Sigma M

User Manual

INSTRUMENTARIUM

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Approved

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The original language of this manual is English.

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1 Sigma M system

1.1 INTRODUCTION

Thank you for purchasing Instrumentarium Dental Sigma M digital intraoral sensor.

The Sigma M sensor is intended for dental x-ray imaging. Sigma M produces high quality digital X-ray images of teeth and adjacent structures instantly without the need for film or chemicals. It allows the user to view, enhance, store, send and print images using the CliniView imaging software.

Two sensor sizes are available for various dental X-ray imaging needs.

Fig 1.1. Sigma M sensor size 1 and 2.

Sigma M sensor type size 1 (S1) is designed for taking anterior, periapical and periodontic images. The purpose of Sigma M sensor type size 2 (S2) is to capture bitewing and horizontal periapical images. The sensor type is marked on the main label (see chapter *Main label* for details).

The use of Sigma M system requires intraoral X-ray unit and a computer with a wireless network (Wi-Fi/Wlan) connectivity. USB port can be used for configuring the sensor or when the wireless (Wi-Fi/ Wlan) is temporarily unavailable.

It is assumed here that the sensor system is properly installed and configured to operate in a desired WLAN network. See Sigma M installation manual and this Sigma M user manual for instructions.

The Sigma M sensor is battery operated. The device is supplied with a rechargeable battery installed. Make sure that the battery is recharged prior the use of the sensor.

Instructions for the Sigma M use include the following manuals:

- Sigma M User Quick Guide
- Sigma M User Manual
- CliniView User Manual

Read all the instructions carefully before the Sigma M use.

1.2 MAIN PARTS OF THE SIGMA M DEVICE

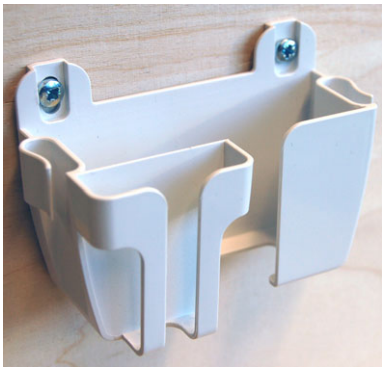
CONNECTORS

BATTERY COVER

1.3 ACCESSORIES

Sigma M Charger
- included in the sales package
- available in various type for local mains voltage and approvals. Consult the local distributor for correct type, If spare part is needed.

Magnet Mount
- included in the sales package
- the magnet place can be decided by the user
  (see page 9)
- can be used for mounting the device during the image capture procedure or during storage
- adhesive tape included for attaching the mount on tube head



Wall mount set
- included in the sales package
- for storage when not used and during battery charge
- screws for wall mounting included

WARNING!

Do not place the magnet on the cover of PC and monitor, or nearby a pacemaker.

USB cable
- included in the sales package

WARNING!

Use only USB cable delivered with the device to ensure proper operation according to specification.

Sigma M Sensor holders (optionally)
- available separately
- consult your local dealer for details

KerrHawe Sensor holders (optionally)
- available separately
- consult your local dealer for details

Hygienic covers
- available separately

SENSOR HOLDERS

When taking intraoral images it is necessary to keep the sensor parallel to the tubehead. Correct positioning is assisted with the help of KerrHawe or Sigma M sensor holders.

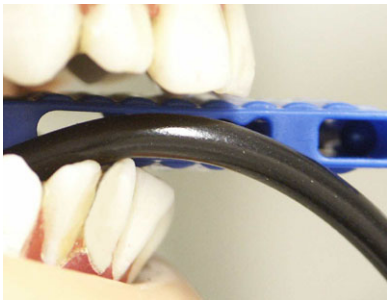
The sensor must be covered with a hygienic cover every time it is used. Only use hygienic covers similar to hygienic covers delivered with the Sigma M system by Instrumentarium Dental.

NOTE!

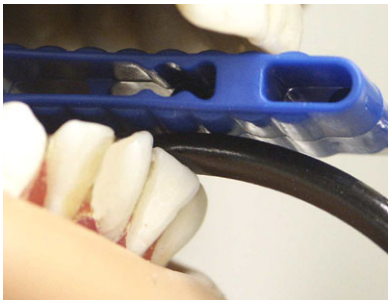
The covers are protected against touch but they are not sterile.

SENSOR CABLE PLACEMENT

To prevent the patient biting the sensor cable, lead the cable alongside the holder as instructed below:



CORRECT



INCORRECT

1.4 BATTERY

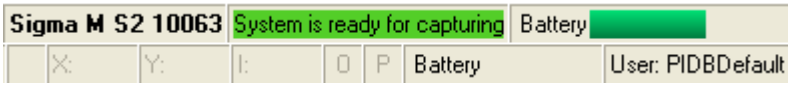
- Sigma M Battery, Spare part number: 5169795

WARNING!

