# sinutronic

# USER MANUAL
# AND WARRANTY CARD



**devices from the ENT line**

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**Dear Customers,**

Thank you for buying our device and welcome among the users of Sinutronic products. We believe that you will appreciate the quality and user-friendliness of devices from the ENT line, which have been developed by applying the latest technologies. We have done our best to make the devices meet your expectations and increase the patient's comfort during the examination.

Please read carefully our manual before starting to work with our product. This will help you to customise your equipment settings.

Our device is protected by patent P-408919 and industrial design ZWW002508317.

Do not hesitate to contact us in case of any technical issues.

Technical Support:

- tel. (58) 305 40 80
- e-mail: serwis@sinutronic.eu

Please visit www.sinutronic.eu to find up-to-date information about our products.

Enjoy your experience.

**Management Board and Employees**

Sinutronic sp. z o.o.

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## Contents

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## 1    Working with the User Manual

Please read this manual carefully before you use the device for the first time and save it for further reference. Please pay special attention to warning symbols and safety instructions.

## 2    Warning symbols and information

**WARNING!**

Indicates a hazard of improper use of the device. Warnings must be followed to prevent injuring the patient or damaging device.

**NOTE!**        Tells to carefully read the information before using device.

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| | |
|---|---|
| | Indicates manufacturer's name and address. |
| | Indicates date of production. |
| **SN** | Indicates the serial number. |
| | Indicates the need to read the instruction. |
| | Indicates the presence of wireless transmission. |
| | Type BF application part. |
| | Indicates the need to protect against moisture. |

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Indicates the scope of moisture in which the device may safely be used.

Indicates the scope of temperature in which the device may safely be used.

Class 1 electrical device.

Indicates use-by date.

Indicates the batch number.

Indicates a disposable product.

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## 3    Safety instructions

- Remove the package and make sure that the device is not damaged. In case of any doubts, do not use the device and contact the manufacturer immediately.
- Make sure that children do not play with the removed foil. Children and unauthorised persons must not have any access to the device.
- Do not pull the cable when removing the plug from the port.
- Do not use the device if the power cable or the device have been damaged.
- If the power cable or plug suffered any damage, for safety reasons, stop using the device and return it to the manufacturer or Sinutronic authorised servicing point for repair.
- Use and store the device in temperatures ranging from 10˚C to 30˚C.
- Protect the device from moisture, freeze, and heat.
- Do not place the device close to an open fire.
- Do not place the device close to a water intake or immerse it in water.
- The packaging with disposable covers must be stored in a clean and dry place.

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## 4   Purpose

ENTviewer is designed for:

- examination of nasopharynx with adenoid in posterior video rhynoscopy,
- examination of larynx in video laryngoscopy and video laryngostroboscopy,
- examination of mesopharynx in video pharyngoscopy.

OTOviewer is designed for:

- examination of the tympanic membrane,
- examination of the external auditory canal.

DUOviewer is designed for:

- examination of nasopharynx with adenoid in posterior video rhynoscopy,
- examination of larynx in video laryngoscopy and video laryngostroboscopy,
- examination of mesopharynx in video pharyngoscopy.
- examination of tympanic membrane,
- examination of external auditory canal.

It must not be used for other purposes. The manufacturer shall not be liable for improper use of the device. Damages resulting from improper use of the device shall immediately render this guarantee null and void.

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## 5    Medical applications

ENT line devices may be used only by physicians.
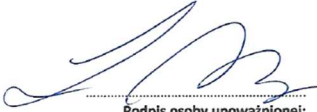
## 6    Meeting requirements concerning medical devices
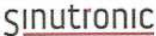
The product meets the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and was classified as class I device.

Bears compliance mark

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# DEKLARACJA ZGODNOŚCI
Declaration of conformity
**Nr**
MDD/14380/02

**WYTWÓRCA:**
Manufacturer:

**SINUTRONIC SP. Z O.O.**
UL. ASESORA 86
80-119 GDAŃSK
POLAND

**Deklarujemy z pełną odpowiedzialnością, że nasz produkt:**
We declare with full responsibility, that our product:

**NAZWA:**
Name:

**ENTviewer**

**MODELE:**
Models:

**L, LS, LCS, M, MS, MCS, UC, UCS**

**ZASTOSOWANIE:**
Application:

OBRAZOWA DIAGNOSTYKA MEDYCZNA. SPECJALIZACJA
– LARYNGOLOGIA. BADANIE MIGDAŁKA
GARDŁOWEGO, KRTANI I STRUN GŁOSOWYCH.

**Jest zgodny z następującymi dokumentami odniesienia:**
Compliance the following documents of reference:

**DYREKTYWY:**
Directives:

**93/42/EWG** Dyrektywa o wyrobach medycznych

**AKTY PRAWNE:**
Local law:

Ustawa z dnia 20 maja 2010 r. o wyrobach
medycznych ( Dz.U. 2010 nr 107 poz. 679)

**NORMY:**
Standards:

PN-EN ISO 14971:2012
PN-EN 1041+A1:2013
PN-EN ISO 15223-1:2012
PN-EN 60601-1:2011
PN-EN 60601-1-2:2007
PN-EN 62366:2008
PN-EN 62304:2010

**Klasyfikacja wyrobu medycznego:**
Classification of medical device:

**KLASA I** – Zgodnie z regułą 5
(Dz.U. 2010 nr 215 poz. 1416)

**Procedura oceny zgodności:**
Conformity assessment procedure:

**ZAŁĄCZNIK VII**
(Dz.U. 2011 nr 16 poz. 74)

......Gdańsk, 13.08.2015 r..................
**Miejsce, data:**
Place, date:

