulses per second
	NaviLase is triggered before the laser has reached the selected target position	The software prevents a laser pulse until NaviLase has reached the selected target position	Trigger NaviLase when the target indicator is visible at the new target position; alternatively wait until the motors stopped moving (no more sound from the motors)

Decommissioning of LaserShot M / NaviLase

For decommissioning of the LaserShot M / NaviLase system please send back to Vitrolife. For contact details please refer to the section Customer Service below.

Customer Service



TECHNICAL SUPPORT

If you need assistance at any time, please contact Vitrolife Technical Services.



Vitrolife GmbH

Roedersteinstrasse 6

84034 Landshut / Germany

phone: + 49 (0)871 4306570

email: support.de@vitrolife.com

PART IV: QUICK GUIDE

The Quick Guide outlines in a tight and concise manner important and frequent operations.

Laser Aiming Verification Procedure

Start the EyeWare by double clicking icon on your desktop, read and confirm the message and select Video page.

- Activate the laser by clicking.

- Move the zona pellucida of the spare cell into the Crosshair area.

- Trigger the laser pulse.

- The Crosshair on the screen should be located straight in the center of the opening introduced into the zona pellucida (51A). If this is not the case (51B), the position of the Crosshair has to be moved to the exact position within the laser drilled opening.

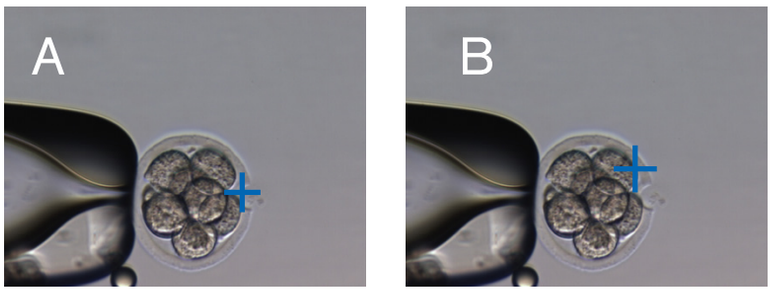
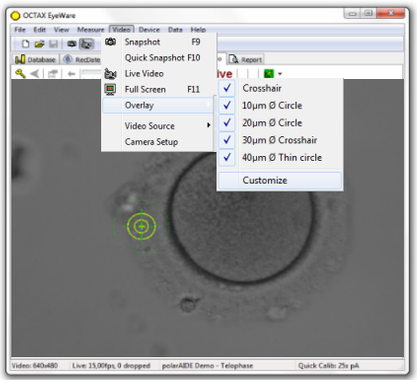
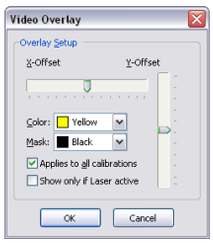


Fig. 51A / B: Cross Hair positioning

If required: correct the position of the crosshair in XY-orientation. Therefore select Video - Overlay – Customize from the menu (Fig. 52A) and scroll the sliders. Alternatively, click and highlight one slider and move the crosshair with the cursors of the keyboard into position. This allows more precise control (Fig. 52B)





Hole Size Predictor Adjustment

The laser Hole Size Predictor is a convenient means of reliably indicating the expected hole size in correlation to the selected pulse time. Displayed as a green circle which is part of the electronic target overlay, it interactively changes its diameter depending on the pulse time selected. Vice versa the Hole Size Predictor allows adjusting the pulse time in accordance to the required hole size

In order to calibrate the diameter of the Hole Size Predictor based on the actual diameter of a drilled hole at a defined pulse time, select Video - Overlay – Calibrate Hole Size Predictor from the menu and adjust the indicated hole size by clicking the arrows on the right side (Fig. 53). The diameter of the Hole Size Predictor can be calibrated in a range between -70% and +200% in steps of 5% relative to the current value.