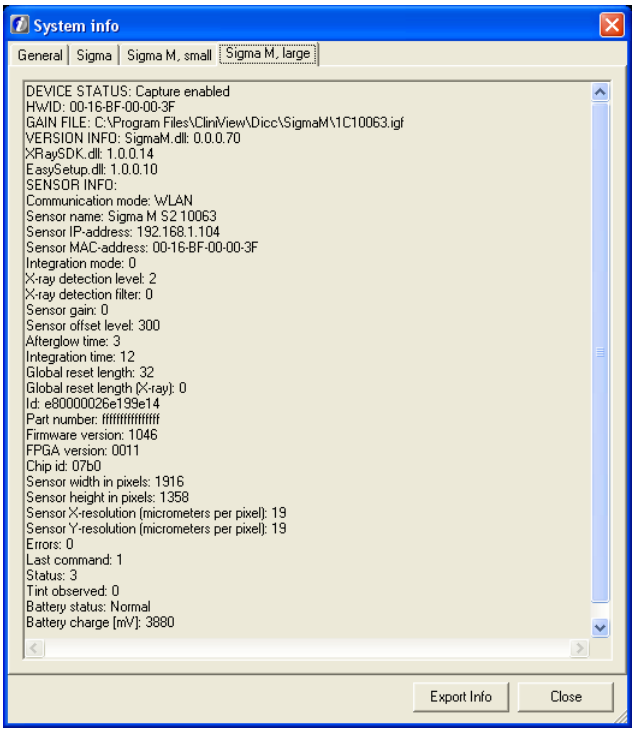
Replace the battery only with Instrumentarium Dental Sigma M battery, part no. 5169795. Charging with equipment other than the original Sigma M charger may cause heat generation or cell leakage. Use of another battery may present a risk of fire or explosion. See instructions for replacing the battery.

CHECKING BATTERY STATUS

The remaining battery charge level is displayed in CliniView, next to the sensor status, when the sensor is in image capture mode.



The battery status can be checked also by clicking Help/system info (Sigma M sheet), when the sensor is in image capture mode.



If the battery´s voltage drops below 3700 mV, the CliniView software informs the user about low battery. Normal operation voltage is 3700-4200 mV. Below 3500 mV the sensor does not turn on.

REPLACING BATTERY

If battery operation has drastically decreased, a change of battery is recommended. Battery capacity will decrease over time.

The battery should be replaced at intervals of 1-3 years or after 500 recharge cycles. Replace only with original Sigma M battery (order part number 5169795). Opening the battery cover must be done so that the cover does not get damaged.

1 Switch off the Sigma M sensor and open the battery cover screw

2 Push the cover in the direction indicated by an arrow and remove the cover carefully. Make sure not to bend the cover when removing it. Disconnect the battery cable and dispose of the battery properly.

3 Replace with a new battery. Do not shortcut the poles of the battery, it may cause danger of explosion.

CAUTION!

The battery used in this device may present a fire or a chemical burn hazard if mistreated. Do not dissemble, heat to 100°C (212 F) or incinerate.

NOTE!

The battery is harmful to the environment and so it must be disposed of in accordance with local regulations.

WARNING!

The battery may explode if two poles are short-circuited.

2 Capturing intraoral images

2.1 BEFORE TAKING SENSOR INTO USE

Refer to chapter “Technical Specifications” and “Image Acquisition System Requirements” for hardware requirement.

1 Make sure the CliniView software (version 6.4.1 or later) has been installed properly.

2 Make sure the necessary WLAN equipments have been installed and WLAN network is working properly.

3 Make sure Sigma M sensor(s) has been properly configured to operate in the desired WLAN network. See *CliniView installation manual* and *Sigma M installation manual* for details.

4 The sensor unit is rechargeable battery operated. It is recharged with the included Sigma M charger. A daily recharge is recommended. Approximately 200 exposures can be taken with a fully recharged battery. Before using the sensor, make sure the battery has been recharged.
Connect the charger connector to the Sigma M charger. The sensor cannot be used when recharging batteries.

5 Disinfect the sensor and the cable before the patient work.

NOTE!

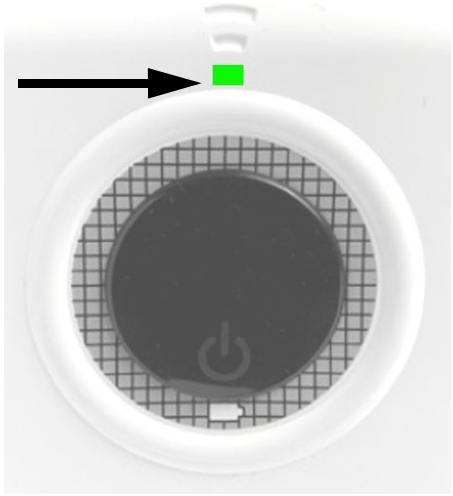
Use the magnet included in the sales package to mount the sensor on the X-ray tube head for ergonomic and efficient workflow.

NOTE!

Ask your sensor dealer for holder offering designed for the Sigma M sensor.

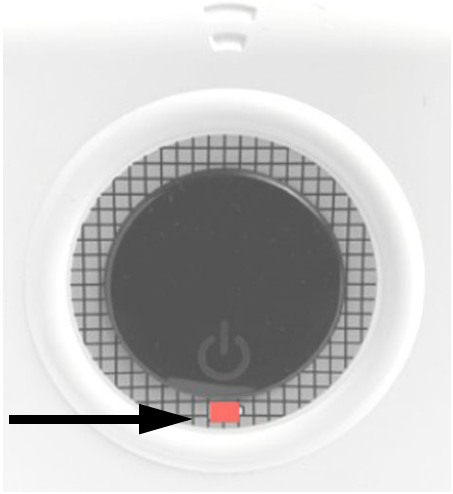
2.2 INDICATORS

Device status indicator

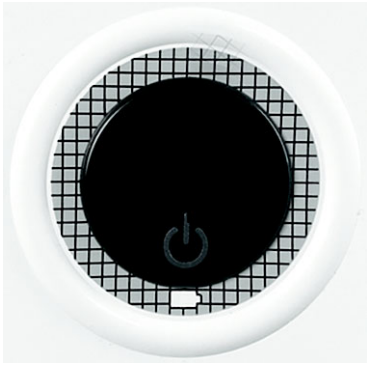


Indicator	Device status
Orange	Power on
Green	Ready for image capture
Green blinking	Image integration
Orange blinking	Image transmission