....................
**Podpis osoby upoważnionej:**
Signature of authorized person:

# sınutronıc

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# DEKLARACJA ZGODNOŚCI
*Declaration of conformity*

**Nr**

*MDD/14380/05*

| | |
|---|---|
| **WYTWÓRCA:**<br>*Manufacturer:* | **SINUTRONIC SP. Z O.O.**<br>UL. ASESORA 86<br>80-119 GDAŃSK<br>POLAND |

**Deklarujemy z pełną odpowiedzialnością, że nasz produkt:**
*We declare with full responsibility, that our product:*

| | |
|---|---|
| **NAZWA:**<br>*Name:* | **OTOviewer** |
| **MODELE:**<br>*Models:* | **O** |
| **ZASTOSOWANIE:**<br>*Application:* | OBRAZOWA DIAGNOSTYKA MEDYCZNA. SPECJALIZACJA – LARYNGOLOGIA. BADANIE BŁONY BĘBENKOWEJ I PRZEWODU SŁUCHOWEGO ZEWNĘTRZNEGO. |

**Jest zgodny z następującymi dokumentami odniesienia:**
*Compliance the following documents of reference:*

| | |
|---|---|
| **DYREKTYWY:**<br>*Directives:* | **93/42/EWG** Dyrektywa o wyrobach medycznych |
| **AKTY PRAWNE:**<br>*Local law:* | Ustawa z dnia 20 maja 2010 r. o wyrobach medycznych ( Dz.U. 2010 nr 107 poz. 679) |
| **NORMY:**<br>*Standards:* | PN-EN ISO 14971:2012<br>PN-EN 1041+A1:2013<br>PN-EN ISO 15223-1:2012<br>PN-EN 60601-1:2011<br>PN-EN 60601-1-2:2007<br>PN-EN 62366:2008<br>PN-EN 62304:2010 |

| | |
|---|---|
| **Klasyfikacja wyrobu medycznego:**<br>*Classification of medical device:* | **KLASA I** – Zgodnie z regułą 5<br>(Dz.U. 2010 nr 215 poz. 1416) |
| **Procedura oceny zgodności:**<br>*Conformity assessment procedure:* | **ZAŁĄCZNIK VII**<br>(Dz.U. 2011 nr 16 poz. 74) |

........Gdańsk, 01.08.2017 r.........
**Miejsce, data:**
*Place, date:*

.......................................
**Podpis osoby upoważnionej:**
*Signature of authorized person:*

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Sinutronic sp. z o.o.    tel. +48 58 305 40 80    www.sinutronic.eu
office@sinutronic.eu   serwis@sinutronic.eu

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# DEKLARACJA ZGODNOŚCI

*Declaration of conformity*

**Nr**

MDD/14380/04

| | |
|---|---|
| **WYTWÓRCA:**<br>*Manufacturer:* | **SINUTRONIC SP. Z O.O.**<br>UL. ASESORA 86<br>80-119 GDAŃSK<br>POLAND |

**Deklarujemy z pełną odpowiedzialnością, że nasz produkt:**
*We declare with full responsibility, that our product:*

| | |
|---|---|
| **NAZWA:**<br>*Name:* | **DUOviewer** |
| **MODELE:**<br>*Models:* | LO, LSO |
| **ZASTOSOWANIE:**<br>*Application:* | OBRAZOWA DIAGNOSTYKA MEDYCZNA. SPECJALIZACJA – LARYNGOLOGIA. BADANIE MIGDAŁKA GARDŁOWEGO, KRTANI, STRUN GŁOSOWYCH, BŁONY BĘBENKOWEJ I PRZEWODU SŁUCHOWEGO ZEWNĘTRZNEGO. |

**Jest zgodny z następującymi dokumentami odniesienia:**
*Compliance the following documents of reference:*

| | |
|---|---|
| **DYREKTYWY:**<br>*Directives:* | **93/42/EWG** Dyrektywa o wyrobach medycznych |
| **AKTY PRAWNE:**<br>*Local law:* | Ustawa z dnia 20 maja 2010 r. o wyrobach medycznych ( Dz.U. 2010 nr 107 poz. 679) |
| **NORMY:**<br>*Standards:* | PN-EN ISO 14971:2012<br>PN-EN 1041+A1:2013<br>PN-EN ISO 15223-1:2012<br>PN-EN 60601-1:2011<br>PN EN 60601-1-2:2007<br>PN-EN 62366:2008<br>PN-EN 62304:2010 |

| | |
|---|---|
| **Klasyfikacja wyrobu medycznego:**<br>*Classification of medical device:* | **KLASA I** – Zgodnie z regułą 5<br>(Dz.U. 2010 nr 215 poz. 1416) |
| **Procedura oceny zgodności:**<br>*Conformity assessment procedure:* | **ZAŁĄCZNIK VII**<br>(Dz.U. 2011 nr 16 poz. 74) |

........Gdańsk, 20.06.2016 r........
**Miejsce, data:**
*Place, date:*

.............................................
**Podpis osoby upoważnionej:**
*Signature of authorized person:*

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# DEKLARACJA ZGODNOŚCI
*Declaration of conformity*

**Nr**
MDD/14380/03

**WYTWÓRCA:**
*Manufacturer:*

**SINUTRONIC SP. Z O.O.**
UL. ASESORA 86
80-119 GDAŃSK
POLAND

Deklarujemy z pełną odpowiedzialnością, że nasz produkt:
*We declare with full responsibility, that our product:*