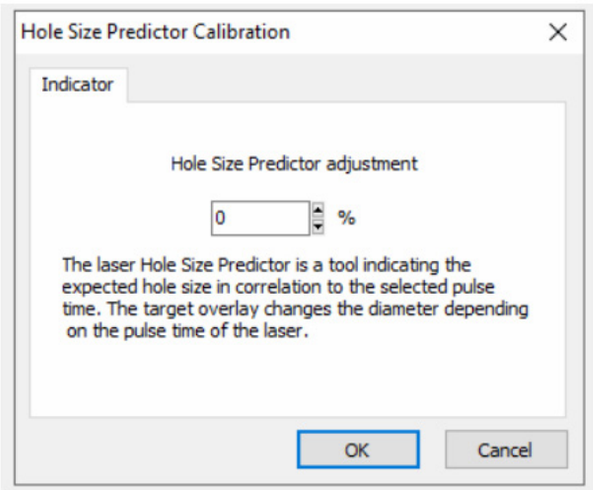
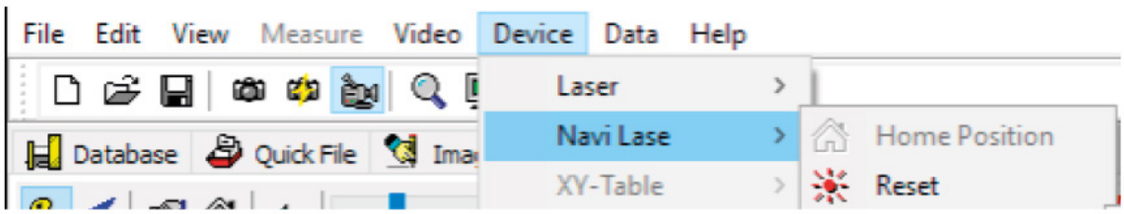


Fig. 53: Hole Size Predictor Adjustment

NaviLase Reset

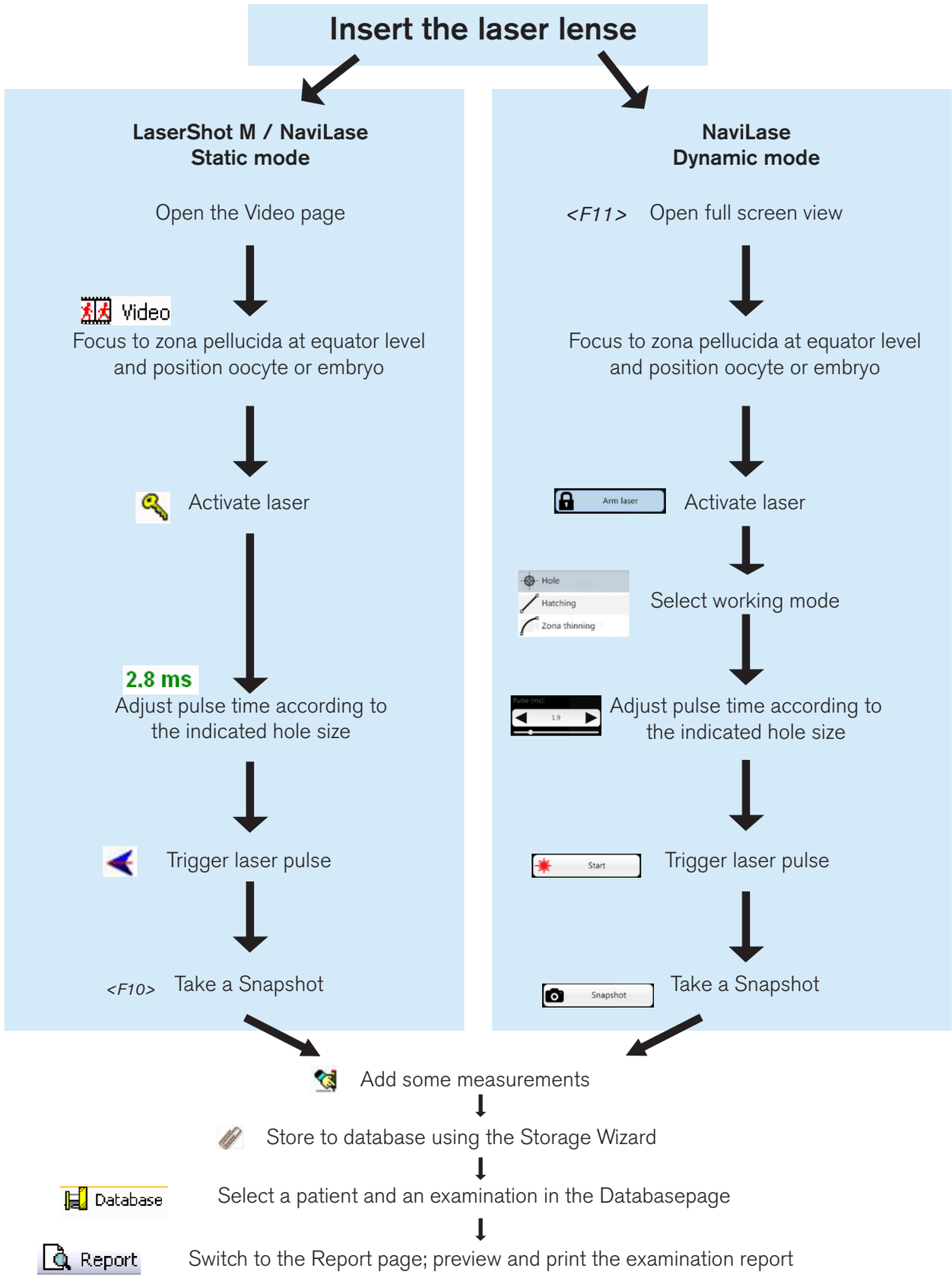
Every time the EyeWare is started, an automatic initial positioning of the NaviLase motors is performed. A forced repositioning can be performed by using the NaviLase Reset function.
It may be used after longer time of pausing the laser while EyeWare was running.
Click on Device -> NaviLase -> Reset to start the process.