Battery status indicator



Indicator	Battery status
Orange blinking	Low battery (a few images can still be captured to complete the patient)
Orange blinking fast	Critically low battery (image capturing not recommended)
Orange	Battery charging
Off	Charge complete, battery is OK



2.3 CAPTURING IMAGE WITH ONE SENSOR

It is assumed here that one, either size 1 or size 2 sensor, is selected from the Installed device -menu on the CliniView software. It is also assumed that this sensor is selected as a default sensor device using the Tools-Intra-Sigma M settings -menu of the CliniView software. See the Sigma M installation manual for details.

1 Start CliniView software and select a patient.

2 Switch on the sensor by pressing the sensor power switch.

NOTE!

For efficient work flow the sensor and Cliniview capture mode can be turned on well before inserting the sensor into the patient's mouth. Consequently the system will be immediately ready for capture when the sensor is in place. If you forget to power the sensor at the beginning of the workflow you can do it also later before the image capture.

3 Protect the sensor with a hygienic cover and place the sensor on to the holder.

- Hold the hygienic cover with the paper side pointing downwards.
- Carefully insert the sensor between the white tab and the base paper.
- Peel away the upper transparent protective foil completely.
- Peel away the base paper completely from the underside.

4 Start image capturing in Cliniview by pressing the Start intraoral image capturing -button.

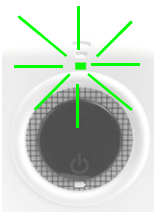
NOTE!

The exposure must be made within 15 minutes maximum after clicking the “Start intraoral image capturing” button, depending on the time-out setting in the CliniView software. As well as the CliniView time-out setting, the sensor also has a power off timer.

NOTE!

The other image capture icon can be used for capturing image using the template if several image are taken in series.

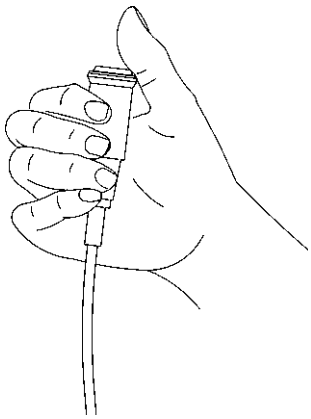
5 Position the sensor in the patient´s mouth. The sensor unit can be either on the patient's chest or with the magnetic mounting on the side of the X-ray unit tube head. Position the Intraoral X-ray unit as appropriate.



NOTE!

Make sure that the device status indicator illumates green before making the exposure.

6 Make the exposure by pressing the exposure button of the x-ray unit. Blinking status indicator on the device indicates image transfer.



NOTE!

If several images are captured in series, do not switch the sensor off between the exposures. The auto power off will turn the sensor off, if the sensor is not used approximately in 10 minutes.

7 After the image capturing click **Abort image capturing** button in CliniView.

1 When capturing is finished switch the sensor off, remove disposable covers and disinfect the sensor if necessary.

WARNING!

During the exposure cycle radiation the control protection guidelines must be observed.

WARNING!

Minimize the number of running programs before image capturing to ensure the necessary operating system resources for the process.

2.4 USING TWO SIZES OF SENSORS

It is assumed here that both sensor size 1 and sensor size 2 have been installed and enabled from the **installed device** -menu on the Cliniview software. It is also assumed that the appropriate sensor device has been configured as the default sensor device using the **Tools - Intra-Sigma M settings** -menu of the Cliniview software. See the Sigma M installation manual for details.

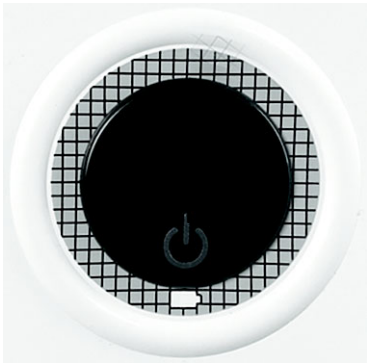
When both sensor sizes are installed, image capturing icons for both size 1 and size 2 sensors are displayed in the CliniView software. The image capturing can be started for either one or two sensors.

Buttons from left to right:
- Image capturing with template (size 2)
- Quick image capturing (size 2)
- Image capturing with template (size 1)
- Quick image capturing (size 1)

The image capture can be started as described in the previous chapter, with either of the sensors installed in the system. It is also possible to use both size 1 and size 2 sensor during one image capture session.

NOTE!

Both sensors can be activated simultaneously by clicking image capture icon of both sensor before exposure. The sensor that receive x-ray sends the image to CliniView. The other sensor remains ready for exposure.



If two sensors are activated simultaneously, there will be two sensor status bars on the PC screen.

1 Start CliniView software and select a patient.

2 Switch on the sensors to be used by pressing the sensor power switch.

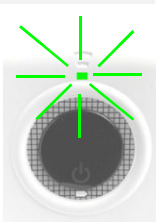
3 Protect the sensor with a hygienic cover and place the sensor to the holder.

