MEDIQ

User Manual

Use, Maintenance and Service of the

Sinuscan™ 201

34679

Version 1.8

This User Manual is updated and checked 17.Oct. 2013

TABLE OF CONTENTS

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 201"

For accepted types of Battery Chargers see paragraph 10 "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 8.0 "Maintenance and Service".
- 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 8.0 "Maintenance and Service".
- To charge the battery of the Sinuscan 201 –device use only 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. 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".
- Do not connect the USB cable to the device in the patient environment. Do not use the printer in the patient environment. See paragraph 5.1 "Patient Environment". The Sinuscan 201 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 201 system. See paragraph 2.3 "Sinuscan Components".
- Do not touch the printer, printer cable or any other non-medical electrical equipment and the patient simultaneously.
- Use only in chapter 3.4.3 listed printers, which are according to standard IEC60950 approved.

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 201 device is used in normal office environment.

The Sinuscan 201 –device will function as an aid for determining a diagnosis or as a base for further examinations. The Physician or doctor makes the diagnosis.

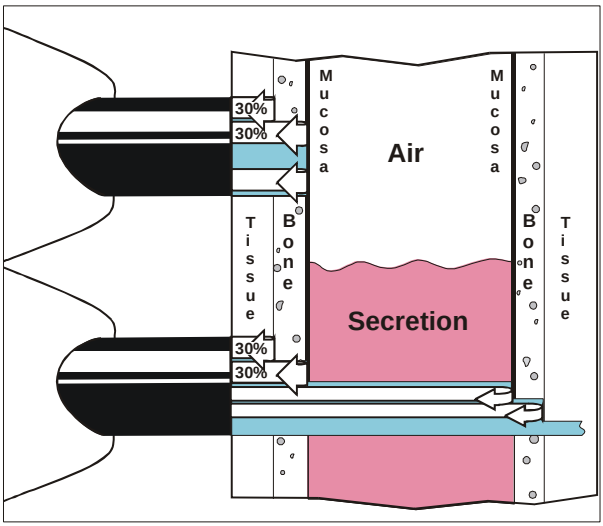
2. GENERAL

2.1 Intended use

This instrument is designed for detecting anomalities 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 LCD 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
- Printer supporting the PictBridge protocol. (Not included in the Sinuscan 201 delivery)

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 201 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.

The printer (not included) supporting PictBridge protocol can be connected to the Sinuscan device to print the measurements. The Printer is connected to the device using the USB cable. The square end of the cable is connected to the Sinuscan and the flat end of the cable to the printer respectively. More details about setting up the printer can be found in the Printer User Manual supplied with printer.

2.5 Sinuscan 201 Features

2.5.1 Orientation

The Sinuscan 201 can be set for right-hand or for left-hand use.

2.5.2 The exploration areas

The device can be set for two or for four exploration area modes. When the two-area-mode is selected, only maxillary sinuses (Sinister / Dexter) are examined / stored in the memory. In the four-area-mode: both maxillary and frontal sinuses are examined / stored.

2.5.3 Memory

Sinuscan 201 device has four memory locations to store measurements. The selection is shown on the display. New scan is stored over the previously stored measurement on the same location. If needed all the stored measurements can be erased from the memory.