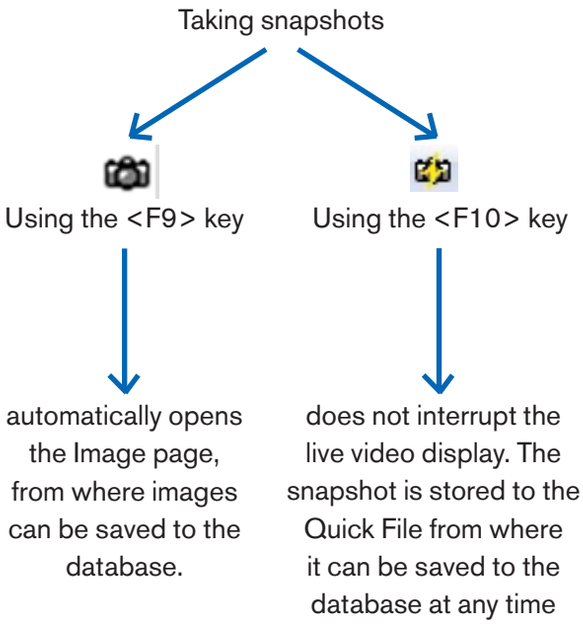
WARNING

Every time the EyeWare is started, an automatic initial positioning of the NaviLase motors is performed. A forced repositioning can be performed by using the NaviLase Reset function.
It may be used after longer time of pausing the laser while EyeWare was running.

Working Principle LaserShot M - NaviLase



Taking snapshots



TECHNICAL SUPPORT

If you need assistance at any time, please contact Technical Service. For contact details please refer to the section Customer Service.

PART IV: APPENDIX

The Appendix contains further documentation

Target Pointer

The Target Pointer is an optional device for LaserShot M and NaviLase which can be used to localize the laser target by the position of a red LED dot when looking through the eyepieces of the inverted microscope. The Target Pointer also features an optical signal pattern of four red LED dots. This square pattern indicates the instant of releasing a laser pulse.

