



MEDIQ

User Manual

Use, Maintenance
and Service
of the

Sinuscan™ 301

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104000

Version 4

This User Manual is checked 23 April 2018

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1. SAFETY INSTRUCTIONS

1.1 Description of symbols



Attention, consult accompanying documents.
For the connection of the Battery Charger see paragraph 3.5
"Charging the Battery of the Sinuscan 301"

For accepted types of Battery Chargers see paragraph 9
"Technical Specifications"



Type B equipment



CE-mark indicates that the device is designed according to
directive for medical devices 93/42/EEC.



USB connection



The crossed-out wheeled bin means that within the European
Union the product must be taken to separate collection at the
product end-of-life. See Paragraph 11 "Discarding the
Device".

1.2 Warnings

- Read this manual carefully and store it for future reference.
- Do not drop the device. The tip of the sensor is fragile.
- Do not scratch the tip of the sensor. For cleaning the device and sensor see paragraph 6 “Cleaning”.
- Do not use any solvents to clean the surface of the device or tip of the sensor. For cleaning the device and sensor see paragraph 6 “Cleaning”.
- Charge the battery of the Sinuscan 301 only with the battery charger supplied by the manufacturer.
- Do not connect any other power supply to the device than the original one supplied by the manufacturer. It is possible to risk the patient safety by using other power supply.
- Do not open or disassemble the unit. There are no serviceable parts inside except the parts specified in the paragraph 8 "Maintenance and Service". As replacement parts use only the parts supplied by the manufacturer.
- Strong electrical or electromagnetic fields (e.g. GSM phone close to the device) may affect to the performance of the device. Keep the device clear from such environments, distance min. 30 cm. It is recommended to use device without battery charger, strong interference from the mains may cause occasionally false echoes on display. See paragraph 12 "EMC-information". Possible false echoes occur momentarily and are not reproducible, so these must not be used for examination results. Charger cable needs to be disconnected if such echoes exist on display during examining. See 4 “ The Examination” ”...and you can repeat this display three times”
- Do not connect the USB cable to the device in the patient environment. See paragraph 5.1 "Patient Environment". The Sinuscan 301 device and the Battery Charger supplied with the device can be used in the patient environment.
- Do not connect items that are not specified as part of the Sinuscan 301 system. See paragraph 2.3 "Sinuscan Components".
- Do not touch USB cable or any other non-medical electrical equipment and the patient simultaneously.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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 Sinuscan 301, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

1.3 Indications

The method is suitable for children from the age of three years and up, for adults, including also pregnant women.

The examination can easily be repeated several times.

1.4 Contraindications

The reliability of the method is not proved for children of age less than three years.

1.5 Precautions

No detrimental biological effects have been found at the power level generated by the instrument. It is thus safe for both the patient and the physician.

No specific protection is needed when using the device.

The Sinuscan 301 is intended to be used in professional healthcare facility environment. Except for near active HF SURGICAL EQUIPMENT and the RF shielded room of a ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

The Sinuscan 301 will function as an aid for determining a diagnosis or as a base for further examinations. The Physician or doctor makes the diagnosis.

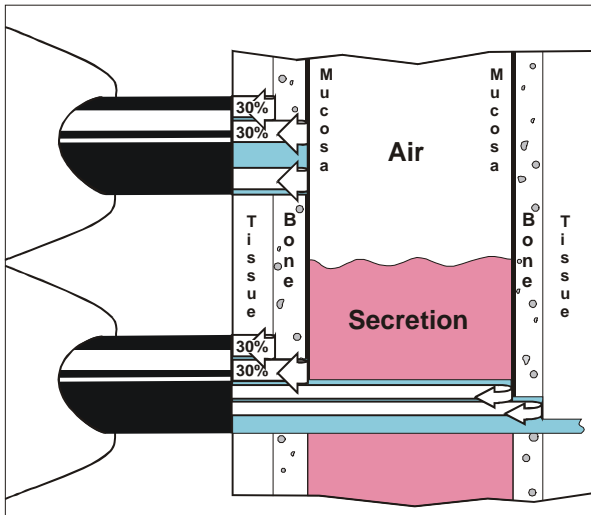
2. GENERAL

2.1 Intended use

This instrument is designed for detecting anomalies as for example fluid in the maxillary and frontal sinuses. This is done by the Sinuscan by indicating the back wall echo received from the bony back wall of a fluid filled cavity; no such echo is received if the cavity contains only air. Thus the instrument will function as an aid for determining a diagnosis or as a base for further examinations.

2.2 Principle of operation

The Sinuscan works by transmitting ultrasonic energy pulses and receiving reflected sonar echoes from acoustic layers in the same manner as an echo sounder. The reflected sound wave is transformed into an electric signal and the signal is indicated by a graph on the OLED display as an A-mode curve, which in turn indicates the layer distances and the strength of the echo. The resolution is 0.5 cm and the exploration depth is 7 cm. The ultrasonic frequency used (3 MHz) is transmitted through human soft tissue and bone, but not through air.