**NAZWA:**
*Name:*

**ENTcover**

**MODELE:**
*Models:*

-

**ZASTOSOWANIE:**
*Application:*

OSŁONA JEDNORAZOWEGO UŻYTKU DO URZĄDZENIA
MEDYCZNEGO ENTVIEWER, DO KONTAKTU Z
NIEUSZKODZONĄ SKÓRĄ I BŁONĄ ŚLUZOWĄ

Jest zgodny z następującymi dokumentami odniesienia:
*Compliance the following documents of reference:*

**DYREKTYWY:**
*Directives:*

**93/42/EWG** Dyrektywa o wyrobach medycznych

**AKTY PRAWNE:**
*Local law:*

Ustawa z dnia 20 maja 2010 r. o wyrobach
medycznych ( Dz.U. 2010 nr 107 poz. 679)

**NORMY:**
*Standards:*

PN-EN ISO 14971:2012
PN-EN 1041+A1:2013
PN-EN ISO 15223-1:2012
PN-EN ISO 10993-5

Klasyfikacja wyrobu medycznego:
*Classification of medical device:*

**KLASA I** – Zgodnie z regułą 5
(Dz.U. 2010 nr 215 poz. 1416)

Procedura oceny zgodności:
*Conformity assessment procedure:*

**ZAŁĄCZNIK VII**
(Dz.U. 2011 nr 16 poz. 74)

........Gdańsk, 20.05.2015 r.........
**Miejsce, data:**
*Place, date:*

**Podpis osoby upoważnionej:**
*Signature of authorized person:*

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## 7   Device models

ENTviewer (model L, LS) is a device comprising interdependent elements: base, videospatula, and software.

OTOviewer (model WO) is a device comprising interdependent elements: base, videootoscope and software.

DUOviewer (model LO, LSO) is a device comprising interdependent elements: base, videospatula, videootoscope and software.

**Models of ENT line devices**

| Name of the device | Name of the base | Model | Laryngostroboscopy function |
|---|---|---|---|
| ENTviewer | uno | L | – |
| | | LS | ✔ |
| OTOviewer | uno | WO | – |
| DUOviewer | duo | LO | – |
| | | LSO | ✔ |

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## 8   Packaging

Packaging contents for ENTviewer device:

| No. | Name | Quantity |
|---|---|---|
| **1.** | Particular ENTviewer model device | 1 item |
| **2.** | The power cord 12V 2-3A, power cord cable, USB cable | 1 set |
| **3.** | Disposable laryngological covers | 30 items |
| **4.** | Disinfection tissues | 5 items |
| **5.** | Optics cleaning accessories | 1 set |
| **6.** | User manual and guarantee card | 1 item |
| **7.** | EndoMaster software | 1 item |

Packaging contents for OTOviewer device:

| No. | Name | Quantity |
|---|---|---|
| **1.** | Particular OTOviewer model device | 1 item |
| **2.** | The power cord 12V 2-3A, power cord cable, USB cable | 1 set |
| **3.** | Disposable specula | 20 items |
| **4.** | Disinfection tissues | 5 items |
| **5.** | Optics cleaning accessories | 1 set |
| **6.** | User manual and guarantee card | 1 item |
| **7.** | EndoMaster software | 1 item |

Packaging contents for DUOviewer device:

| No. | Name | Quantity |
|-----|------|----------|
| **1.** | Particular DUOviewer model device | 1 item |
| **2.** | The power cord 12A 2-3A, power cord cable, USB cable | 1 set |
| **3.** | Disposable laryngological covers | 30 items |
| **4.** | Disposable specula | 20 items |
| **5.** | Disinfection tissues | 5 items |
| **6.** | Optics cleaning accessories | 1 set |
| **7.** | User manual and guarantee card | 1 item |
| **8.** | EndoMaster software | 1 item |

# 9    ENT line devices technical parameters

Technical parameters of ENTviewer

| No. | Technical parameters | Value |
|-----|----------------------|-------|
| **1.** | Base uno dimensions (L x W x H) | 305x105x90 mm |
| **2.** | Weight | 1,6 kg |
| **3.** | Power supply | ~110 / ~230 V 50Hz |

| | | |
|---|---|---|
| **4.** | Power consumption | 24 W |
| **5.** | Class of device | I |

Technical parameters of OTOviewer

| No. | Technical parameters | Value |
|---|---|---|
| **1.** | Base uno dimensions (L x W x H) | 305x90x90 mm |
| **2.** | Weight | 1,5 kg |
| **3.** | Power supply | ~110 / ~230 V 50Hz |
| **4.** | Power consumption | 24 W |
| **5.** | Class of device | I |

Technical parameters of DUOviewer

| No. | Technical parameters | Value |
|---|---|---|
| **1.** | Base duo dimensions (L x W x H) | 305x185x90 mm |
| **2.** | Weight | 2,4 kg |
| **3.** | Power supply | ~110 / ~230 V 50Hz |
| **4.** | Power consumption | 24 W |
| **5.** | Class of device | I |

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Types of device bases from the ENT line

| Name of device | Name of the base | Model of device | Heater switch | Stroboscopy switch |
|---|---|---|---|---|
| ENTviewer | uno | L | ✓ | – |
| | | LS | ✓ | ✓ |
| OTOviewer | uno | WO | – | – |
| DUOviewer | duo | LO | ✓ | – |
| | | LSO | ✓ | ✓ |

Product lifetime is 10 years.