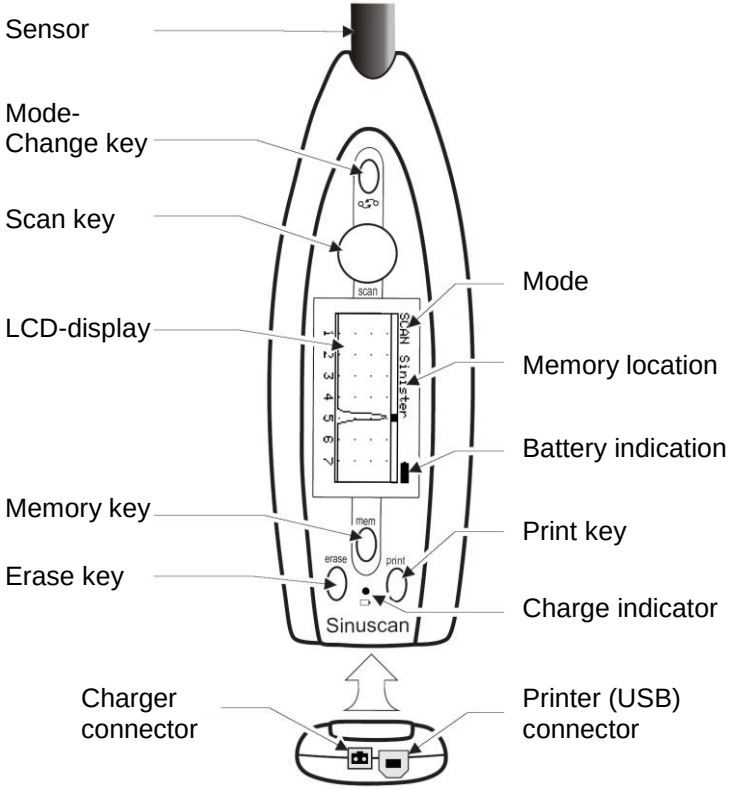
Memory locations:

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

2.5.4 Factory Settings

Device is pre-set for examination of maxillary sinuses (Sinister and Dexter) and for right-hand-use.

If you wish to use the unit as left-handed or wish to measure also frontals 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 201".

3.2 Description of the Keys

The Sinuscan 201 has five keys to operate the functions of the device.

If the Sinuscan is used without printing option just the SCAN –key and the  -key are needed for normal operation. The keys are:

- SCAN -key (turn the scanning ON/OFF)
- MEM -key (review measurements)
- ERASE -key (erase measurements)
- PRINT -key (print measurements)
- MODE-CHANGE -key  (to scroll the memory location and to change mode)

3.3 Operation Stages of the Device

The device has the following stages of operation:

- off (OFF)
- scanning (SCAN) (live graph)
- memory review (MEM) (freezed graph)
- settings / info (INFO)

3.3.1 Off (OFF)

The device goes automatically to the OFF –stage if no key is pressed for approx. three minutes.

The display of the device is blank in the OFF –stage.

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.

The device can be forced to the OFF stage by holding the  - key and then pressing the ERASE -key. (RESET) (May cause loss of the measurement data).

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
- print the measurements stored by pressing the PRINT –key once.
- erase the measurements by pressing the ERASE –key for three seconds. The display will show –symbol to indicate that all the measurements are erased.

Sinuscan 201 device 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 (Sinister)
- Dexter, right maxillary sinus (Dexter)
- Frontal, left sinus (FroLeft)
- Frontal, right sinus (FroRight)

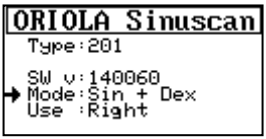
3.3.4 Settings / info, INFO-stage

When the device is not connected into charger, you may turn the device into INFO –stage by the following procedure:

- Turn the unit OFF by holding the - key and then pressing the ERASE -key. (RESET)
- The unit switches off and the display goes blank

- 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:

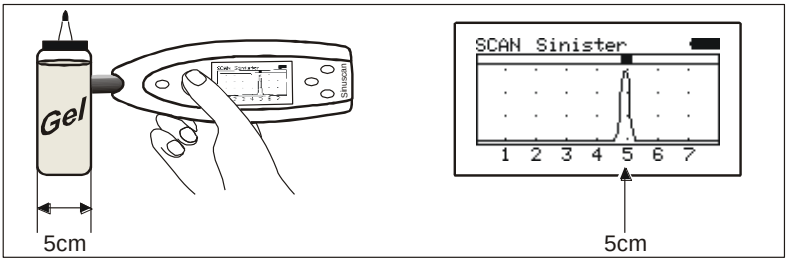
- select the left- or the right-handed use by moving the arrow in the display to the line "Use" with ⟲- key and then choosing: "Right" or "Left" by pressing the ERASE –key once.
- select the two exploration area mode (Sinister and Dexter) or alternatively the four exploration area mode (Sinister, Dexter, FroL and FroR) by moving the arrow in the display to the line "Mode" with ⟲-key and then choosing: "Sin + Dex" or "Sin + Dex + Fro" by pressing the PRINT –key once.
- adjust the contrast of the display by pressing the MEM –key. Observe the display when adjusting the contrast and press the MEM –key as many times as needed to set the contrast. (Four contrast levels).