2.3 Sinuscan Components

- Sinuscan Scanner
- Battery Charger
- USB cable for computer data connection

For detailed list of the contents of the packaging see the paragraph 7 "Contents of the Package".

2.4 Interconnecting the Components of the Sinuscan-system

Sinuscan 301 is designed to be used as a stand-alone device. It has an internal battery providing adequate scanning time (e.g. 10 hours) without recharging. The charger plug connector is located at the end of the device. The plug fits into the connector only in one position.

Sinuscan 301 could be connected to the computer with included USB cable. The square end of the cable is connected to the Sinuscan and the flat end of the cable to the computer. The device will be shown on the computer as a removable storage. Connection is read only. It is only possible to view and copy measurement data from the device. Content on the device could not be modified by any means from the attached computer.

Note! USB-connector could not be used to charge the Sinuscan 301.

2.5 Sinuscan 301 Features

2.5.1 Orientation

The Sinuscan 301 can be set for right-hand or for left-hand use.

2.5.2 The exploration areas

The device can be set for two, for four or for all-in-one exploration area modes. When the two-area-mode (Sin+Dex) is selected, only maxillary sinuses are examined / stored in the memory. In the four-area-mode (Sin+Dex+Fro) both maxillary and frontal sinuses are examined / stored. Easy all-in-one mode (Easy) is for all four examination areas but only the last measurement is kept on the memory without a specifying name.

2.5.3 Memory

Dependent of the settings the Sinuscan 301 has maximum of four memory locations to store measurements. Selected memory location is shown on the display with the curve. New measurement is stored over the previously stored measurement on the same location. All of the stored measurements can be erased from the memory. See paragraph 3.3.3 "Memory review, MEM-stage".

Memory locations:

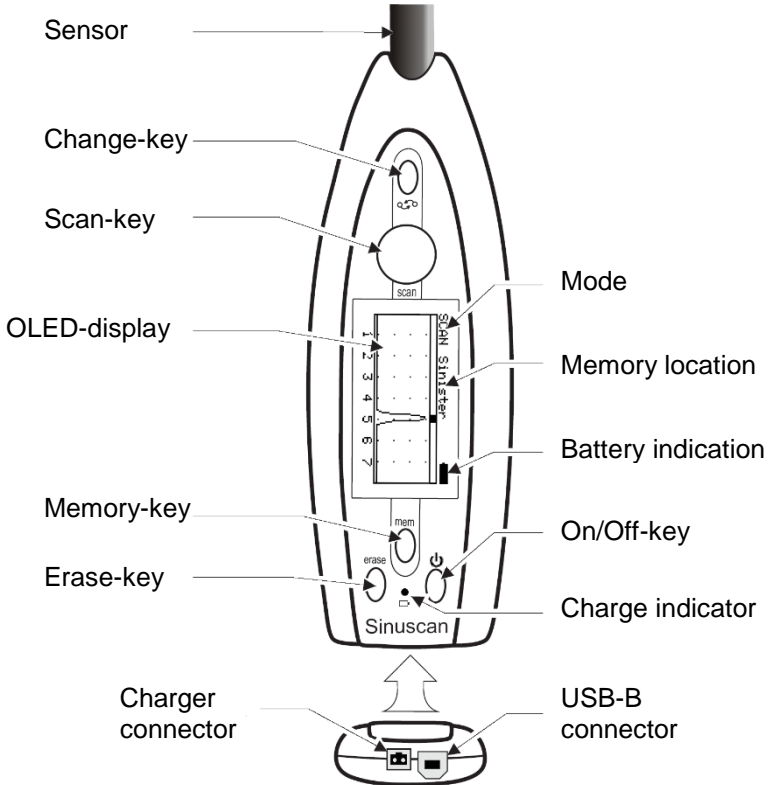
- Sinister, left maxillary sinus (Sinister)
- Dexter, right maxillary sinus (Dexter)
- Frontal, left sinus (FroLeft)
- Frontal, right sinus (FroRight)

Note! Named memory locations are not used and not shown on the display in Easy mode because only the last measurement is kept on the memory.

2.5.4 Factory Settings

Device is pre-set for easy mode and for right-hand-use.

If you wish to use the unit as left-handed or wish to use more than one memory location please refer the paragraph 3.3.4 "Settings / info".



3. BEFORE OPERATION


3.1 Sinuscan Setup

Ensure that there is sufficient battery capacity to perform an examination. See paragraph 3.5 "Charging the Battery of the Sinuscan 301".

3.2 Description of the Keys

The Sinuscan 301 has five keys to operate the functions of the device.

Only the SCAN-key is needed for normal operation in easy mode. All of the keys are:

- SCAN-key (start or stop the scanning)
- MEM-key (review measurements)
- ERASE-key (erase measurements and change settings)
- CHANGE-key  (to scroll the memory location and to move cursor on settings)
- ON/OFF-key (to power off the device and to power on to previous usage state)

3.3 Operation Stages of the Device

The device has the following stages of operation:


- OFF, off
- SCAN, scanning (live graph)
- MEM, memory review (frozen graph)
- INFO, settings / info
- USB, USB connected (copy measurements to PC)

3.3.1 Off (OFF)

The device goes automatically to the OFF-stage if no key is pressed for approx. three minutes. On/Off button will toggle Power On and Power Off.