Key Features of the Target Pointer

The Target Pointer offers an optional indicator of the laser target in addition to the target overlay of the EyeWare software. Whereas the digital overlay can only be observed on the screen, the Target Pointer emits red LED light which is visible both on the screen as well as through the eye pieces of the inverted microscope.

A static LED module consisting of five red LEDs is built into the mirror block of the laser system. Four LED lights are arranged in a square pattern and one LED light is at the center of the square pattern. The Target Pointer LED module can be adjusted manually by two screws (see Fig. 54). Turning the screw(s) will shift the position of the Target Pointer LEDs on the screen in X and/or Y directions. This way, the position of the central red LED dot of the Target Pointer is superimposed with the digital laser target overlay on the screen to indicate the laser target of LaserShot M and of NaviLase in home position.

Working with the Target Pointer

Target Pointer function is activated or deactivated in the Device menu, section Pointer. To activate, check On and visible; uncheck box to deactivate Target Pointer function. When Target Pointer function is active, the red Target Pointer LED dot will be turned on automatically when LaserShot M / NaviLase function is activated using the Key symbol.



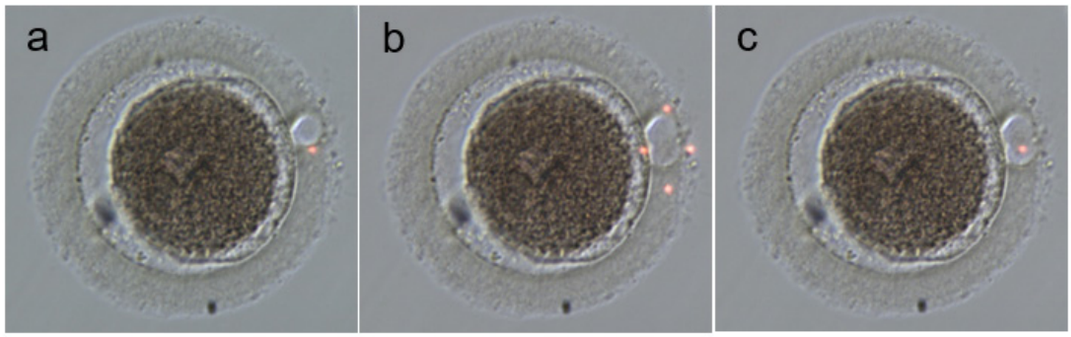
Check that the central LED dot of the Target Pointer is superimposed with the digital laser target overlay on the screen and verify the selected hole size before using the Target Pointer for laser aiming.

Functional states of the Target Pointer LED lights when working with the laser (also see figures a-c):

a. The central LED is turned on and indicates the laser target position when the laser is activated. The central LED stays on as long as the laser stays activated without being released.

b. When releasing a laser pulse, simultaneously the central LED is switched off and the square pattern of four LED dots is turned on for a 2 seconds interval. This optical pattern indicates the instant of laser impact and enables for unhindered view at the targeting area of the laser.

c. Following the 2 seconds interval in b., the central LED is turned on again (now visible in the center of the laser induced opening).



Functional states of Target Pointer LED dots: a, c: central LED dot indicating laser target position; b: square pattern of four LED dots, activated for a 2 seconds interval when a laser pulse was released.