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## 10   Accessories

Accessories for ENT line devices are sold separately. They are available at www.sinutronic.eu.

## 11   Preparation for usage

**NOTE!**      **Risk of severe damage!**
            If the device was transported in low temperatures for a longer period of time, it should be left for at least 15 minutes in room temperature before the first start-up.
            Long-term transport in sub-zero temperatures may cause the battery to discharge.

**NOTE!**      **Risk of severe damage!**
            Before using, carefully remove the product from its packaging. Careful handling is essential for the proper operation of a device. Improper use (throwing the videospatula/videootoscope, falling on the floor etc.) may cause damage of the product.

The base of uno/duo should be placed on a flat, hard floor to prevent it from falling and enable connection to the power socket. **To ensure optimum conditions for image transmission, special attention should be paid to place the base in a position facing the videospatula/videootoscope when it is turned on.**

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The computer screen should be placed in such a way to enable the user comfortable observation of the examination (suggested position – behind the patient). The base of the device should be placed sideways to the patient, within the distance of at least 1.2 m.

1. Connect the base to the power source with a power cable. Turn the base on using the button (Fig. 2). The sound alarm indicates that the base is on.
2. Place the videospatula/videootoscope in the base bearing (Fig.1) for charging.
3. Connect the base to the computer with a USB cable supplied with the set or another cable which is not longer than 2 m.
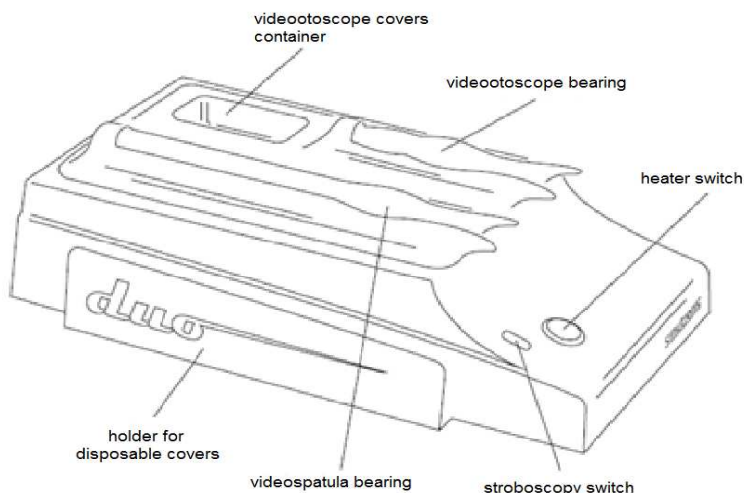4. Proceed to install the software (section 12).
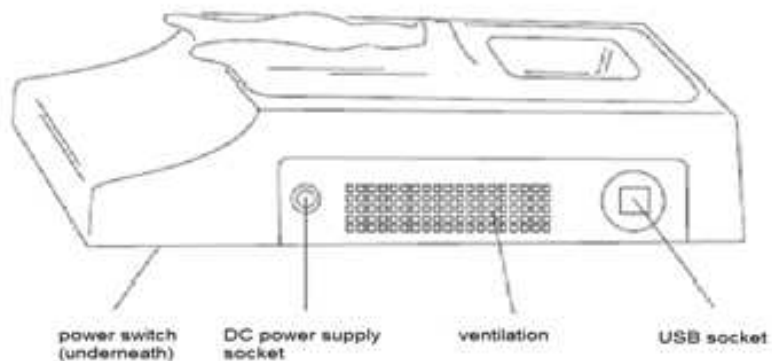


Fig. 1 Front side of base duo
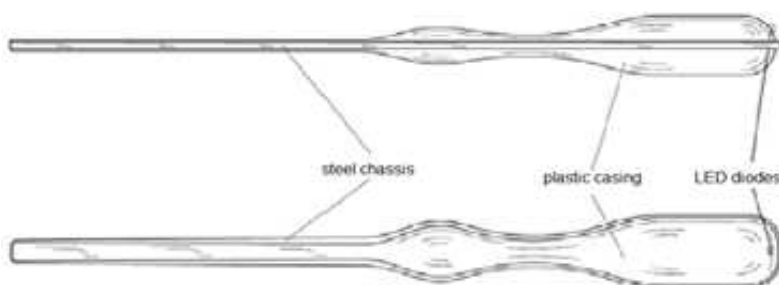
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Fig. 2 Back side of base duo



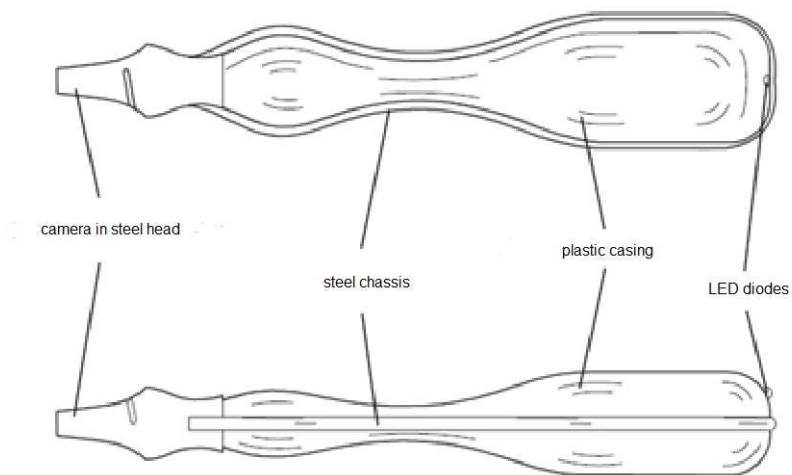Fig. 3 Videospatula side A

Fig. 4 Videospatula side B



Fig. 5 Videootoscope

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## 12  Installation guide

Minimum hardware requirements:

- processor i3 or better
- 4 GB RAM
- operating system Windows
- one available USB 2.0 port
- screen with IPS matrix

EndoMaster software is supplied with the purchased device as a DVD.