The display of the device is blank in the OFF-stage if charging is not ongoing.

From the OFF-stage the user can:

- Start scanning by pressing SCAN-key.
- Review the previously scanned graphs by pressing MEM-key.
- Enter to the settings / info -stage by holding the -key and then pressing the MEM-key.

Note! The device does not shut down completely if USB cable is connected.

3.3.2 Scanning, SCAN-stage

The device is transmitting ultrasonic energy pulses and is receiving the echoes.

The graph on the display is live, real-time presentation of returned echoes.

- By pressing SCAN-key the user can start the scanning and freeze the display by pressing once again the SCAN-key.

3.3.3 Memory review, MEM-stage



To enter to the MEM-stage press either:

- SCAN-key while in SCAN-stage. (To freeze the graph)

Or:

- MEM-key while in OFF-stage. (To enter to the memory review)

In the MEM-stage the user can:

- scroll the memory location by pressing the -key or the MEM-key.
- erase the measurements by pressing the ERASE-key for two seconds. The display will show -symbol to indicate that all the measurements are erased.

Sinuscan 301 has four memory locations to store measurements. The selected cavity is shown on the display. New scan is stored over the previously stored measurement on the same location.


The memory locations are:

- Sinister, left maxillary sinus
- Dexter, right maxillary sinus
- FroLeft, left frontal sinus
- FroRight, right frontal sinus

Note! Named memory locations are not used and not shown on the display in Easy mode because only the last measurement is kept on the memory.

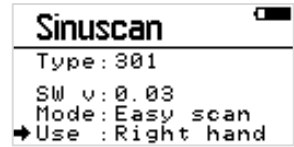
3.3.4 Settings / info, INFO-stage

The device may be turned into INFO-stage by the following procedure:

- Turn the unit OFF by pressing the ON/OFF-key if the device is not already on the OFF-stage.
- Enter to the settings / info -stage by holding the -key continuously and then pressing the MEM -key once.

In the settings / info -stage the display shows:

- name and type of the device
- software version



In the settings / info -stage the user can:

- select the left- or the right-handed use by moving the arrow to the "Use" line with \leftarrow -key and then choosing "Right" or "Left" by pressing the ERASE-key.
- select the mode by moving the arrow to the "Mode" line with \leftarrow -key and then choosing the mode by pressing the ERASE-key. Possible values are "Sin + Dex" i.e. Sinister and Dexter for two exploration area mode, "Sin+Dex+Fro" i.e. Sinister, Dexter, Frontal Left and Frontal Right for four exploration area mode and "Easy scan" for all in one exploration area mode.
- adjust the brightness of the display by pressing the MEM-key. Observe the display when adjusting the brightness and press the MEM-key as many times as needed to set the brightness. Sinuscan have four different levels of brightness to choose from.

All settings are automatically stored when leaving the settings / info -stage by pressing SCAN- or ON/OFF-key.

3.3.5 USB connected -stage

To enter to the USB connected -stage connect the USB cable between Sinuscan 301 and a computer. The device will automatically switch to USB connected -stage.

In the USB connected -stage the user can:

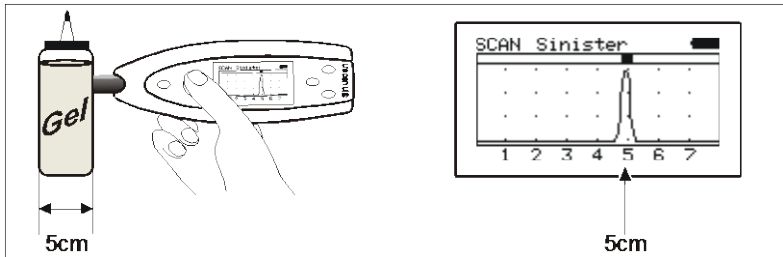
- Not to do anything controlled by Sinuscan 301 while USB is connected.
- Copy measurements from the Sinuscan 301 to the computer. Connection is read only.

Note! USB-connector could not be used to charge the Sinuscan 301.

3.4 Functions of the Sinuscan Device / Quick Test

Quick test for the device proper functionality could be performed with a small plastic bottle filled with water or gel. Apply some transmission gel on tip of the sensor and then place the sensor to the side of the filled bottle. The back wall echo from a filled water bottle must show as a graph near the rear end of the display. A 5 cm diameter bottle should show an echo near to the 5 to 6 cm marks on the display.