4 Start image capturing in Cliniview by pressing the Start intraoral image capturing -button.

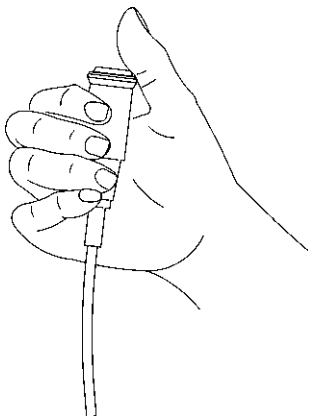
5 Position the sensor in the patient´s mouth. The sensor unit can be either on patient's chest or with the magnetic mounting on the side of the x-ray unit tube head. Position the Intraoral x-ray unit as appropriate.

NOTE!

Make sure that the sensor, which is intended to use is powered on and ready for image capture before exposure. Status indicator illuminates green when the sensor is ready.



6 Make the exposure by pressing the exposure button of the x-ray unit. Blinking status indicator on the device indicates image transfer.



NOTE!

If several images are captured in series, do not switch the sensor off between the exposures. The auto power off will turn the sensor off, if the sensor is not used approximately in 10 minutes.

7 After the image capturing click **Abort image capturing** button in CliniView.

8 When capturing is finished switch the sensor off, remove disposable covers and disinfect the sensor if necessary.

WARNING!

During the exposure cycle radiation the control protection guidelines must be observed.

WARNING!

Minimize the number of running programs before image capturing to ensure the necessary operating system resources for the process.

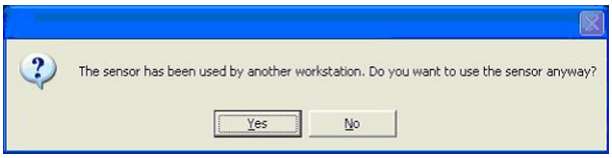
2.5 SHARING SENSOR WITH OTHER USERS

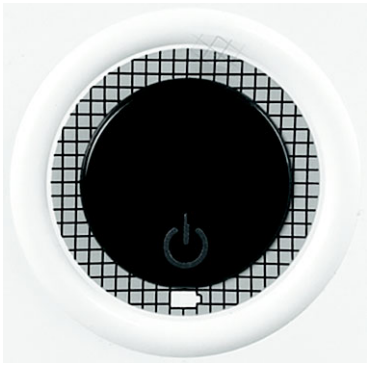
It is assumed here that two or more workstations in different rooms have been configured to operate in the same Sigma M network.

It is possible to use default sensor assignment for each room or alternatively select the sensor to be used from a list of available sensors in each image capture session. Select "Use preselected sensors" from Tools - Intra - Sigma M settings -menu to use default sensor assignment. See Sigma installation manual and user manual for details.

NOTE!

Several rooms can select one shared sensor as their default sensor device. The sensor allows only one user at a time. If the sensor has been previously used by someone else, the user is asked to confirm selection when activated to avoid unintentional connection to the sensor.



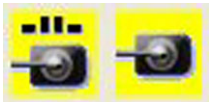


1 Start CliniView software and select a patient.

2 Switch on the sensors to be used by pressing the sensor power switch.

3 Protect the sensor with a hygienic cover and place the sensor on to the holder.

4 Start image capturing in CliniView by pressing the **Start intraoral image capturing** button of the appropriate sensor.

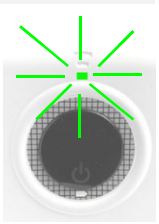


5 If default sensor assignment -mode is not used, select the desired sensor from the *Select device* dialogue that opens. If the sensor has been transferred from one room to another, the user will be notified that the sensor was previously assigned to another workstation.

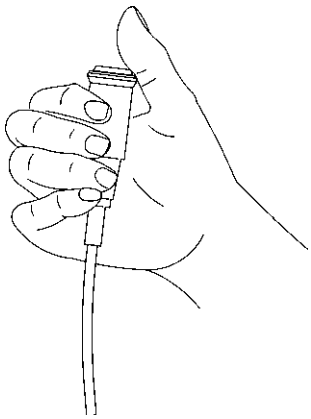
6 Position the sensor in the patient´s mouth. The sensor unit can be either on patient's chest or with the magnetic mounting on the side of the x-ray unit tube head. Position the Intraoral x-ray unit as appropriate.

NOTE!

Make sure that the device status indicator illuminates green before making the exposure.



7 Make the exposure by pressing the exposure button of the x-ray unit. Blinking status indicator on the device indicates image transfer.



NOTE!

If several images are captured in series, do not switch the sensor off between the exposures. The auto power off will turn the sensor off, if the sensor is not used approximately in 10 minutes.

8 After the image capturing click **Abort image capturing** button in CliniView.

9 When capturing is finished switch the sensor off, remove disposable covers and disinfect the sensor if necessary.

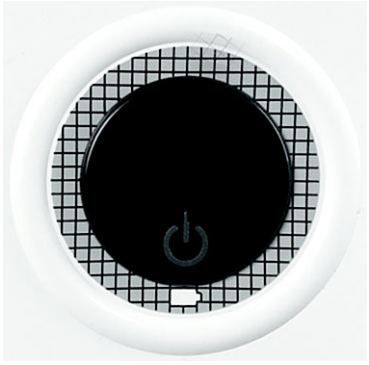
WARNING!

During the exposure cycle radiation the control protection guidelines must be observed.

WARNING!

Minimize the number of running programs before image capturing to ensure the necessary operating system resources for the process.