To install EndoMaster make sure that the base has been connected to the computer with a USB cable, and then run the installation programme from the attached carrier. When the installation is complete, restart the computer.

## 13  Instructions for use

**WARNING!**

ENT line devices may be used only by physicians. Children and unauthorised persons must not have any access to the device.

**NOTE!**   ENT line devices are designed for continuous use, and don't need to be turned off. To ensure optimum working conditions for the videospatula/videootoscope battery it is recommended to have the device running for at least a few hours during the working day.

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**NOTE!**    Place a disposable cover on the videospatula before each examination and a disposable speculum on videootoscope. Remove the used cover/speculum after the examination. Sinutronic shall not be liable for using the covers/specula contrary to the instructions. **Damages of videospatula/videootoscope resulting from failure to use disposable covers/specula immediately render this guarantee null and void.**

## 13.1   Light-signalling

Both the videospatula and videootoscope as well as the base are equipped in coloured LEDs signalling the current status of the device. Videospatula and videootoscope postponed back to the base in the suitable bearings are in standby mode in a process of charging (the diode is off). LEDs of videospatula and videootoscope will light on, when picked up from the base and indicate their current status.

- **green colour** in the base – heating of videospatula is completed, the device is ready to work.
- **green colour** in the videospatula/videootoscope – all parameters are correct, the videospatula/videootoscope is ready to work.
- **pulsating green colour** in the videospatula – stroboscopy function is on (optionally).
- **pulsating red and green colour** in the videospatula/videootoscope **–** the videospatula's/videootoscope's battery is close being low, place the videospatula/videootoscope on the base after the examination to recharge it.
- **red colour** in the base – heating is in process, wait until the diode turns green.

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- **red colour** in the videospatula/videootoscope - the device is not ready to work, place the videospatula/videootoscope on the base to regenerate (maximum regeneration time - 15 minutes).
- **orange colour** in the base – the device ready to work.
- **no light in the base** - absence of power supply, connect the device to a power source.

## 13.2   Heating up the videospatula

To prevent the optical elements from fogging heat up the videospatula before each examination. To do this (after placing the disposable cover on the videospatula – see section 13.3) press the heat up button (Fig. 1) directly before the examination. It is recommended that the videospatula was placed with the camera facing down. The red colour of the LED diode and a sound signal indicate that the stream of hot air has begun the heating process. The process lasts for about 45 seconds, and it is completed when the LED diode goes green and a sound signal is emitted. To prevent accidental over-heating of the device, restart the heating no sooner than after 45 seconds until the LED diode will have turned off. The device will not react if the button is pressed before this time has passed.

## 13.3   Carrying out of the rhinolaryngological examination and using ENTcovers

Before each examination check the status of diodes on the videospatula and base to ensure that the device is ready for use (see section 13.1). Take a paper and foil pack with 10 disposable covers, open it where indicated,

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and take out one piece. During the next examination, take another cover from the pack which has been stored in a clean place. Spreading the edges of the cover, place it on the videospatula. Put the spatula with the cover back to the base and press the heat up button. Turn on the previously installed EndoMaster programme by clicking the icon on the desktop. Select the patient or enter a new one (see section 13.6.2 and 13.6.3), and start a new examination (of larynx or nasopharynx) (see section 13.6.5). When the videospatula is removed from the base the camera and the LED diode are automatically turned on and the image is displayed on the computer screen. Carry out the examination. Fig.6 shows how to hold the spatula properly in your hand.
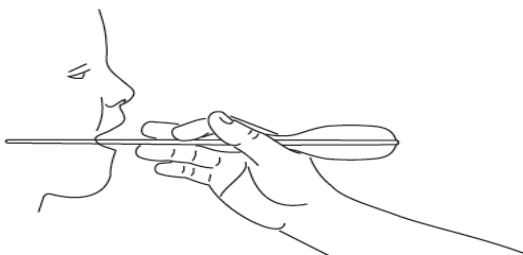


Fig. 6 A proper grip of videospatula

After the examination, remove the cover, wrapping the edge, put it in a container for medical waste, and place the videospatula on the base. The recording will be registered automatically and it will be prepared for edition.

The models LS / LSO have an extra function to examine vocal cords in the video laryngostroboscopy technology. To carry out this examination, turn on the appropriate operating mode by touching indicated place on the base

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STROBE ON/OFF by the back part of the videospatula (Fig. 1). A correct launch of the stroboscopy mode is signalled by the pulsating of the green LED diode. During examination of vocal cords, the LED lighting in the camera will automatically switch to the stroboscopy mode upon detecting the patient's voice. If the indicated place on the base is touched again by the back part of the videospatula, the device will return to the basic mode – stroboscopy will be turned off.