The selection is automatically stored when leaving the settings / info –stage by pressing SCAN –key.

3.4 Functions of the Sinuscan Device / Quick Test

Applying some transmission gel on tip of the sensor and then directing the sensor to the side of a full gel bottle can check proper functions of the instrument. The back wall echo from a full gel bottle must show as a graph near the rear end of the display, at a distance of 4-5 cm. (5 cm if the gel bottle which is delivered with the Sinuscan unit is used)

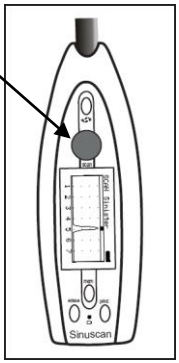
If no echo is found, please check if there is sufficient amount of gel in the bottle. For detailed information about troubleshooting the Sinuscan 201 see paragraph 8.3 "Troubleshooting"



3.4.1 Scanning without printing

To scan with the Sinuscan device:

- 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.



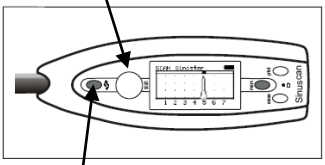
Repeat the procedure for cavities intended to be measured.

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

3.4.2 Scanning and Printing

If you want to print measurements:

- Turn the unit on by pressing the SCAN –key once.
- Start with the cavity shown on the display
- Put small amount of gel to the tip of the sensor
- Aim the sensor towards the selected exploration area and push the sensor *gently* at the skin
- Observe the display while slowly tilting and moving the sensor.
- As proper graph is obtained, press SCAN –key to freeze the graph.



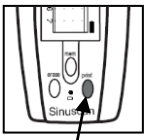
- Select the subsequent area to be explored by using -key and start over.

When all the cavities are scanned, print the measurements as described in the paragraph 3.4.3 "Printing the Measurements".

3.4.3 Printing the measurements (Printer is not included)

Measurements stored in the memory of the Sinuscan 201 can be printed as follows:

- A list of printers which can be connected to the Sinuscan 201 device and which support the PictBridge Protocol* can be found at the end of this paragraph.
- Prepare the printer as described in the user manual of the printer. Switch the printer on.
- Connect the printer to the Sinuscan with the USB –cable supplied.
- Start the printing by pressing PRINT –key.

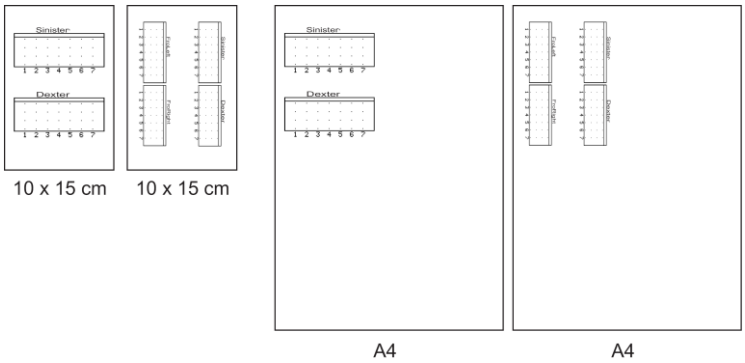


The Sinuscan display will show a text "PRINTING…" during the printing. Depending on the selected mode, two or four measurements are printed.

To change the mode, please see the paragraph 3.3.4 "Settings / info".

The layout of the printout varies depending on the printer used.

The recommended paper size is 4 x 6 inches (10 x 15 cm). The A4 size can also be used. The normal printouts are shown below:



Measurements are printed to the left corner of the paper to speed up the printing process.

If printing is interrupted for paper error, printer running out of ink or any other printer related issue, please refer the instruction manual for printer.

Keep the printer and printer cable away from the Patient Environment for safety reasons. Connect the printer cable to the Sinuscan 201 outside of Patient Environment.

* PictBridge is a protocol with which you can print photographs and which is commonly used by many printer manufacturers.