If no echo is found, please check if there is sufficient amount of water or gel in the bottle. For detailed information about troubleshooting the Sinuscan 301 see paragraph 8.3 "Troubleshooting"



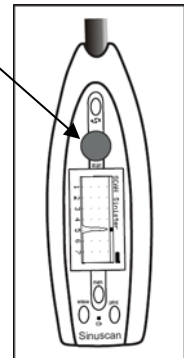
3.4.1 Scanning

To scan with the Sinuscan 301:

- Turn the unit on by pressing the SCAN-key once.
- Put small amount of gel to the tip of the sensor
- Aim the sensor towards the area to be explored and push the sensor *gently* to the skin
- Observe the display while slowly tilting and moving the sensor.

Repeat the procedure for cavities intended to be measured.

If you want to freeze the display, press SCAN-key once. By pressing the SCAN-key once more the Sinuscan begins to scan again.



3.4.2 Copying measurements to the computer

Measurements stored in the memory of the Sinuscan 301 can be copied to the computer as follows:


- Connect the Sinuscan 301 and the computer with the USB-cable supplied.
- Perform a copy function with our computer.

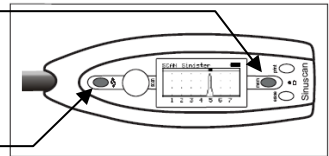
The Sinuscan display will show a text "USB Connected" while it is connected to the computer. All other functionality is denied while the computer is connected.

Sinuscan 301 will be shown on the computer as a removable storage. Measurements on the device memory will be shown on the USB storage as a CVS-files which could for example be imported to a spreadsheet. Copy the files of your choice to the computer for later use.

3.4.3 Reviewing the previous measurements

The measurements are kept in the memory when the unit is in OFF-stage. Previous measurements can be reviewed by turning the unit on with the MEM-key.

- Turn the unit on by pressing MEM-key.
- Select the measurement to be observed by using -key.




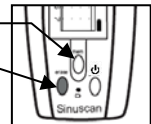
Existing measurements can be copied to the computer as described in the paragraph 3.4.2 "Copying measurements to the computer".

3.4.4 Deleting the measurements from the memory

The measurements are erased automatically when the unit is turned on by pressing the SCAN-key.

If you want to erase the measurements manually:

- Turn the unit on by pressing MEM-key.
- Press and hold the ERASE-key for two seconds. The display will show -symbol to indicate that all the measurements are erased.



3.5 Charging the Battery of the Sinuscan 301

The battery should be charged as soon as the battery icon in the display indicates that capacity is below one third of the full capacity.

Full battery:  Empty battery: 

To charge the battery of the Sinuscan 301 please note the following:

- The charger plug connector is located at the end of the device. The plug fits into the connector only in one position.
- Connect the charger plug to the Sinuscan 301 and connect the charger into the mains terminal.
- Charger shows a steady green light when operating
- Sinuscan 301 is blinking it's green charge indicator light when charging. If the battery is fully charged the green light is on continuously.
- Nominal charging time for empty battery is 8 hours.
- There is no possibility of overcharging even if the device is charged longer than 8 hours.

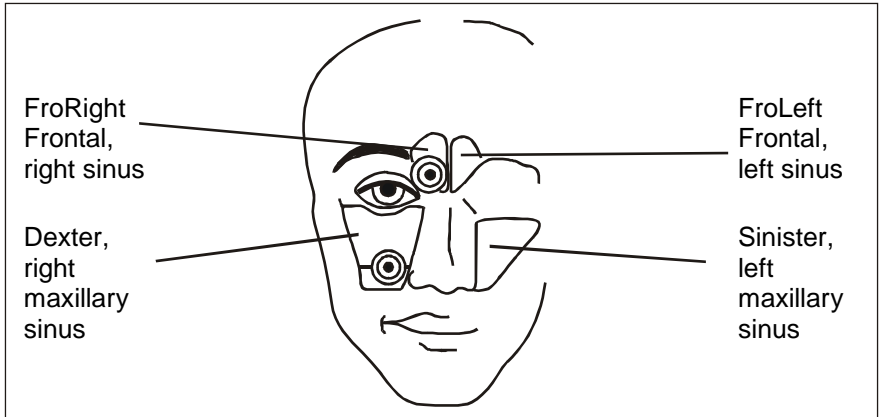
When fully charged the new battery will run approximately for 10 hours when scanning continuously.

The battery should be charged monthly if the device is not used. The battery should last a minimum of 500 recharge cycles before there is a need to replace it. Use only replacement battery packs available from the manufacturer. See the paragraph 8.4 "Accessories and Spare Parts".

If the device do not start due to empty battery and the charger indicator do not start to blink while charger is connected, the Sinuscan battery might be broken. See Paragraph 8.2 "Replacement of the Battery Pack".