## 13.4  Carrying out the otoscopic examination and using otoscope speculum

Before starting the examination, check the status of the videootoscope diodes and base and make sure that the device is ready for use (see point 13.1). Turn on the installed EndoMaster software by clicking the icon on the desktop. Select the patient or enter a new one (see point 13.6.2 and 13.6.3), and then select the option to start a new ear examination (see point 13.6.5). Taking the videootoscope out from the base will cause the camera and LED diodes to turn on, and the computer screen will display images. Then you should take the plastic packaging with disposable otoscope specula, open it where indicated, take one speculum, close the packaging and put it back onto the base. Grab the speculum on the convex surface and put it on the videootoscope cone. Then turn the speculum right until the resistance is felt. You can now begin the actual examination. The proper grip of videootoscope, accounting for the hand anatomy is shown in Fig. 7.
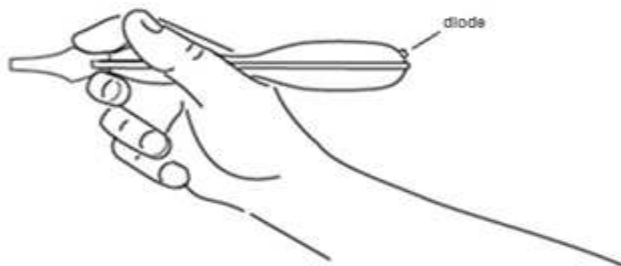
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Fig. 7 The proper grip of videootoscope

After completing the examination, remove the disposable speculum, not touching the area that was inside the patient's ear, throw it out to the container for medical waste, and put the videootoscope back to the base. The recording process will end automatically and the video will be ready to be edited.

## 13.5   Detailed instructions for using the Endomaster software

EndoMaster application was designed to ensure extremely intuitive use which does not require any additional IT skills.

The application comprises 3 parts:

- **patient and examination database** – contains information about all the examined patients (name, surname, PESEL (Personal ID), phone number, date of birth, and address), and full medical history

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of a given patient, i.e. previous recordings, selected frames and examination descriptions.

- ▪ **LIVE VIEW** – a live preview from the camera during the examination.
- ▪ **editing** – a place for cutting the film, selecting a frame, editing the material and preparing a final recording.

## 13.6   Detailed instructions for using the software

| | |
|---|---|
| **NOTE!** | Check the connection between the computer and the base with a USB cable. In the bottom right corner ACTIVE CONNECTION indicates a proper communication between the computer and the base. NO CONNECTION indicates that the base is disconnected from the computer. |

### 13.6.1   Language selection

After starting the software, select the appropriate software language by pressing the SETTINGS button and then the LANGUAGE button.

### 13.6.2   Selecting a patient

After running the programme, an up-to-date patient database is displayed (Fig. 8). To select a given patient, click on the person's name. The name will become highlighted, and all the previous examinations will be displayed in the PATIENT'S HISTORY table. To simplify the searching process, you may

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use a search engine by entering the name, surname, or at least the first digits of the PESEL no. , and click on the PATIENT SEARCH button.

### 13.6.3   Adding a new patient

New patients are added by clicking on the NEW PATIENT button (Fig. 8). Enter the patient's data in a newly opened window, and click SAVE. Now the patient is listed and can be examined for the first time. The patient's data may be previewed or edited after pressing the EDIT PATIENT'S DATA button.

### 13.6.4   Patient history

Upon selecting the patient from the list all the examinations previously carried for that patient will be displayed in chronological order (Fig. 8). When clicked, a specific date is highlighted, and the selected examination is displayed in the large window on the right-hand side.

### 13.6.5   Carrying out a new examination

To carry out a new examination, select a patient from the list or add a new patient, if necessary, and then click on NEW LARYNX EXAMINATION or NEW NASOPHARYNX EXAMINATION or NEW LEFT or RIGHT EAR EXAMINATION (Fig. 8), depending on the examined area. It is important to specify the examination type, as the application will automatically mark either the left or right part of the patient's body. If the examined area has to be changed from the nasopharynx to larynx, complete the examination, and select a new one. Otherwise, the sides of the examined area may be wrongly interpreted. After selecting new examination, the application will switch to the LIVE VIEW preview mode (Fig. 9). Now the application is ready to start the examination. Take one videospatula/videootoscope from the base. The videospatula/videootoscope will start to work automatically, and the recorded image will appear on the screen. The examination will end

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automatically after returning the videospatula/videootoscope to the base, while the entire recording will be loaded and ready to be watched and edited (Fig. 10 and Fig. 11). A difference between larynx and nasopharynx examination is that in the nasopharynx examination the registered image is a mirror reflection, and thus navigation of the spatula becomes more intuitive.

### 13.6.6 Shortcut

There is a special immediate examination mode, which is activated by pressing the SHORTCUT button (Fig.8). After pressing the button, a new patient will be created, and the programme will turn into recording mode. The patient's data will temporarily be marked with the word "EMERGENCY" to distinguish them from the others. If possible, it is recommended to edit and complete the patient's data after ending work in the immediate mode. This will help to prevent confusion and difficulty in distinguishing examinations performed incognito.

### 13.6.7 Selection and editing the material

The editing window will open automatically after the examination (Fig. 10). To return to editing after some time, press RETURN TO MENU. The recording will be saved in an unedited form. To return to editing after some time, highlight the material to be edited and press OPEN MATERIAL (Fig. 8).

Since the recording may be large in size or require editing it is recommended to cut out/edit the fragments of the film and/or images that are of interest to the user. To make this easier, individual frame will be displayed at the bottom of the screen to help navigate the material. For a quick preview of the entire recording, press the red indicator on the FILM PREVIEW belt with the left mouse button and move it to the left and right.

