sinutronic

USER MANUAL
AND WARRANTY CARD

ENTviewer

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 ENTviewer, which has been developed by applying the latest technologies. We have done our best to make the device 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 ENTviewer's 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 ENTviewer experience.

Management Board and Employees

Sinutronic sp. z o.o.

Contents

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 ENTviewer.

NOTE!

NOTE!

Tells to carefully read the information before using ENTviewer.

Indicates manufacturer's name and address.

Indicates date of production.

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.

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 2 electrical device.

Indicates use-by date.

Indicates the batch number.

Indicates a disposable product.

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.
- The device has a fuse at the back of the base casing. In case the fuse needs to be replaced, disconnect the power supply and use the fuse with the rated current of 1,6 A 230 V AC.
- 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 window.
- 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.

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.

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.

5 Medical applications

ENTviewer 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

CE

sinutronic

CE

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:

sinutronic

CE

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, 30.03.2016 r.....
Miejsce, data:
Place, date:

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

7 Device models

ENTviewer is a device comprising interdependent elements: base, spatula, and software.

ENTviewer models

Model	Base type	Laryngostroboscopy function	Desktop computer
L	stationary	-	-
LS		✓	-
LCS		✓	✓
M	portable casing	-	-
MS		✓	-
MCS		✓	✓
UC	laryngological unit	-	✓
UCS		✓	✓

8 Packaging

Packaging contents:

No.	Name	Quantity
1.	Particular ENTviewer model	1 item
2.	Wiring with spare fuse	1 item
3.	Disposable covers	30 items
4.	Disinfection tissues	5 items
5.	Optics cleaning accessories	1 set
6.	User manual and guarantee card	1 item

9 Technical parameters

No.	ENTviewer technical parameters	Value
1.	Base and spatula dimensions (L x W x H)	200x300x100
2.	Weight	1 kg
3.	Power supply	~110 / ~230 V 50Hz
4.	Power consumption	100 W
5.	Class of device	II

10 Accessories

ENTviewer accessories are sold separately. They are available on 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 subzero 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 ENTviewer. Improper use (throwing the spatula, falling on the floor etc.) may cause damage of the product.

The base of ENTviewer 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 spatula when it is turned on (Fig.1).**

The computer screen should be placed in such a way to enable the user comfortable observation of the examination (suggested position – behind the patient)

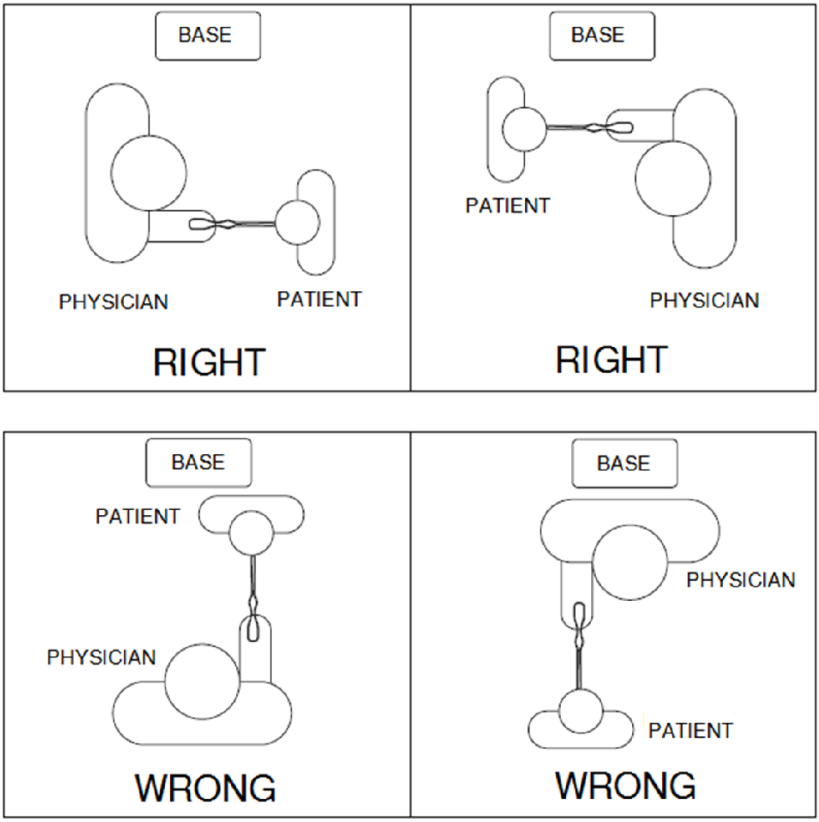


Fig. 1 A proper positioning of the base in relation to the spatula during the examination to minimize interference