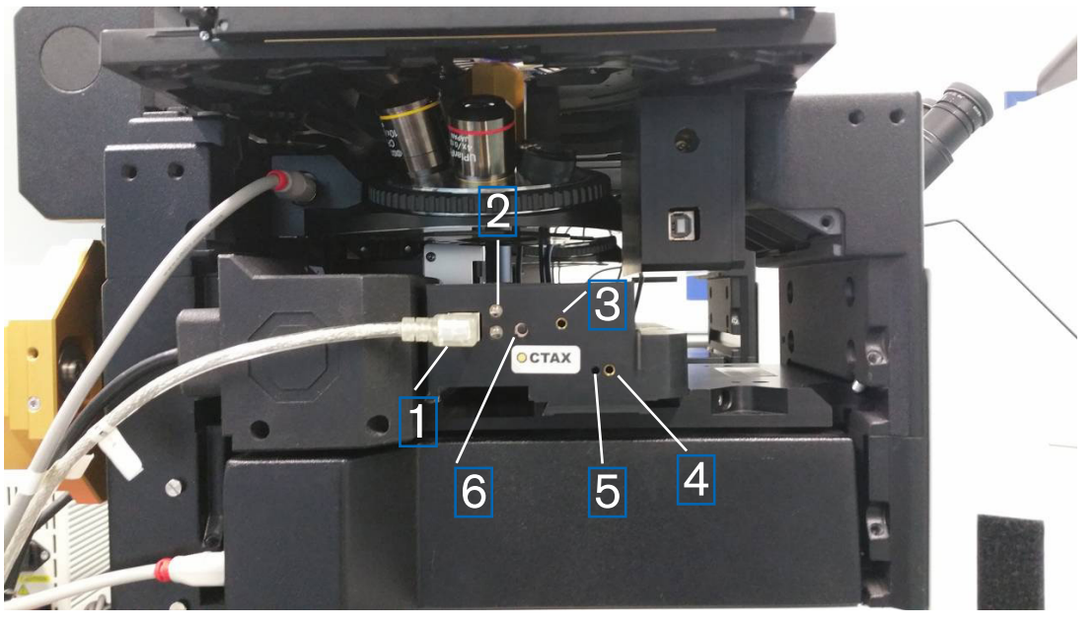


Fig. 54: Target Pointer

1. USB Port
2. Status LED
3. Y – adjustment (allen wrench key 1.5 mm required)
4. X – adjustment (allen wrench key 1.5 mm required)
5. Focusing of the red light dot (allen wrench key 1.5 mm required)
6. Switch

Adjustment procedure

First check if dioptre is set to ZERO for both of the eyepieces (Fig. 55). Indicators are seen on each eye piece lens.



Fig. 55: Diopter adjustment (example: Olympus inverted microscopes)

Then verify ase shot position matching with the cross hair on screen. If not, adjust laser cross hair position. See chapter "Alignment of the Crosshair". Activate laser and crosshair will appear. If there is mismatch between crosshair and red dot move the red dot to the crosshair position using the X and Y adjustment until red dot will match with the crosshair. Make use of the 1.5 mm wrench key. Therefore insert the tool into the small hole and turn the key clockwise or counter clockwise until the red dot moved to desired position. Start with correcting X position of the red dot (Fig. 56) and proceed with Y position (Fig. 57)

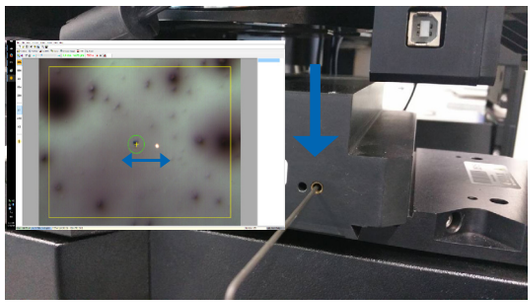


Fig. 56: X position adjustment

Correct Y position of the red dot

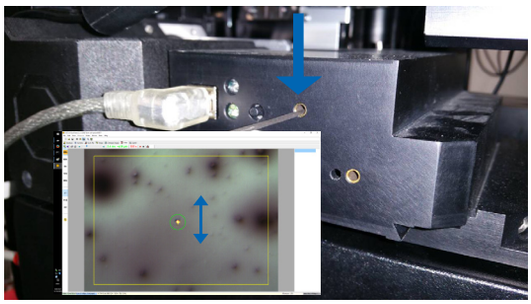


Fig. 57: Y position adjustment

If red light beam is seen very weak or widely spread (Fig. 58) correct the focus of the beam. Use 1.5 mm wrench key (Fig. 60) and turn clockwise and check how the spot changes its appearance. If spot is getting smaller continue turning the focus screw until red dot is set sharp pointed. If spot spreads wider turn into opposite direction until red dot is seen sharp (Fig. 59).