2.6 TAKING IMAGES WITH USB CABLE CONNECTED



NOTE!

The Windows XP operating system will open a Windows Explorer dialogue when Sigma M is connected via USB. Close this window.

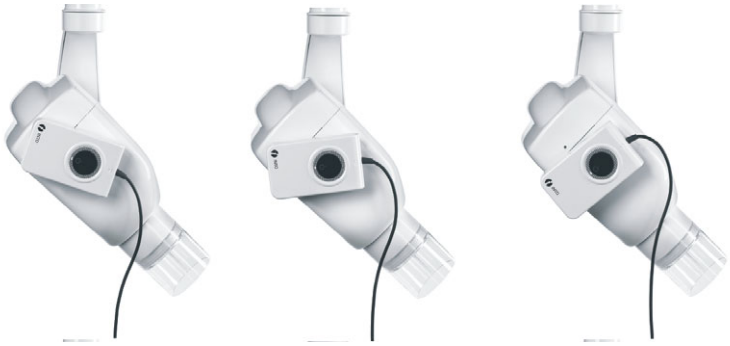
1 Start CliniView software and select a patient

2 Switch on the sensor by pressing the sensor power switch.

3 Protect the sensor with a hygienic cover and place the sensor on to the holder.

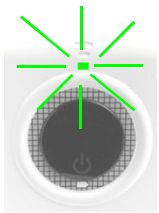
4 Start image capturing in CliniView by pressing the **Start intraoral image capturing** button.

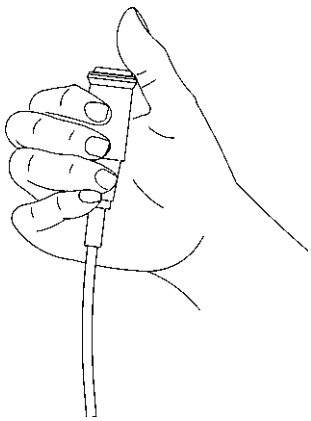
5 Position the sensor in the patient´s mouth. The sensor unit can be either on patient's chest or with the magnetic mounting on the side of the x-ray unit tube head. Position the Intraoral x-ray unit as appropriate.



NOTE!

Make sure that the device status indicator illuminates green before making the exposure.





6 Make the exposure by pressing the exposure button of the x-ray unit. Blinking status indicator on the device indicates image transfer.

NOTE!

If several images are captured in series, do not switch the sensor off between the exposures. The auto power off will turn the sensor off, if the sensor is not used approximately in 10 minutes.

7 After the image capturing click **Abort image capturing** button in CliniView.

8 When capturing is finished switch the sensor off, remove disposable covers and disinfect the sensor if necessary.

WARNING!

During the exposure cycle radiation the control protection guidelines must be observed.

WARNING!

Minimize the number of running programs before image capturing to ensure the necessary operating system resources for the process.

9 Before unplugging the USB cable, click the “Unplug or eject hardware” icon on the desktop. Choose Sigma M and then click OK. “Safely remove hardware” icon on the toolbar, Sigma M = X-ray device.

2.7 RECHARGING THE BATTERY

The battery is recharged with the charger supplied with the device.

More than 200 image captures can be made with a fully charged fresh battery. Low battery status is indicated with a flashing orange LED. A few images can still be taken to complete the patient until the orange LED starts flashing fast. Fast flashing indicates critically low battery and image capturing is no more recommended.

Charge the empty battery by first plugging the charger cable in to the sensor unit, and then plugging in to the mains. Charging takes about 2 hours and it is indicated with an orange LED that switches off when charging is complete.

The device cannot be used when the charger is connected.

WARNING!

Charging with equipment other than the original Sigma M charger may cause heat generation or cell leakage.

2.8 RECOMMENDED EXPOSURE TIMES

The table below provides guidelines for exposure times for an average DC generator at 70 kV and 7 mA. These values might need to be adjusted for specific generator characteristics (kV, mA).

70 kV	Adult	Adult	Child	Child
SSD	**9”**	**12”**	**9”**	**12”**
Maxillary Incisor	0,100	0,200	0,050	0,100
Maxillary Cuspid	0,100	0,200	0,050	0,100
Maxillary Molar	0,160	0,320	0,080	0,160
Mandibular Incisor	0,100	0,200	0,050	0,100
Mandibular Cuspid	0,100	0,200	0,050	0,100
Mandibular Molar	0,125	0,250	0,063	0,125
Bitewing	0,125	0,250	0,063	0,125

NOTE!

The selected time varies as the square of the distance. The dose should be increased if the distance from the sensor to the focal spot increases.

3 Care instructions

The user must perform the following inspections monthly:

- Visually check that all visible labels are intact and legible
- Check Sigma M sensor cable(s) for wear and damages
- Inspect a test image for sensor defect

NOTE!

The sensor unit must not be opened or repaired by the user. There are no user serviceable parts in the equipment. In case of malfunction always contact your dealer.

3.1 CLEANING THE SIGMA UNIT

The Sigma M sensor unit contains sophisticated electronics. Treat the device with care. Use a cloth moistened in mild cleaning solution (soap) or mild disinfectant to clean the Sigma M unit.

Do not let any water or cleaning fluid to enter the device. Always follow the instructions of the cleaning agent.

Use a new disposable hygienic cover for every sensor usage. If required the sensor can be immersed in disinfectant solution. Follow the disinfectant instructions carefully. However immersion should not exceed 12 hours. Be carefull not to let any disinfectant to enter the sensor unit.