1. Place the spatula in the base bearing (Fig.2 or Fig. 4).
2. Turn the base on using the button (Fig. 3 or Fig.4). The sound alarm and red colour of the LED diode (Fig. 2 or Fig. 4) indicate that the charging process has begun.
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 11).

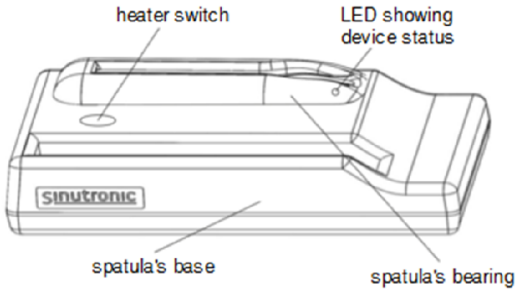


Fig. 2 Front view of base model L/LS/LCS/UC/UCS

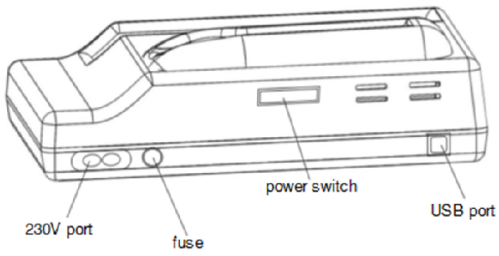


Fig. 3 Rear view of base model L/LS/LCS/UC/UCS

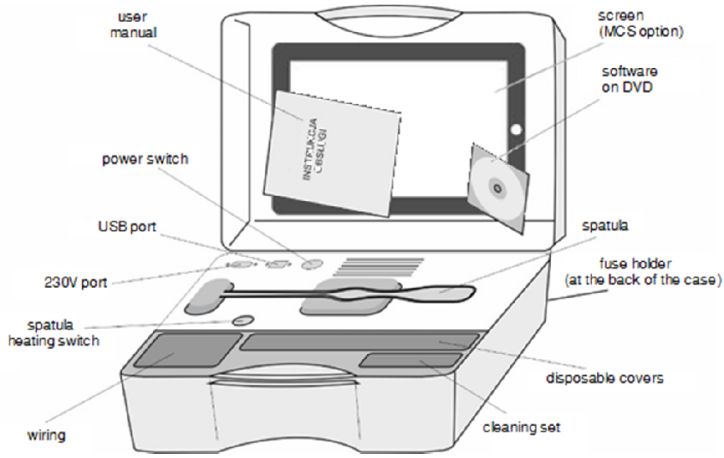


Fig. 4 Base model M/MS/MCS

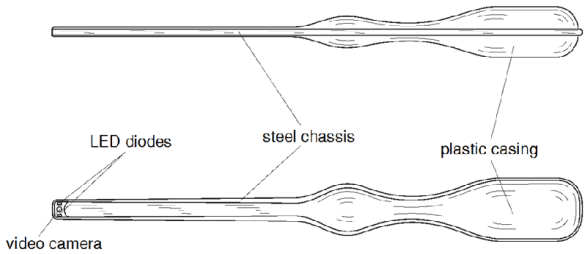


Fig. 5 Side A of the spatula

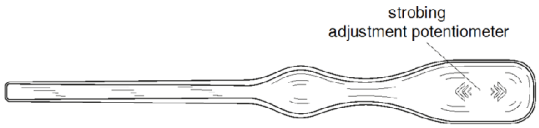


Fig. 6 Side B of the spatula

12 Installation guide

Minimum hardware requirements:

- processor Pentium Core 2 Duo 2 GHz or better
- 4 GB RAM
- hard drive capacity minimum 500 GB
- operating system Windows XP or newer
- standard graphics card
- one available USB 2.0 port
- calibrated screen

EndoMaster 1.1 software is supplied with the purchased device as a DVD/pendrive.

To install EndoMaster 1.1 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.

13 Instructions for use

WARNING!