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This action enables watching individual frames of the film and quick navigation throughout the material.

**To cut a fragment of the film**, move the red indicator on the FILM PREVIEW belt to the place where the fragment begins. Next, with the use of a scroll wheel or left and right arrows on the keyboard, select the exact frame and press MARK THE BEGINNING OF THE FILM. In the same manner, select the final frame and press MARK THE END OF THE FILM. In result, the CUT AND SAVE THE FILM button will be activated, which should be pressed to cut the actual film.

**To save the image**, move the indicator of the FILM PREVIEW belt close to the film. Next, with the use of a scroll wheel or left and right arrows on the keyboard, select the exact frame. To save the selected frame, press SAVE SELECTED IMAGE.

**To edit the material** please select the button EDIT THE MATERIAL (Fig. 10).

**To adjust contrast, colour, and brightness** press one of the BRIGHTNESS/CONTRAST/COLOUR buttons and adjust the selected value using the slider. (Fig. 11)

**To change the film speed**, press FILM SPEED and adjust the speed using the slider above the button. (Fig. 11)

**To reset the colour, contrast, brightness, or frame settings** press the given value and select RESET. The RESET button will display the name of the reset value.  (Fig. 11)

**To reduce interference caused by strobing,** press FILTER STROBING INTERFERENCE. (Fig. 11)

**To end the work with selected material**, press RETURN TO MENU/SAVE. The programme will ask if you want to save the changes to the image. After returning to the home page, the recently edited material will be highlighted.

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### 13.6.8    Entering the examination description

Select the image and enter the text in the field DESCRIPTION OF SELECTED EXAMINATION (Fig. 8). The description is saved automatically and will be printed out in the field EXAMINATION DESCRIPTION.

### 13.6.9    Printing the examination

Select the image and press PRINT EXAMINATION (Fig. 8). The print preview window will open. To add or change the heading, press the CHANGE HEADING button used for editing graphics and heading content. The heading is saved after pressing SAVE AND CLOSE. The saved heading is automatically applied to the examination printout.

### 13.6.10  Saving material on a carrier

To save a given examination/image, highlight it and press SAVE ON: and select the location and name of the target file (Fig. 8). After confirming, the file will be saved in the selected place.

### 13.6.11  Deleting material

To delete any material, select the examination/photo to be deleted and press DELETE MATERIAL (Fig.8). This will result in removing only the selected material. After deleting the last material in a given examination the entire entry will be removed.
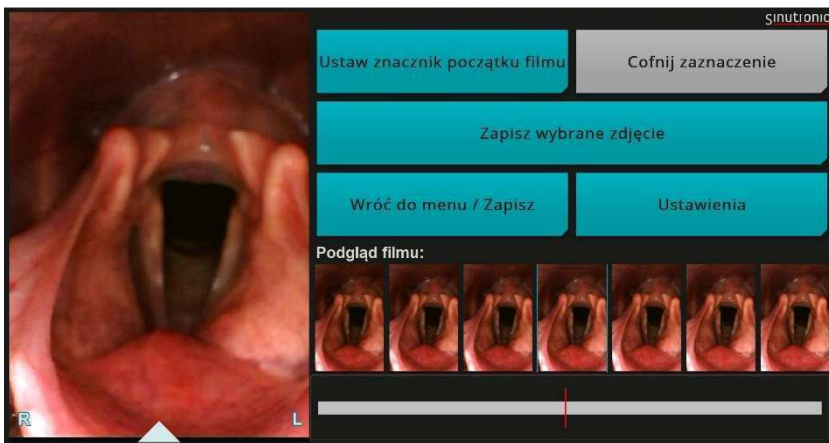
Fig. 8 Interface 1
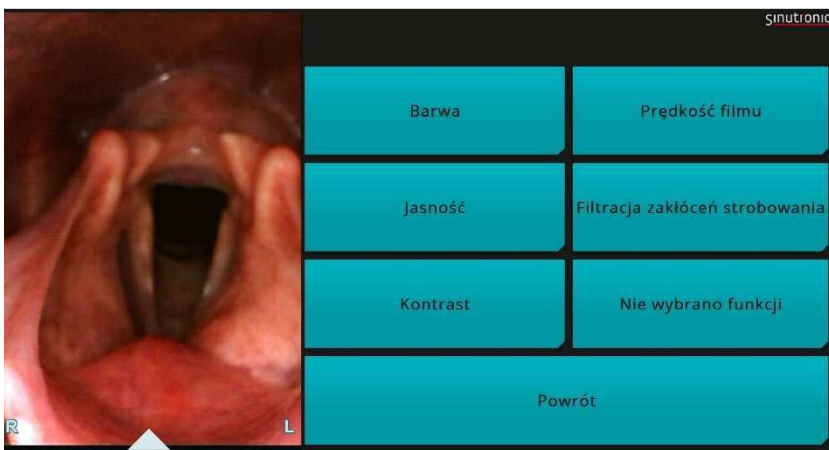


Fig. 9 Interface 2

Fig. 10 Interface 3



Fig. 11 Interface 4

## 14   After use

After each examination, used covers/specula must be placed in a container for medical waste.

## 15   Cleaning and maintenance

Cleaning and maintenance may take place only after disconnecting the device from the power source.

Cleaning and maintenance consist on wiping only the outer surfaces of devices from the ENT line with a microfibre cloth soaked with a disinfectant which may include the following components: 0.25 g of didecyldimethylammonium chloride, 0.5 g quaternary ammonium compound chloride – benzyl-C12-16-alkyldimethyl ammonium chlorides per 100 g of solution.