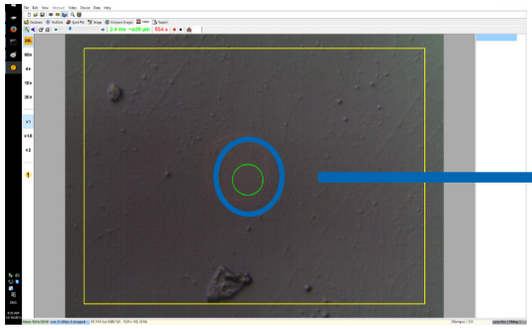


Fig. 58: widely spread red dot

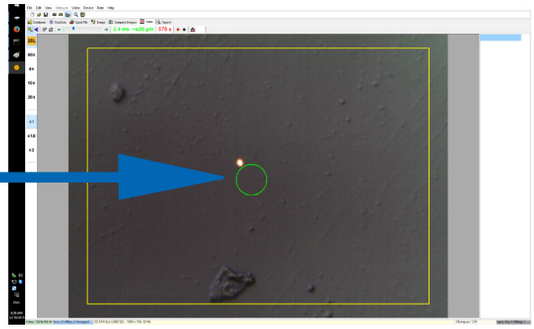


Fig. 59: red dot focused

If red LED light is not visible at all first turn off the light of the microscope or reduce to a minimum level of light in order to see the red light trough the eyepiece. If the red light is seen weak or widely spread focus the red light see chapter above.

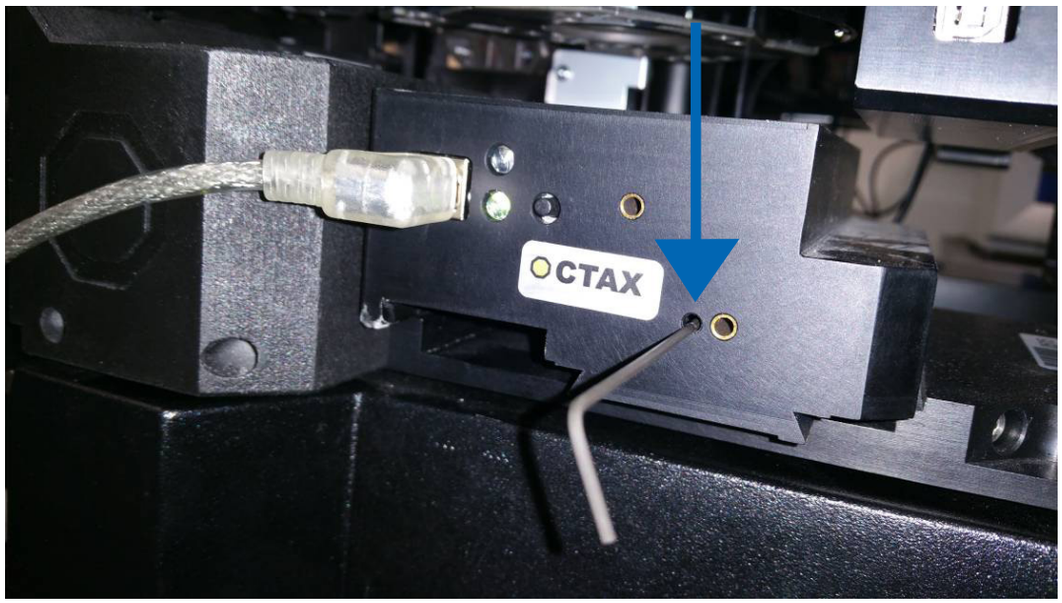


Fig. 60: Adjusting focus of red dot Target Pointer

If red dot is still not visible (Fig. 61) check the X and Y alignment. Focus at any specimen located at the bottom of the dish. Watch the spot trough eyepiece and turn the screws for LEFT/RIGHT and UP/DOWN slowly but steady several revolutions until red light gets back into the field of view.