4. THE EXAMINATION

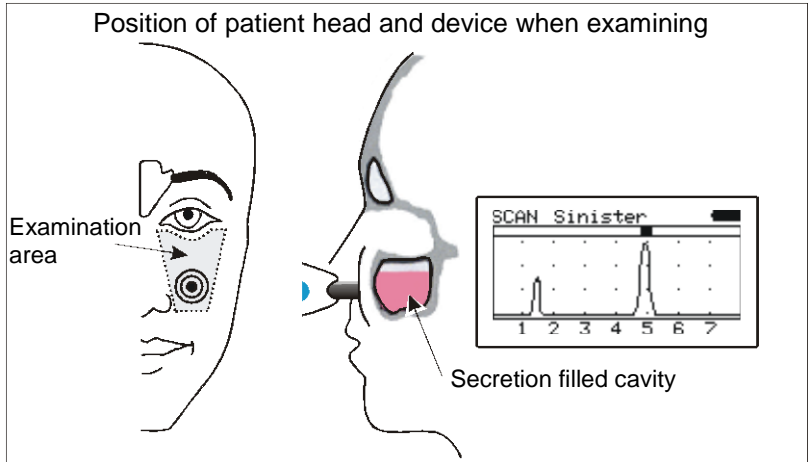
The exploration areas



4.1 Examining the Adult Maxillary Sinuses

- First explain the procedure to the patient.
- Study the functions of the device described in the paragraph 3.4 "Functions of the Sinuscan device / Quick test"
- Apply ultrasonic gel to the tip of the sensor. Direct the sensor towards the area to be explored and press the sensor gently to the skin.
- Aim the sensor at the protuberantia occipitalis, or medially and slightly downwards in the sagittal plane with the head upright. If echoes are displayed at a depth of 3.5 to 6 cm and you can repeat this display three times there is a high possibility that there is secretion in the cavity.
- Tilt slowly the probe up and down within the sector in order to find a probe position perpendicular to the rear wall. If no back wall echo is found, move the sensor in different sagittal planes, charting the exploration area in sectors.

Note! The instrument is adjusted so as to give echoes from the front wall area of a normal air-filled cavity indicated by a peak at 1 – 1.5 cm on the display. A sound pulse reflected back and forth between the crystal and the air surface may cause one repeated echo on the display from a completely normal cavity. The position of the patient's head must be observed, as tilting the head backwards may cause the fluid in the cavity to loose contact with the front wall, leading to loss of the back wall echo.



The boundaries for the sensor movement are formed by the lateral corner of the eye, the lower nasal border and lower orbital border as well as the side of the nose.

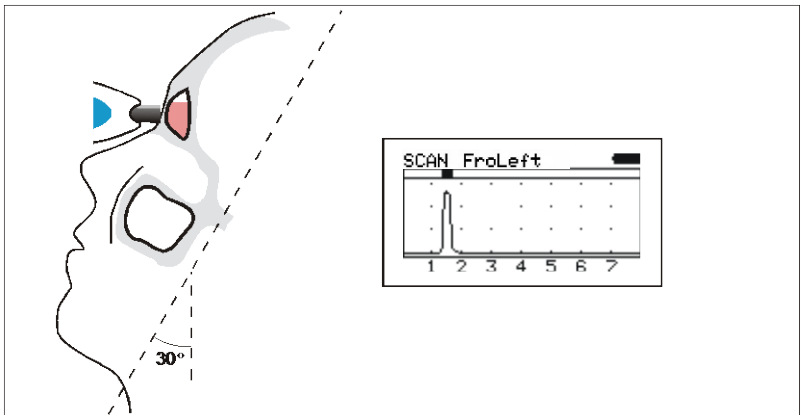
4.2 Examining the Adult Frontal Sinuses

- First explain the procedure to the patient.
- Apply ultrasonic gel to the tip of the sensor.
- Tilt the head back about 30 degrees in order to hold any fluid present in the cavity for the best pulse coupling to the rear wall.
- Position the probe against the base of the frontal sinus almost parallel to the nasal ridge and tilt slowly back and forth within a sector in the sagittal plane. A back wall echo from a cavity containing fluid is usually found at the depth of 1 – 3 cm.

Note! The location of the frontal sinus is difficult to define without previous X-ray pictures.

If previous X-ray pictures are not available, explore 2 cm on either side of the medial line.

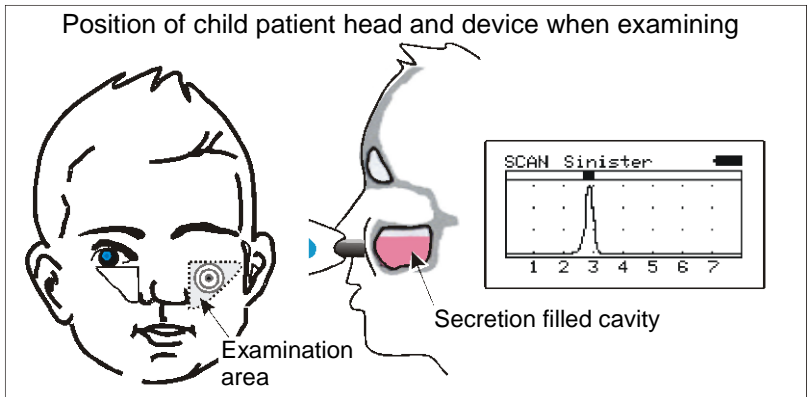
Note! If exploration is extended beyond these areas, spurious depth echoes may be received from, for instance, the orbit, the mandible, the base of the skull and the oral cavity.