To protect the optical elements, do not spray the disinfectant directly on the videospatula/videootoscope.

Disposable covers/specula do not require cleaning and are ready-to-use.

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## 16 Problems and corrective actions

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| Problem | Corrective action |
| --- | --- |
| The videospatula/videootoscope does not work, the diode at the back of the videospatula/videootoscope is off after taking out from the base. | The battery has been over-discharged. Place the videospatula/videootoscope on the base to charge it. |
| The base does not work. | Check if the power cable is properly connected with the power source. |
| The diode on the videospatula/videootoscope is red. | The videospatula/videootoscope is not ready for work. Return the videospatula/videootoscope to the base to charge it. |
| The diode on the videospatula/videootoscope is pulsating red and green. | It is recommended to return the videospatula/videootoscope to the base to charge it. |

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| | |
|---|---|
| The diode on the base is red. | The device is not ready for work. It is recommended to return the videospatula/videootoscope to the base to regenerate it. |
| The image is blurred. | Wipe the sapphire glass on the camera delicately with a stick or cloth. |
| The image is noisy. | Check if there are any strong sources of energy within a close distance, as they may distort transmission. Move the base to another place. |
| No image in the application. | Check if the USB cable is properly connected with the computer. |

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## 17   Repairs and servicing

All servicing work and repairs should be carried out by the manufacturer or Sinutronic authorised servicing point.

Interim service recommended every two years.

## 18   Ecology

**Let's participate in environmental protection**

This device is made of materials that may be processed or recycled.

Worn out devices should be returned to the manufacturer or Sinutronic authorised servicing point.

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## 19  Warranty card

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**WARRANTY CARD**

valid only with a proof of purchase

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**Product name**

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**Model**

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**Serial number**

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**Date of purchase**

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**The seller's stamp and signature**

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## 20  Terms of warranty

1) Sinutronic sp. z o.o. grants warranty for the sold product, covering the period of 24 months from the date of purchase specified on this warranty and the proof of purchase.

2) The right to warranty is ensured by a properly completed warranty card with the original proof of purchase. All changes and deletions shall deem this warranty card null and void.

3) To have the device repaired, in the first place, a complaint has to be made via electronic mail to serwis@sinutronic.eu or via electronic form available on our website www.sinutronic.eu, and a complete product has to be delivered with a warranty card and proof of purchase.

4) The product should be delivered to the manufacturer or Sinutronic authorised servicing point, or passed for transport in original packaging. If original packaging is missing, the risk of product damage shall be borne by the person who lodged the complaint.

5) Faults occurring during the warranty period will be rectified free of charge during 14 working days from the date of receiving the product by the manufacturer or Sinutronic servicing point. Any delays due to transport shall not give rise to additional complaints.

6) After the guarantee repair, the product shall be delivered free of charge to the address provided by the person lodging the complaint.

7) The method of repair shall be determined by the warrantor.

8) The person lodging the complaint is entitled to replace the product or a part thereof for a new one which is free from defects, if:
   a) the manufacturer's servicing point performs four significant repairs during the warranty period, and the product still has defects (material defects) which deem it unable to be used in accordance with its purpose.
   b) the manufacturer's servicing point acknowledges in writing that the fault cannot be rectified.

9) A complaint procedure excludes a product and software installation as well as maintenance.

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10) The warranty also excludes:
    a) products with illegible or changed serial numbers,
    b) products which were used, maintained, or stored improperly (contrary to the instructions),
    c) products which were damaged due to not using disposable covers/specula,
    d) products which suffered mechanical, electrical, thermal, or chemical damage and all other damages caused thereby,
    e) actions referred to in the user manual, which the users must perform on their own,
    f) maintenance due to normal wear and tear, e.g. replacement of LEDs, batteries, or cables,
    g) deterioration of image quality due to normal wear and tear of LED,
    h) products damaged due to chance events (liquid spill, lightning), and other not inherent in the product.
    i) incompatibilities caused by technical modifications, innovations, and standards after the date of sale.
11) The person lodging the complaint loses the right to warranty also when unauthorised repairs or design changes have been made.
12) Sinutronic sp. z o.o. shall not be liable for the loss of any product user's data during the warranty repair.
13) Sinutronic sp. z o.o. shall not be liable for any incidental, indirect, special, or any other damages (including unlimited losses of profit or any other financial losses), which might be caused by use or inability to use the product. Also excluded shall be any liability that might arise from claims by third parties.

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## 21 Contact

Sinutronic sp. z o.o.

ul. Asesora 86

80-119 Gdańsk

tel. (58) 305 40 80

e-mail: serwis@sinutronic.eu

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## 22   Notes on completed repairs

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| Date of reporting a fault | Description of reported fault |
| --- | --- |
| | |

| Date of repair | Description of repair |
| --- | --- |
| | |

| Date of delivery | Servicing point stamp / signature |
| --- | --- |
| | |

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| Date of reporting a fault | Description of reported fault |
| --- | --- |
| | |

| Date of repair | Description of repair |
| --- | --- |
| | |

| Date of delivery | Servicing point stamp / signature |
| --- | --- |
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Date of reporting a fault                    Description of reported fault

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Date of repair                               Description of repair

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Date of delivery                             Servicing point stamp / signature

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Date of reporting a fault                    Description of reported fault

_____

Date of repair                               Description of repair

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Date of delivery                             Servicing point stamp / signature

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User manual publication date:   2017

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