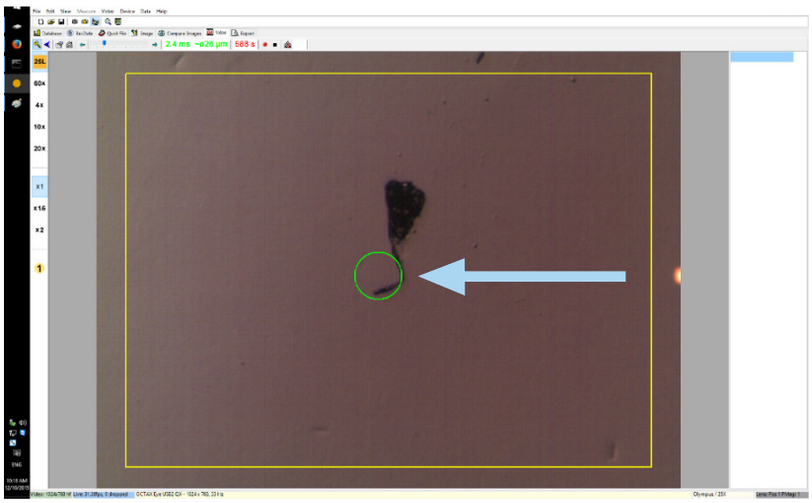
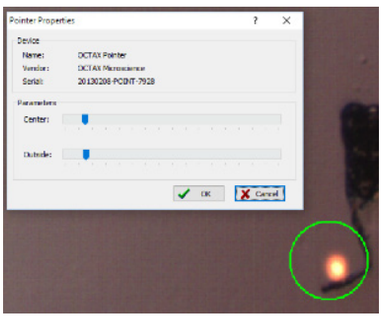


Fig. 61: Target Pointer

Finally adjust red light dot to convenient brightness. Brightness is automatically corrected on screen but brightness of the beam seen through the eyepiece depends on user preferences. Therefore open the menu DEVICE / POINTER and click on CUSTOMISE. Move slider left for decreasing brightness and move to the right for increasing brightness.





EYE SAFETY OF THE OPERATOR

Eye safety of the operator is guaranteed as the visible light is in the range of visible light.



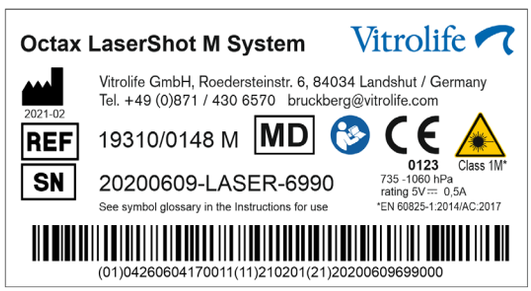
TECHNICAL SUPPORT

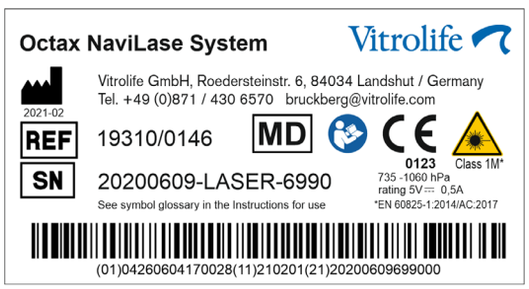
If you need assistance at any time, please contact Technical Service. For contact details please refer to the section Customer Service.