Supported PictBridge printers:

Canon	PIXMA IP90
Canon	PIXMA IP100
Canon	PIXMA IP2000
Canon	PIXMA IP3000
Canon	PIXMA IP3300
Canon	PIXMA IP3600
Canon	PIXMA IP4000
Canon	PIXMA IP4200
Canon	PIXMA IP4850
Canon	PIXMA IP5000
Canon	PIXMA IP5200
Canon	PIXMA IP6000

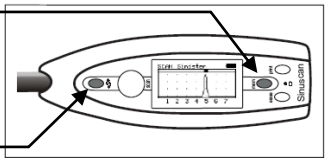
Hewlett-Packard; only with paper size 4 x 6 inches (10 x 15 cm)

Hewlett-Packard	Deskjet 6620
Hewlett-Packard	Deskjet 6840

3.4.4 Reviewing the previous measurements

The measurements are automatically stored in the memory when the unit is in OFF –stage. 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.



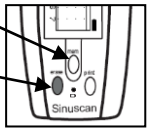
Stored measurements can be printed as described in the paragraph 3.4.3 "Printing the Measurements".

3.4.5 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:

- Press MEM –key.
- Press and hold the ERASE –key for three seconds. The display will show –symbol to indicate that all the measurements are erased.



3.5 Charging the Battery of the Sinuscan 201

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

Full battery:  Empty battery: 

To charge the battery of the Sinuscan 201 device please note 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 device and connect the charger into the mains terminal.
- Charger shows a steady green light when operating
- The green light *on the Sinuscan 201* is blinking when charging. When the battery is fully charged the green light is on continuously
- Nominal charging time for empty batteries is 14 hours
- There is no possibility of overcharging even if the device is charged longer than 14 hours

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

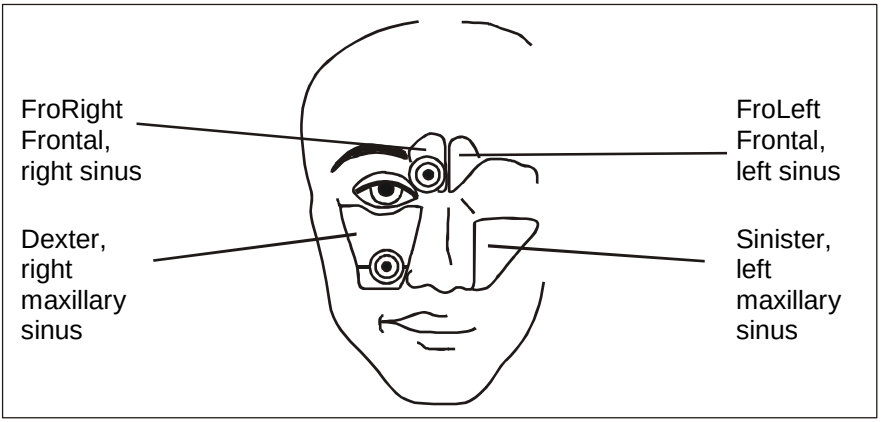
If the device is not used the battery should be charged monthly. The battery should last a minimum of 300 recharge cycles before there is a need to replace it. Use only replacement battery packs available from manufacturer. See the paragraph 8.4 "Accessories and Spare Parts".

When the Sinuscan 201 has been in stock or unused for a longer period, and hence the battery is completely empty, it is possible that problems with charging occur: i.e. that the device does not begin to charge the battery as it should as described in point 3.5. If this is the case please solve the problem as follows:

1. Connect the charger to Sinuscan 201 and wait for 15 min.
2. If the green charging light begins to blink after 15 min the charging of the battery is working as it should
3. If the green charging light does not blink but lights continuously then: push “mode change key” (please look at page 6) and “erase key” simultaneously approx. 3-5 min. In this way you get the device to RESET mode. If the green light after this begins to blink again the charging works normally. If the charging light does not begin to blink then repeat the process.