Do not use aggressive chemicals that may damage the sensor (i.e. hypochlorite or other bleaching chemicals). As a guideline the sensors withstand CIDEX (glutaraldehyde 2,2 - 2,6% and inert components) disinfecting solution.

WARNING!

DO NOT:

- Sterilize the sensor using autoclave or an UV oven
- Immersion in bleach or alcohol content solution
- Clean the sensor using in-appropriate instruments

3.2 HANDLING THE DEVICE

WARNING!

DO NOT:
- Sterilize the sensor using autoclave or an UV oven
- Immersion in bleach or alcohol content solution
- Clean the sensor using in-appropriate instruments
- Pinch or bite sensor or cable
- Pull or bend cable with force
- Unplug charger or USB cable by pulling cable out
- Remove hygienic cover by pulling the cable
- Let sensor fall down
- Touch the connector contacts by hand
- Open sensor unit covers (except battery cover)
- Do not touch open connectors by hand, to avoid malfunctions due to electrostatic discharge
- Do not expose the device to flammable vapour or anesthesia gas.

- Use the sensor with a proper sensor holder
- Make sure the sensor never strikes a hard surface.
- Arrange sensor cable smoothly in its storage place when not in use

4 Trouble shooting

4.1 DIAGNOSING IMAGE QUALITY PROBLEMS

High quality images with sharp contrast and fine details give optimum diagnostic information. Images of lesser quality are usually a result of one or more common problems, which are discussed here.

NOTE!

If using the system in an extremely high electromagnetic environment, some interference in image quality may occur.

PROBLEM	POSSIBLE CAUSE	REMEDY
Images are too grainy and light	1 Exposure factors (kV, mA, s) used are too low	1 Increase exposure factors (see *ch 2.8 recommended exposure times*)
	2 Image adjustments have not been performed	2 Adjust the image brightness, contrast and gamma using CliniView software
	3 Incorrect integration time or generator type (AC/DC)	3 Set the generator type and the integration time for AC generator in CliniView
Images are too dark	1 Exposure factors used are too high	1 Decrease exposure factors
	2 Image adjustments have not been performed	2 Adjust the image brightness, contrast and gamma using CliniView software
Lack of image contrast	1 Image adjustments have not been performed	1 Adjust the image contrast using CliniView software
	2 Exposure factors (kV, mA, s) used are not optimal	2 Increase exposure factors (see *ch 2.8 recommended exposure times*)

PROBLEM	POSSIBLE CAUSE	REMEDY
Images are blurred	1 The patient moved	1 Prevent patient movement
	2 The X-ray source moved	2 Prevent X-ray unit movement or have the unit serviced
	3 Incorrect integration time	3 Set the integration time in CliniView to be longer than the exposure time
Images are burned out	1 Excessive exposure time	1 Set shorter exposure time
		2 Change a long cone on the X-ray unit

4.2 DIAGNOSING EQUIPMENT SPECIFIC PROBLEMS

PROBLEM	POSSIBLE CAUSE	REMEDY
Sensor cannot be powered	1 The battery is empty	1 Recharge the battery
	2 The battery is not inside the electronics	2 Insert the battery
Image capturing icons are missing	1 Sigma M is not selected as an “installed device” in CliniView	1 Select Sigma M as an installed device from *Tools* menu in CliniView
	2 The patient is not selected in CliniView	2 Select the patient

PROBLEM	POSSIBLE CAUSE	REMEDY
Image capturing cannot be started	1 The battery is empty (The battery status indicator is blinking)	1 Recharge the battery
	2 The sensor is not powered	2 Power up the sensor
	3 The wireless network is not available	3 Refer to installation manual or contact IT support
	4 The gainfile is not installed	4 Use Gain Installer to install the gainfile
	5 Used sensor is not set as default	5 Set the used sensor as a default in *Tools* menu in CliniView
CliniView cannot find the sensor / Sensor is not ready for the image capturing	1 Sigma M is off	1 Switch on the sensor
	2 Wrong sensor switched on	2 Switch on the sensor assigned to the workstation
	3 WLAN network not set up	3 Set up the wireless network according to the installation manual
	4 Another WLAN network is in use	4 Choose a WLAN network used for Sigma M
	5 WLAN network is down because: – Access point not connected – Access point not powered – LAN cable not connected	5 Connect USB dongle, Power access point, Connect LAN cable More information from network administrator or adapter manuafacturer
	6 WLAN settings are incorrect	6 Check SSID, IP address and encryption
	7 Charger is connected	7 Disconnect the charger

PROBLEM	POSSIBLE CAUSE	REMEDY
Charging the battery does not start / red battery status indicator illuminates	1 Wrong charger used 2 Charger not plugged to the mains	1 Use only the charger accompanied with a sensor 2 Plug the charger to the mains
Image capturing icon cannot be activated	1 Patient not selected 2 Sigma M not selected in CV installed devices list 3 Sensor is not preselected 4 Gain file not installed	1 Select the patient 2 Select the correct Sigma M sensor type in CV installed devices list 3 Click Select sensor and assign the sensor 4 Install gain file
Image capturing fails (image transfer does not start after the exposure)	1 Unactivated sensor has been exposed	1 Retake an image with an activated sensor
Image transfer fails (image transfer starts after the exposure, but the image does not appear on the screen)	1 Network error	1 Reload the image by restarting image capturing mode in CliniView **WARNING** *Do not shut off the sensor. Do not connect USB cable.* 2 Reset the Access Point

5 General information

5.1 MANUFACTURER'S LIABILITY

When installing the Sigma M system it is important to observe all warnings and precautions described in this manual. As a manufacturer we can only assume liability for safe and reliable operation of the Sigma M system when:

- PC installation was performed according to manuals supplied with the PC
- CliniView PC software is installed and used according to the Installation & User Manual for CliniView Software.
- Sigma M system is installed and used according to the Installation & User Manual for Sigma M system
- Maintenance and repairs are performed by a qualified Sigma M Dealer and
- Original or authorized replacement parts are used.