Laser Module Specifications / Labeling

Laser Radiation, do not view directly into light path using optical instruments

Laser:	1.48 µm Infrared Diode Laser, Class 1M. Definition of a class 1M laser according to DIN EN 60825-1:2014: Class 1M lasers emit in the wavelength range from 302,5 nm to 4000 nm.
Power in focus:	100 - 250 mW (depending on microscope, optics, heated stage & operation mode)
Impulse time:	0.1 - 10.0 ms, in 0.1 ms steps (CPU Clock +/- 1,5 %)
Laser targeting:	live video display with crosshair and calibrated measurement grid overlay
Video display:	with EyeWare on computer monitor
Status indication:	LED on LaserShot M module, EyeWare user interface
Laser irradiation release:	via mouse or external foot trigger
Laser irradiation indication:	LED on laser module, EyeWare user interface
External connectors:	laser module is connected to computer via USB cable
Power supply:	via USB, NaviLase option includes PS 5V/2A
Dimensions:	laser module: 11.5 x 11.5 x 9.8 cm (+/- 10%)
Operating conditions:	10°- +35 °C ambient temperature relative humidity 20%-80% (non-condensing), 735 - 1060 hPa
Transport conditions:	-20° - 70°C, relative humidity 20%-80% (non condensing), 735 - 1060 hPa
Storage conditions:	-20° - 70°C, relative humidity 20%-80% (non condensing), 735 - 1060 hPa
Objective:	25x ELWD biopsy objective for simultaneous micromanipulation and laser use, compatible with Hofmann modulation contrast
Compatibility:	compatible with all major brands and models of inverted microscopes complying with at least IVD 98/79/EG
Labelling:	This system bears the CE-mark Labelling Sample





Related Products / System components of the ME System

REF	Description
19310/0010	Replacement PC without monitor
400602	Replacement Laser module
19310/0145	Replacement motor modules

Object / part No.	Manufacturer/ trademark	Type / model	Technical data
Laser module	Vitrolife	400602	Laser Class 1M 5V, max. 0.5A
Target Pointer (optional)	Vitrolife		5V, max. 0.5A
USB camera	Vitrolife	Eye USB2 QX	5V, max. 0.5A; Resolutions: 1024 x 768 uncompressed 2048 x 1536 uncompressed
USB camera	iDS	U3-3800SE-C-HQ	5V, max 0,7A; Resolution: 5536 x 3692
Navilase Motion Module	Vitrolife		
Navilase Controller	Vitrolife		5V, max. 2A
SMPS NaviLase controller (power supply)	FRIWO Gerätebau GmbH	FW8004M/DT/05	Input: 100-240VAC, 50-60Hz, 250-130mA output: 5V, 2A class II
Alternative SMPS Navilase controller (power supply)	FRIWO Gerätebau GmbH	FW7401M/05	Input: 100-240VAC, 50-60Hz, 280-140mA output: 5V, 2A class II
Footswitch (optional)	LINEMASTER Switch Corporation	Ref.-Nr. 19310/1148US	5V, max. 0.5A
PC	LENOVO	MT-M-10FM-000FMX	20V
SMPS PC **(power supply)**	LENOVO	PA-1650-72	Input: 100-240VAC, 1.8A, 50-60Hz Output: 20VDC, 3.25A, Class I
Monitor	Neovo		
SMPS monitor (power supply)	ADAPTER TECH.	ATM065T-P120	Input: 100-240V, 50-60Hz, 1.6-0.7A Output: 12.0VDC, 5.0A, 60W, Class I
Microscope	NIKON	ECLIPSE Ti2-U	12VDC, 3.3A
SMPS Microscope (power supply)	FSP	FSP040-RHAN3	100-240VAC, 50-60Hz, 1.5A Output: 12.0VDC, 3.33A, 40W, Class I
Power supply cord USA	Longwell	Connector: LS-75 Cord: VCTEK Plug: LP-70	7A, 125V 2x0.75mm^2

Power supply cord USA	Volex	Plug: PS204 Cord: HSING Connector: V1625	Plug: 10, 250V Cord: 300V, VW-1, SVT, 18AWGFT-2 Connector: 10A, 125V
Power supply cord CANADA	Feller GmbH	Plug: HG/TR (TRANSPARENT) Cord: SJT3X16AWG Connector: C13M	Plug: 125V, 15A Cord: 3.05 m, 300V, JF, FT2 Connector: 13A, 250VAC

Related Products



SALES

For sales information please contact your local Vitrolife distributor or



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Roedersteinstrasse 6

84034 Landshut/ Germany

phone: +49 (0)871-430657-0

email: support.de@vitrolife.com

The following Accessories are optional parts of the MDR 2017/745 versions of laser systems:

Order code	Product name
19310/4150	Target Pointer for laser systems
19310/0141	Breadboard for installating laser systems to Olympus IX53/73/83

TOGETHER.
ALL THE WAY™

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