4.3 Examining the Maxillary Sinuses of a Child

Position the probe on the cheek with its top edge below the lower border of the orbital and resting lightly against the side of the nose. The exploration area and aiming directions are the same as in the case of an adult patient, and the same applies to the sources of error. The back wall echo is found at the depth of 2 – 4 cm if there is liquid in the cavity.

Note! The maxillary sinuses of 3 year or older children can usually be explored.



The floor of the maxillary sinus is located relatively higher up in a child, and the exploration should begin by palpating the lower margin of the orbital.

4.4 Interpretation of the A-mode Display

The diagnosis information provided by the Sinuscan 301 device is whether there is or is not secretion in the cavity.

The device does NOT tell how much or what kind of secretion there is in the cavity.

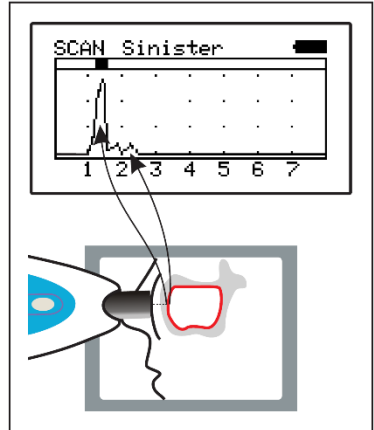
The height of the curve does not indicate that there would be more secretion than when the curve is lower.

To get the reliable result from the scan the user should perform the scanning of the same cavity three times and get the same result on each scan.

Below are some EXAMPLES of displays and how to interpret them. It is impossible to give exact examples, which would be valid for all patients, since the cavities of different people, as well as the measurement situations differ widely. Also the cavities for the same patient rarely are symmetric.

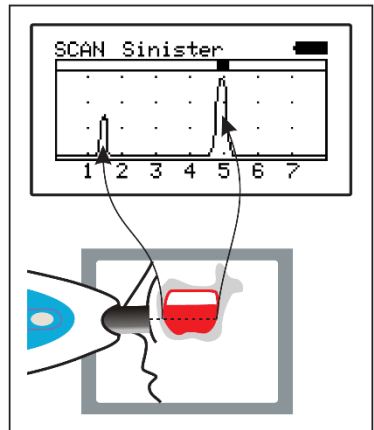
**Normal maxillary sinus.
No indication or indication
between 0 and 1,5 cm.**

Negative indication

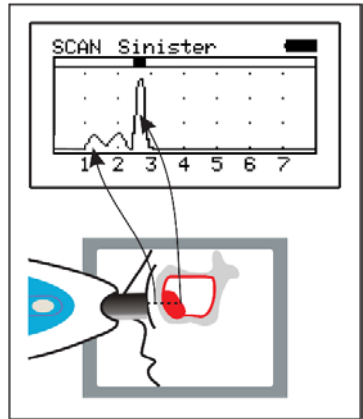


**Secretion in the maxillary sinus.
Indication between 3,5 and 6 cm.**

Positive indication

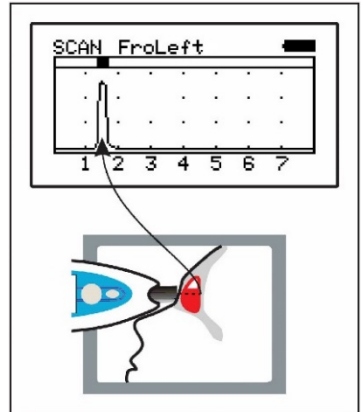


**Cyst or polyp in the maxillary sinus.
Indication between 2 and 3 cm.**



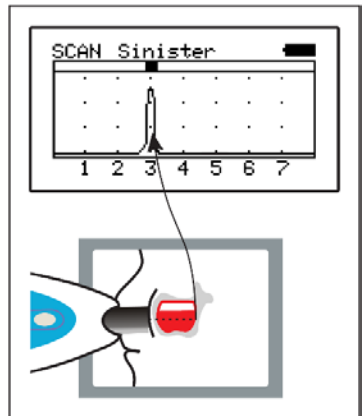
**Secretion in the frontal sinus.
Indication between 1 and 3 cm.**

Positive indication



**Secretion in the maxillary sinus
of a child. Indication between 2 and
4 cm.**

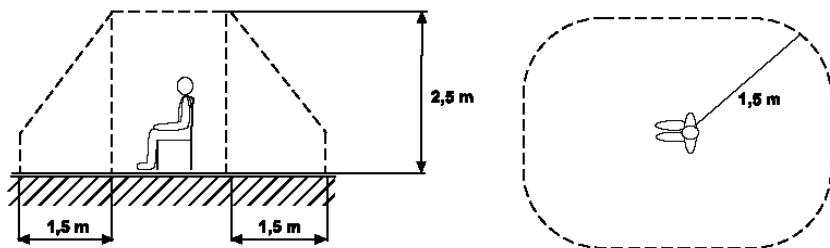
Positive indication



5. USE, TRANSPORT AND STORAGE CONDITIONS

5.1 Patient Environment

Patient environment is described below:



5.2 Use, Transport and Storage Conditions

The device is capable of use, transport and storage in environmental conditions within the following ranges:

	Ambient Temperature	Relative Humidity	Note
Use	10 – 35 C	20 – 90 %	non-condensing
Transport	0 – 40 C	10 – 90 %	non-condensing
Storage	0 – 40 C	10 – 90 %	non-condensing

6. CLEANING

Clean Sinuscan 301 between each patient.