4. THE EXAMINATION

The exploration areas

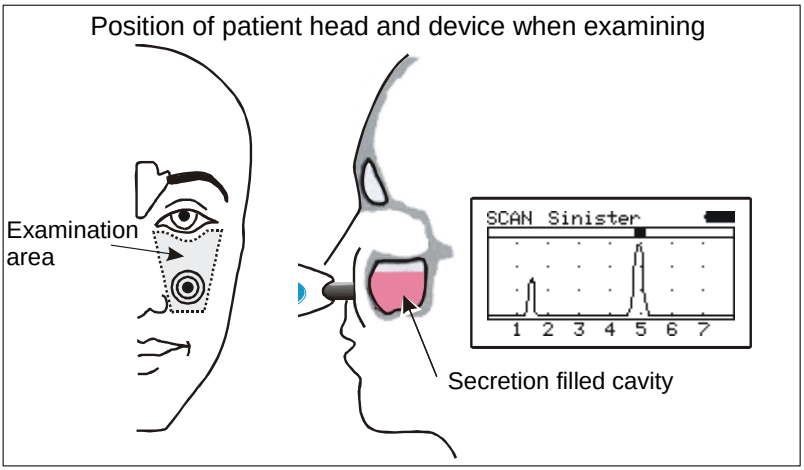


4.1 Examining the Adult Maxillary Sinuses

- 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.

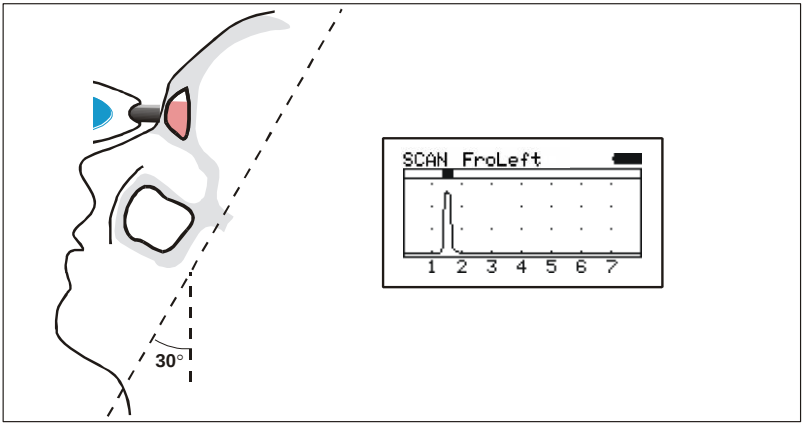
4.2 Examining the Adult Frontal Sinuses

- 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.

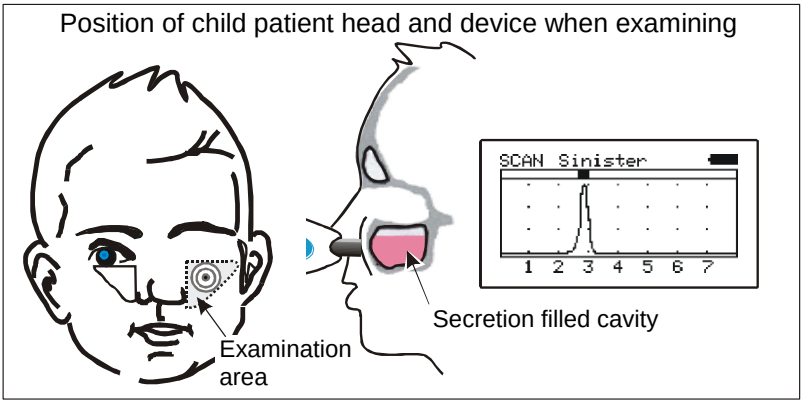
Note: If exploration is extended beyond these areas, spurious depth echoes may be received from, for instance, the orbit, the mandible, the base of the skull and the oral cavity.



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 201 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.

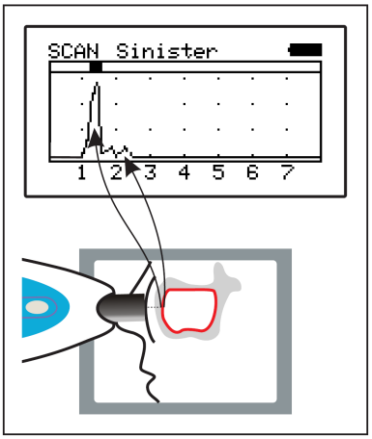
The height of the curve does not indicate that there would be more secretion than when the curve is lower.

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.