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

NOTE! ENTviewer is designed for continuous use, and does not need to be turned off. To ensure optimum working conditions for the spatula battery it is recommended to have the device running for at least a few hours during the working day.

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

13.1 Light-signalling

Both the spatula and the base are equipped in coloured LEDs signalling the current status of the device:

- **green colour** in the base and spatula – all parameters are correct, the spatula is ready for work.

- **pulsating green colour** in the spatula – stroboscopy function is on (optionally).
- **pulsating red and green colour** in the spatula **–** the spatula's battery is close being low, place the spatula on the base after the examination to recharge it.
- **red colour** in the base or spatula - the device is not ready for work, place the spatula on the base to regenerate (maximum regeneration time - 15 minutes).
- **orange colour** in the base – the device ready for work, waiting to be heated up.
- **no light in the spatula or base** - absence of power supply, connect the device to a power source.

13.2 Heating up the spatula

To prevent the optical elements from fogging heat up the spatula before each examination. To do this (after placing the disposable cover on the spatula – see section 13.3) press the heat up button (Fig. 2 or Fig. 4) directly before the examination. It is recommended that the spatula 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 the examination and using covers

Before each examination check the status of diodes on the spatula 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, 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 spatula. Put the spatula with the cover back to the base and press the heat up button. Turn on the previously installed EndoMaster 1.1 programme by clicking the icon on the desktop. Select the patient or enter a new one (see section 12.4), and start a new examination (of larynx or nasopharynx). When the spatula 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.7 shows how to hold the spatula properly in your hand.

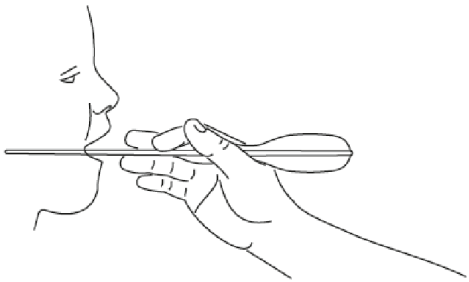


Fig. 7 A proper grip, accounting for the hand anatomy

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

The model has the LS / MS mark and an extra function to examine vocal cords in the video laryngostroboscopy technology. To carry out this examination, turn on the appropriate operating mode by tapping the spatula's touch panel twice. A correct launch of the stroboscopy mode is signalled by the pulsating of the green LED diode. If the panel is tapped twice again, the device will return to the basic mode – stroboscopy will be turned on. During examination of vocal cords, the LED lighting in the camera will automatically switch to the stroboscopy mode upon detecting the patient's voice. The speed of movement may be adjusted during the examination with the use of a touch panel placed on the back of the spatula (Fig. 6). In order to speed up, move your finger firmly on the marked field towards the patient. To decrease the speed, you should move your finder away from the patient.

13.4 Using EndoMaster 1.1

EndoMaster 1.1 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 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.

13.5 Detailed instructions for using the software

13.5.1 Selecting a patient

After running the programme, an up-to-date patient database is displayed (Fig. 8). In the bottom left corner, a green circle is displayed, indicating a proper communication between the computer and the base. A red circle indicates that the base is disconnected from the computer. In such a case, check the USB connection.

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 medical history table. To simplify the searching process, you may use a search engine by entering the name, surname, or at least the first digits of the PESEL no. , and click on the SEARCH button.

13.5.2 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 DATA button.

13.5.3 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 MATERIAL PREVIEW window.

13.5.4 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 (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. Now the application is ready to start the examination. Take one spatula from the base and place a disposable cover on it. The spatula will start to work automatically, and the recorded image will appear on the screen. The symbol "REC" in the upper right corner of the screen indicates that the material is being saved on the computer disk. The examination will end automatically after returning the spatula to the base, while the entire recording will be loaded and ready to be watched and edited (Fig. 9). 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.

13.5.5 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.

13.5.6 Editing the material

The editing window will open automatically after the examination (Fig. 9). To return to editing after some time, press RETURN TO MENU/SAVE. 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 frames will be displayed at the bottom of the screen to help navigate the material. The programme will automatically set a preview mode in the place which is probably of most interest to the user. 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. 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 watch the selected fragment before cutting it, click the image in the FILM PREVIEW window. Pressing the CUT AND SAVE THE FILM button to save the film without editing it and return to the menu or save the film and prepare it for edition.