Clean the device, cables and power supply as described below:

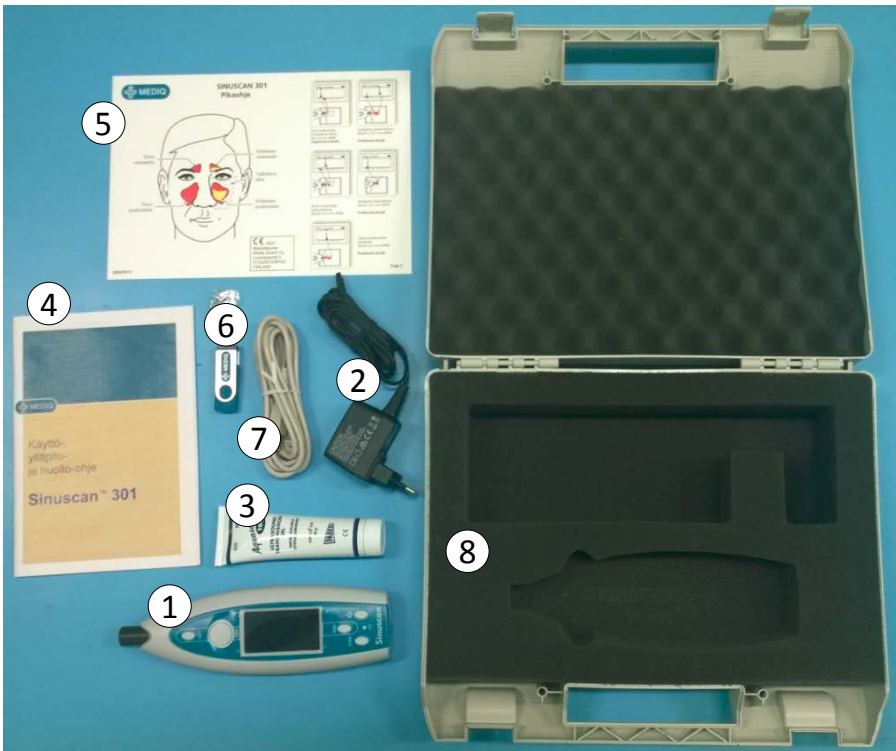
- Disconnect the charger if connected.
- Use clean tissue or cotton lightly moistured with 50-70% isopropanol. Take care that no water or other liquids enter inside the device or connectors. Do not use a wet tissue, a lightly moistured tissue is enough.
- Dry the surfaces with dry tissue if needed.

Note! Never use ethanol or any other dissolvent, silicone based or abrasive cleaning liquids.

7. CONTENTS OF THE PACKAGE

The main components of the Sinuscan delivery are:

- 1) Sinuscan 301 ultrasonic scanner
- 2) Battery charger of Sinuscan 301
Friwo FW8002M/12 with euro or UK adapter
- 3) Gel tube 60 g (Ultrasound transmission gel)
- 4) Manual
- 5) Quick Reference Guide
- 6) Info-USB memory
- 7) USB-cable
- 8) Carrying Case



8. MAINTENANCE AND SERVICE

8.1 Service and Calibration

There are no serviceable parts inside the device and it doesn't need any calibration. If there are any problems with the device, contact your dealer.

8.2 Replacement of the Battery Pack

Note! Do not use any other battery pack than the one designed for the Sinuscan 301 and delivered by the manufacturer.

The battery is already installed when the device is delivered. When it is time to change the battery, follow the steps below:

- Open the screw with torx T10 screwdriver and remove the battery cover.
- Lift the battery slightly.
- Release the wire connector from the connector on the circuit board.
- Connect a new battery wire connector to the connector on the circuit board.
- The terminal fits to the connector only in one position – don't use excessive force. Check the proper connection.
- Place the battery in the battery compartment.
- Route the wire to prevent it to be pressed between the covers.
- Replace the battery cover and tighten the screw.

Note! Use only the battery designed to the device. Use of other types of batteries may create a safety hazard.

The use of conducting wrist strap connected to the earth potential is recommended.

Only qualified technical personnel may perform the maintenance.


8.3 Troubleshooting

Check the proper operation of the device as described in paragraph 3.4 "Functions of the Sinuscan device / Quick test".