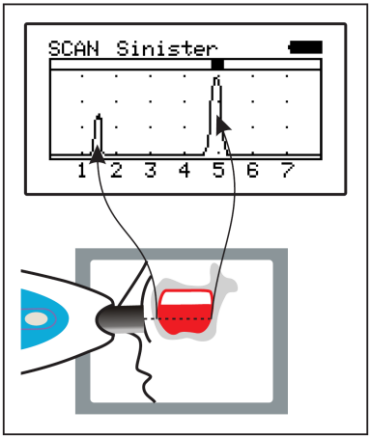
Normal maxillary sinus.
No indication or indication between 0 and 1,5 cm.

Negative indication

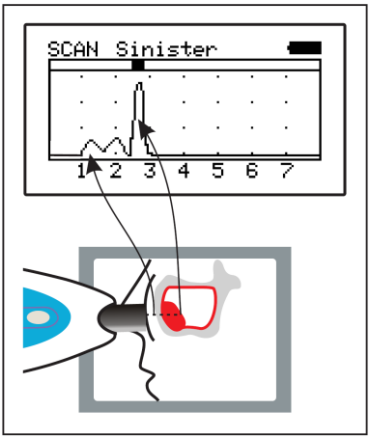


Secretion in the maxillary sinus.
Indication between 3,5 and 6 cm.

Positive indication

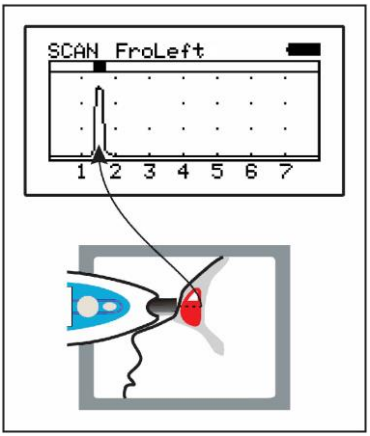


Cyst or polyp in the maxillary sinus. Indication between 2 and 3 cm.



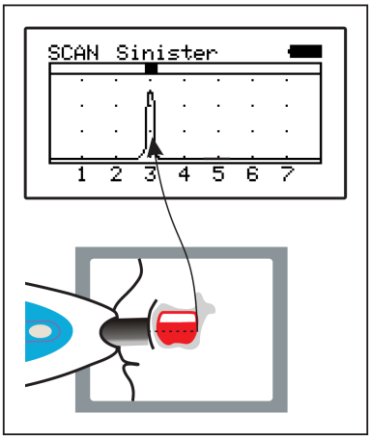
Secretion in the frontal sinus. Indication between 1 and 3 cm.

Positive indication



Secretion in the maxillary sinus of a child. Indication between2 and 4 cm.

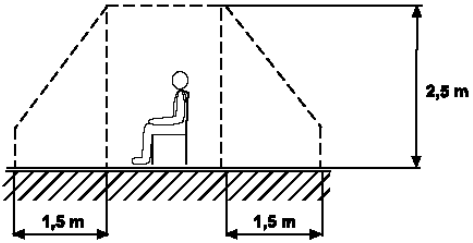
Positive indication

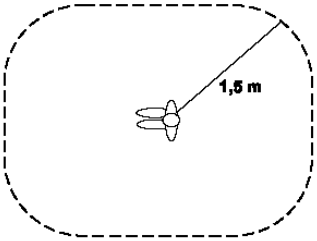


5. USE, TRANSPORT AND STORAGE CONDITIONS

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

Between each patient clean the device as described below:

Clean the device, cables, power supply and the printer 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 201 ultrasonic scanner
2) Battery charger of Sinuscan 201
   Friwo FW7660M/12 with euro or UK adapter
   euro:Friwo FW7333M/12
   UK: Friwo FW7333M/12 UK
   universal: Friwo FW7555M/12
   } only one charger is included
3) Gel tube 60 g (Ultrasound transmission gel)
4) Manual
5) Quick Reference Guide
6) Info-USB memofy
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 201 –device and delivered by the manufacturer.

The battery is already installed in 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 201"

If the Quick Test will not show any echoes:

- Check that there is sufficient amount of gel on the tip of the sensor
- Check if there is enough gel in the bottle
- Check the battery indicator on the display of the Sinuscan 201 device

In the case of malfunction contact your distributor.