If service on the equipment is performed, a work order describing the type and extent of repair must be provided by the service technician. This must contain information of changes of nominal data or work range performed. The work order must furthermore indicate the date of repair, the name of the company concerned and a valid signature. The user should keep this Service Report for future reference.

If you have any problems or difficulties when capturing images, please refer to troubleshooting in the user manual.

Please find the electromagnetic compatibility tables according to IEC 60601-1-1-2 Ed 2 in this Sigma M user manual.

Use only USB cable delivered with the device to ensure proper operation according to specification.

5.2 MARKINGS AND GRAPHICS SYMBOLS

The following markings are used in this manual:

NOTE!

Contains useful information for the reader about the unit and its use.

CAUTION!

Contains important instructions. If these instructions are not observed, malfunction of the unit or damage to the unit or other property may occur.

WARNING!

Contains warnings and instructions about the safety of the unit. If these warnings are not respected, serious risks and injury may be caused to the patient and operator.

The following symbols are used in the Sigma M device and in the manuals:

Attention, consult accompanying documents. Contains warnings and instructions about the safety of the unit. If these warnings are not observed, serious risks and injury may be caused to the patient and operator.

If the unit has CE-marking it is CE-marked according to the Medical Device Directive 93/42/EEC.

USB connection

DC connector

Indoor, dry location use only

Power

Non-ionizing radiation

The device complies with Part 15 of the FCC Rules.

IP21

The degree of protection provided by the sensor unit enclosure against solid objects greater than 12.5 mm in diameter and against vertically dripping water.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

The instructions in this manual contain essential information necessary for the installation and use of the Sigma M system. As manufacturer we strongly recommend that you read this manual before installation and use.

The following abbreviations may be used in this manual:

PC	Personal computer
HD	Hard disk
Hz	Herz; cycles per second
MHz	Millions of hertz
CPU	Central processing unit (computer)
RAM	Random access memory
MB	Mega bytes
GB	Giga bytes
CD-R	Compact disc (recordable)
CD-RW	Compact disc (re-writable)
DVD-RW	Digital Versatile Disc (re-writable)
HDD	High density drive
PCI	Peripheral Component Interconnect
LAN	Local Area Network
USB	Universal Serial Bus
MAC	Medium Access Control
WLAN	Wireless local area network
Wi-Fi	Wireless network compliant with IEEE802.11

5.3 MAIN LABEL

The sensor model Sigma M is available in two product type. The exact type of the device is shown on the main label.

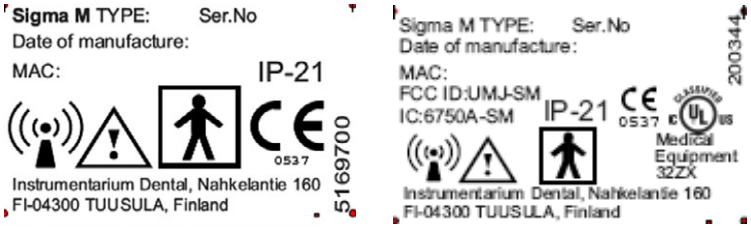


Fig 5.1. Label on CE-marked device

MAC is a unique MAC-address of the internal WLAN terminal.

Type	Description	Part number
S1	Sensor size 1	900003
S2	Sensor size 2	900004

The main label with the serial number of the product of the device is attached to the battery cover. The battery cover must not be replaced by an unauthorized person. Contact your local dealer for servicing a damaged cover if needed.

5.4 MANUALS

The following manuals and documents are shipped with the Sigma M system:

- Sigma M User Quick Guide
- Sigma M Installation Manual
- Sigma M User Manual
- CliniView User Manual
- CliniView Installation Manual

5.5 DISPOSAL

At the end of useful working life of the device, its spare and replacement parts and accessories make sure that you follow all local, national and international regulations regarding the correct and safe disposal and/or recycling of the device, its spare and replacement parts and accessories.

The device and its spare and replacement parts and accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

The following hazardous materials and substances can be found in the device its spare and replacement parts and assemblies:

– lead (Pb): sensor, circuit board

The locations of all the spare and replacement parts and assemblies listed above can be found in the service and/or installation manual supplied with the device.

5.6 WARNINGS

- Minimize the number of running programs before image capturing to ensure the necessary operating system resources for the process.
- Computer should only be connected to grounded outlet
- Do not forcefully bend sensor cables. Avoid mechanical wear and stress (pulling the cable)
- Use only the power supply specified by the manufacturer
- Make sure that the Ready LED illuminates before making an exposure.
- Don't sterilize the sensor using autoclave or UV oven
- Use a disposable hygienic cover or disinfect the sensor after every patient
- The battery is harmful to the environment and so it must be disposed of in accordance with local regulations.
- The electronics box must not be opened or repaired by the user
- Do not allow water or other cleaning liquids to enter the electronics
- Connect the system only to a PC conforming with IEC60950 or IEC60601-1

5.7 NOTICE OF WIRELESS LAN USAGE

WLAN operation is based on emitting and receiving RF energy.