If the equipment doesn't start or works only for a while, the battery has to be recharged. See paragraph 3.5 "Charging the Battery of the Sinuscan 301"

If the Quick Test will not show any echoes:

- Check that there is sufficient amount of gel on the tip of the sensor
- Check that there is enough water or gel in the bottle

The device can be forced to restart by holding the -key and then pressing the ERASE-key. This resets the whole device and may cause loss of the measurement data.

8.4 Accessories and spare parts

The following accessories and spare parts for the Sinuscan 301 are available on the manufacturer:

- Battery 34676
- Battery Charger
universal:.....Friwo FW8002M/12
- Sensor (including instructions for replacing the sensor)
- Ultrasound Gel
- USB-cable

9. TECHNICAL SPECIFICATIONS

Sinuscan 301:

Sensor	Ultrasound crystal, \varnothing 8 mm
Acoustic frequency	3.0 MHz
Peak-negative acoustic pressure	< 1 MPa
Output beam intensity	< 20 mW / cm ²
Spatial-peak temporal-average int.	< 100 mW / cm ²

Battery: 6 V / 730 mAh NiMH

Battery Charger:

Models accepted for Sinuscan 301 Battery Charging:

Universal: Friwo FW8002M/12	in: 100 – 240V AC, 50 – 60 Hz/250mA out: 12 V DC/800mA
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Charger type FW8002M/12 adapter assembly

Charging time 8 hours from empty battery to the full charge

10. MANUFACTURER

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FINLAND

tel. +358 20 112 1500

fax +358 20 112 1501

Web sites:

Company site: www.mediq.fi

Product site: www.mediq.fi/sinuscan

Manufacturer's ISO 9001 and ISO 13485 certificate

Device's EC-certificate with attachments

Manufacturer's Declaration of conformity

11. DISCARDING THE DEVICE

Within the European Union the product must be taken to separate collection at the product end-of-life. For other areas please note that the following components demand special treatment while discarding:

- Battery, type NiMH

Follow local rules of discarding the unit. The other choice is to send the whole device to the manufacturer for discarding.

12. EMC-information

The Sinuscan 301 meets the requirements of the EMC-standard IEC 60601-1-2 for Medical electrical equipment. Medical electrical equipment needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided here.

Fixed RF transmitters, portable and mobile RF communications equipment can affect to Sinuscan 301 and the table 3 is guiding to prevent from interferences.

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Table 1: Emission


Guidance and manufacturer's declaration – electromagnetic emissions		
The SINUSCAN 301 is intended for use in the electromagnetic environment specified below. The customer or the user of the type device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishment, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable, active input power <50 W	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2: Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The SINUSCAN 301 is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2,4,8,15 kV air	±8 kV contact ±2,4,8,15 kV air	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	±2 kV for power supply lines	±2 kV for power supply lines	Occasional false echoes may occur even with mains power quality of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	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	<5 % U_t (>95% dip in U_t) for 0.5 cycle 0,45,90,135,180,225,270,315 degr. phase <5 % U_t (95% dip in U_t) for 1 cycle 0 degr. phase 70 % U_t (30 % dip in U_t) for 25 cycles 50 Hz (30 cycles for 60 Hz) <5 % U_t (>95% dip in U_t) for 5 sec 0 degr. phase	<5 % U_t (>95% dip in U_t) for 0.5 cycle 0,45,90,135,180,225,270,315 degr. phase <5 % U_t (95% dip in U_t) for 1 cycle 0 degr. phase 70 % U_t (30 % dip in U_t) for 25 cycles 50 Hz (30 cycles for 60 Hz) <5 % U_t (>95% dip in U_t) for 5 sec 0 degr. phase	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	This test level assumes a minimum distance between the Sinuscan 301 and sources of power frequency magnetic field of at least 15 cm.

Note: U_t is the a.c. mains voltage prior to application of the test level

Table 3: Immunity in RF-field

Guidance and manufacturer’s declaration – electromagnetic immunity			
The SINUSCAN 301 is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 to 80 MHz	3 Vrms	
	6V in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz	6 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SINUSCAN 301, including cables than the 30 cm separation distance. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: <div style="text-align: center;">  </div>
Proximity fields from RF wireless communications equipments IEC 61000-4-3	385 MHz Pulse Modulation: 18Hz 27 V/m	27 V/m	
	450 MHz 50 % pulse modulation at 18Hz 28 V/m	28 V/m	
	710, 745, 780 MHz Pulse Modulation: 217Hz 9 V/m	9 V/m	
	810, 870, 930 MHz Pulse Modulation: 18Hz 28 V/m	28 V/m	
	1720, 1845, 1970 MHz Pulse Modulation: 217Hz 28 V/m	28 V/m	
	2450 MHz Pulse Modulation: 217Hz 28 V/m	28 V/m	
	5240, 5500, 5785 MHz Pulse Modulation: 217Hz 9 V/m	9 V/m	
Note 1: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz. Note 2: 50 % duty cycle is used for pulse modulation.			
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 RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SINUSCAN 301 is used exceeds the applicable RF compliance level above, the SINUSCAN 301 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SINUSCAN 301.			

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