8.4 Error messages

The device may identify some problems while printing and shows on the display next error codes:

- error code: 100, no more paper in the printer
- error code: 101, no more ink in the printer
- error code: 102, nonspecified printing problem

8.5 Accessories and spare parts

The following accessories and spare parts for the Sinuscan 201 are available on the manufacturer:

- Battery 34676
- Battery Charger
  universal:……Friwo FW7660M/12
  euro:..... Friwo FW7333SM/12
  UK: ..... Friwo FW7333SM/12 UK
  universal: ..... Friwo FW7555M/12
- Sensor (including instructions for replacing the sensor)
- Ultrasound Gel
- USB –cable

9. TECHNICAL SPECIFICATIONS

Sinuscan 201:

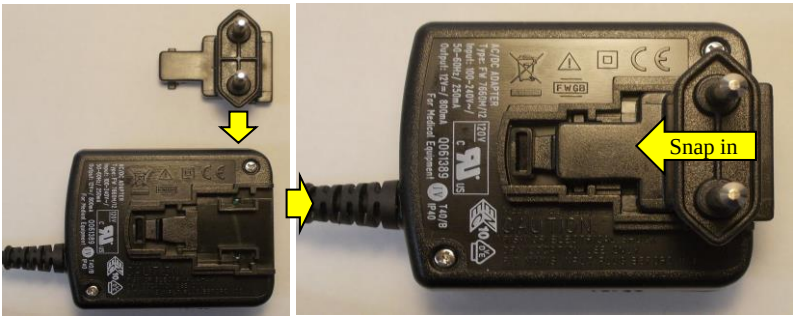
Sensor	Ultrasound crystal, ∅ 8 mm
Acoustic frequency	3.0 MHz
Peak-negative acoustic pressure	< 1 MPa
Output beam intensity	< 20 mW / cm^2
Spatial-peak temporal-average int.	< 100 mW / cm^2

Battery: 6 V / 730 mAh NiMH

Battery Charger:

Models accepted for Sinuscan 201 Battery Charging:

Universal:	Friwo FW7660M/12	in: 100 – 240V AC, 50 – 60 Hz/250mA out: 12 V DC/800mA
Euro:	Friwo FW7333SM/12	in: 100 – 240V AC, 50 – 60 Hz/200mA
UK:	Friwo FW7333SM/12	out: 12 V DC/700mA
Euro:	Friwo FW7555M/12	in: 100 – 240V AC, 50 – 60 Hz/400mA out: 12 V DC/1,25mA



Charger type FW7660M/12 adapter assembly

Charging time: 14 hours from empty battery to the full charge

10. MANUFACTURER

Mediq Suomi Oy
Luomanportti 3
FIN-02200 ESPOO
FINLAND
tel. +358 20 112 1500
fax +358 20 112 1501
Web sites:
Company site: www.mediq.fi
Product site: www.mediq.fi/sinuscan

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
- Lead in solder tin on printed circuit board.

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 201 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 201 and the tables 3 and 4 are guiding to prevent from interferences.

The device is suitable for use in all establishments, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Table 1: Emission

Guidance and manufacturer's declaration – electromagnetic emissions		
The SINUSCAN 201 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, Class D	Not applicable, active input power <50 W	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2: Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The SINUSCAN 201 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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 ±1 kV for input/output lines	< ±1 kV for input/output 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 ±2 kV common mode	±1 kV differential mode ±2 kV common 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 40 % U_t (60% dip in U_t) for 5 cycle 70 % U_t 30 % dip in U_t) for 25 cycle <5 % U_t (>95% dip in U_t) for 5 sec	<5 % U_t (>95% dip in U_t) for 0.5 cycle 40 % U_t (60% dip in U_t) for 5 cycle 70 % U_t 30 % dip in U_t) for 25 cycle <5 % U_t (>95% dip in U_t) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

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 201 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SINUSCAN 201, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**: $d = 1,2\sqrt{P}$ 80 MHZ to 800 MHZ $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (**m**). 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: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) 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 201 is used exceeds the applicable RF compliance level above, the SINUSCAN 201 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SINUSCAN 201.			