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 adjust contrast, colour, and brightness press one of the BRIGHTNESS/CONTRAST/COLOUR buttons and adjust the selected value using the slider.

To start cropping, press the CROPPING button. In the IMAGE PREVIEW window mark the central point of the frame with the left mouse button and, still holding the button, extend the framed area. A frame will appear around the selected area, and upon releasing the mouse button the image will be cropped.

To change the film speed, press FILM SPEED and adjust the speed using the slider above the button.

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.

To reduce interference caused by strobing, press FILTER STROBING INTERFERENCE.

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

13.5.7 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.

13.5.8 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.

13.5.9 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.

13.5.10 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.

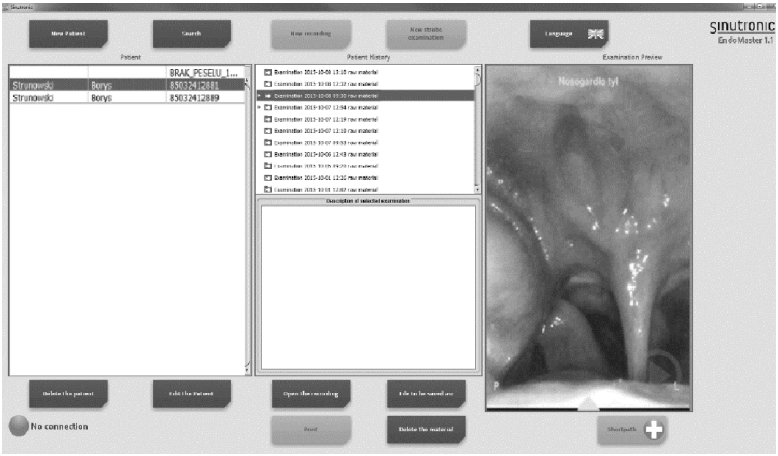


Fig. 8 Interface 1

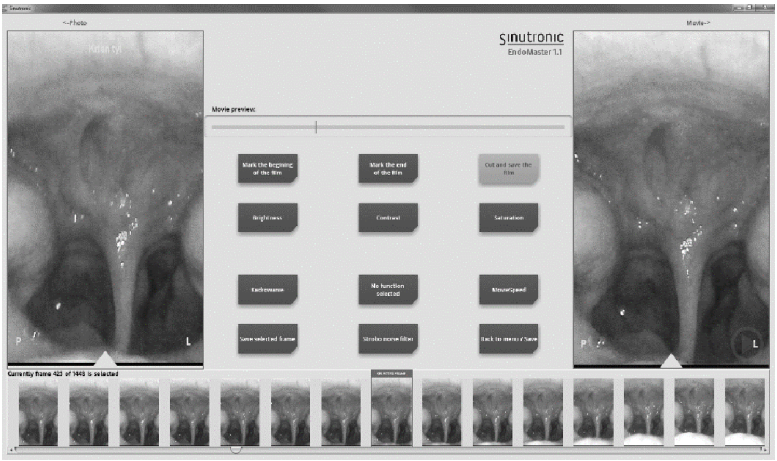


Fig. 9 Interface 2

14 After use

After each examination, used covers 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 in wiping the device 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 spatula.

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

16 Problems and corrective actions

Problem	Corrective action
The spatula does not work, the diode at the back of the spatula is off.	The battery has been over-discharged. Place the spatula on the base to charge it.
The base is off, it does not start.	Check if the base power cord has been plugged and if the fuse hasn't blown.
The diode on the spatula is red	The spatula is not ready for work. Return the spatula to the base to charge it.
The diode on the spatula is pulsating red and green	It is recommended to return the spatula to the base to charge it.
The diode on the base is red	The device is not ready for work. It is recommended to return the spatula 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

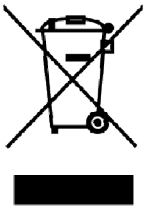
	another place.
No image in the application	Check if the USB cable is properly connected with the computer.

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.

19 *Warranty card*

WARANTY CARD

valid only with a proof of purchase

Product name

Model

Serial number

Date of purchase

The seller's stamp and signature

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. Any and 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.
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,
    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, lightnings), 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.

21 Contact

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22 Notes on completed repairs

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

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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