Table 4: Separation distances

Recommended separation distances between portable and mobile RF communications equipment and Sinuscan 201			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sinuscan 201 as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in meters **(m)** can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

13. APPENDIX

13.1 Certificate

LRQA
Business Assurance

CERTIFICATE OF APPROVAL

This is to certify that the Management System of:

Mediq Suomi Oy
Luomanportti 3, 02200 Espoo, Finland
Koskelonkuja 4, 02920 Espoo, Finland

has been approved by Lloyd's Register Quality Assurance
to the following Standards:

ISO 9001:2008
ISO 13485:2012

The scope of this approval is applicable to:

Import, marketing, sales and distribution of medical equipment and supplies and laboratory products, installation, repair and maintenance of medical and laboratory equipment. Manufacturing of medical products.

Approval
Certificate No: HEQ6016647

Original Approval: 12 April 2010 (DNV)
Current Certificate: 18 February 2013
Certificate Expiry: 17 February 2016

Issued by: Lloyd's Register Quality Assurance Ltd,
Branch Office Finland for and on behalf of LRQA Ltd

UKAS MANAGEMENT SYSTEMS
001

This document is subject to the provision on the reverse
Aleksanterinkatu 48 A, 00100 Helsinki, Finland
For and on behalf of 71 Fenchurch Street, London EC3M 4BS United Kingdom
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001
Mediq Revision 13

13.2 Declaration of conformity

DECLARATION OF CONFORMITY

Manufacturer:	**Mediq Suomi Oy** **Luomanportti 3** **FIN-02200 ESPOO** **FINLAND**
Declaration that the Product:	**Sinuscan ultrasound instrument, type 201, with power supplies Friwo FW7333M/12 or Friwo FW7333M/12 UK or Friwo7555M/12 Conforms to the following European Union directives and standards identified in this declaration.**
Technical File:	**Issued for Sinuscan 201, level 1.5**
EC Product Class:	**IIa**
EU Directive:	**93/42/EEC, Medical devices**
Conformity Assessment Procedure:	**Annex VI, Quality system is verified by VTT Technical Research Centre of Finland – Notified Body No 0537 (EC Certificate No. TUO1027-188)**
Standards:	**ISO 14971;2003, Medical devices – Application of risk management to medical devices IEC 60601-1+A1+A2 Medical electric equipment: Part 1 general requirements for safety** **IEC 60601-1-1, General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.** **IEC 60601-1-2, Medical electric equipment: Part 1: General requirements for safety.2. Collateral Standard : Electromagnetic compatibility – Requirements and tests IEC 60601-2-37, Medical electrical equipment – Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment** **IEC 61157, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment**
Signature:	**16th August 2011, Espoo**

Ilari Vaalavirta
CEO
Mediq Suomi Oy

Pasi Hotinen
Sales Director
Mediq Suomi Oy

VTT EXPERT SERVICES LTD

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer:	Mediq Suomi Oy Luomanportti 3 02200 Espoo Finland
Coverage of Certificate:	Final inspection
Product category:	Ultrasound diagnostic equipment
Valid until:	22nd April 2018

The manufacturer´s quality system for the final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex VI Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex VI in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Tampere, 22nd April 2013

VTT EXPERT SERVICES OY VTT EXPERT SERVICES LTD

Mika Riihimaa

Tuomas Toivonen

Certificate no.

VTT-C-9718-01-1027-488-13

Notified Body no. 0537:
VTT Expert Services Ltd.
P.O. Box 345 (Tekniikankatu 1)
FI-33101 TAMPERE
FINLAND
Tel.+358 20 722 111

VTT EXPERT SERVICES LTD

Attachment 1 to the Certificate number: VTT-C-9718-01-1027-488-13

Manufacturer:	Mediq Suomi Oy Luomanportti 3, 02200 Espoo Finland
Activity and product category:	Final inspection of ultrasound diagnostic equipment
Products:	The certificate covers the following products:

Name	*Brand name*	*Model*	*Class*
Ultrasound diagnostic equipment	Sinuscan	201	IIa

Date:	Tampere, 22.4.2013

Mika Riihimaa

VTT EXPERT SERVICES OY VTT EXPERT SERVICES LTD

Tuomas Toivonen

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.

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