This equipment complies with European R & TTE directives, and may be operated without a licence in Europe (ETSI). The declaration of conformity can be consulted at Instrumentarium Dental. Although this and other use environment devices comply with CISPR requirements for RF emissions, interference may still occur.

Monitor the performance of the wireless link. If it behaves in a strange or unexpected way that may endanger patient safety, use the USB connecting cable until the problem is resolved.

Hereby, Instrumentarium Dental, declares that this Sigma M - sensor is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

5.8 FCC CERTIFICATION

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1 This device may not cause harmful interference

2 This device must accept any interference received, including interference that may cause undesired operation.

Sigma M sensor

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE!

This equipment has been tested and found to comply with the limits for Class B digital device, pursuant to Part 15 or the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- reorient or relocate the receiving antenna
- increase the separation between the equipment and receiver
- connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- consult the dealer or an experienced radio/TV technician for help

6 Technical specifications

6.1 GENERAL

Manufacturer´s quality system:	ISO 9001, ISO 13485
Electrical and Mechanical safety:	Medical Equipment with respect to electrical shock, fire and mechanical hazards only in accordance with UL60601, CAN/CSA C22.2 no 601.1
	According to IEC 60601-1, CE models marked according to the Medical Device Directive 93/42/EEC (Device classification: II b), Mobile sensor unit that is IEEE 802.11b (WLAN) compliant
Patient connection (sensor):	BF-type
Sensor technology:	CMOS Active Pixel technology (CMOS APS)
IMAGE QUALITY	
Resolution:	26.3 lp/mm (theoretical)
Grayscale:	4096 gray levels.
Holders:	A full set of color coded KerrHawe and Sigma M sensor holders, with easy instructions, for comfortable and accurate positioning.
SOFTWARE MAIN FEATURES	
Operating system:	Windows 2000 or XP (SP2)
Operating software:	CliniView version 6.4 or later
Full Mouth Series:	FMS, user defined
File sizes:	3,17 MB, uncompressed file,Sensor size1 4,96 MB, uncompressed file,Sensor size2
X-ray shield in the sensor:	Lead (Pb)

6.2 DIMENSIONS

Outer dimensions:	Sensor unit:	102 x 60 x 22 mm
	Sensor size 1:	26 x 37 mm
	Sensor size 2:	31 x 44 mm
Active image area:	Sensor size 1:	30.02 x 19,95 mm²
	Sensor size 2:	36,48 x 25,84 mm²

Sensor shape:	Four rounded corners, two corners with greater radius for better patient comfort in Sensor size 2.	

PIXEL SIZE

Sensor size 1:	19 µm x 19 µm	1580 x 1050 pixels
Sensor size 2:	19 µm x 19 µm	1916 x 1358 pixels

Sensor cable length	Sensor size 1:	40 cm
	Sensor size 2:	40 cm

6.3 SENSOR UNIT

Sensor unit box:	Vertically or horizontally mounted on desktop or wall mounted. A Sigma M Sensor that is connected to the sensor unit can be shared between rooms without need to switch off the PC.
PC connection:	802.11b/g 2.4 GHz Access Point or USB
USB:	USB 2.0 Full speed, mini USB-B port connector, 500 mA.
USB cable length:	maximum 3 meters (9,8 feet), ferrite required.
General applied part (sensor):	BF type
Battery type:	Rechargable lithium Polymer battery
Battery capacity:	1000 mAh (correspond approx 200 image capture). (Battery life expectancy: 500 cycles C/2, 20°C) in WLAN use.
External power supply:	DC connector, 6V, center pin positive

6.4 RF EXPOSURE INFO

WLAN:	According to IEEE 802.11b
Frequency:	2400 MHz - 2483 MHz
Output power:	max 0,25 W (FCC) max 0,1 W (ETSI)
Separation:	Keep the sensor unit min. 20 cm away from the patient

6.5 AMBIENT CONDITIONS

The Sigma M unit

Transportation and storage temperature:	-40°...+60°C (-40F...+158F), note battery discharge during long storage and high temperature
Operating temperature:	+10°...+40°C (+50F...+104F)
Relative humidity (storage):	10-93%
Water tightness:	IP67 (sensor) IP21 (sensor unit)

The battery

Charge Temperature	**Charge:** 0°...+45°C (+32F...+113F)
Storage Temperature and time to prevent self discharge	**1 Year at** -20°...+20°C (-4F...+68F) **3 Month at** -20°...+45°C (-4F...+113F) **1 Month at** -20°...+60°C (-4F...+140F)

Materials

Sensor cover	PA
Sensor cable	PUR
Hygienic cover	Ethylene Methyl Acrylate Copolymer

6.6 IMAGE ACQUISITION SYSTEM REQUIREMENTS

The Sigma M acquisition system consists of Sigma M sensor and PC hardware. Sigma M sensor is a medical device.

WARNING!

If a IEC 60950-compliant (non-medical) PC is used, it must not be brought in to the patient environment (see Sigma M installation manual for details).

WARNING!

Do not bring open (unconnected) USB cable to the patient area. If the sensor is used with USB cable in the patient area, the user must make sure that system leakage current does not exceed IEC/ISO 60601-1-1 limits (see Sigma M installation manual for details).

Sigma M IMAGE ACQUISITION SYSTEM REQUIREMENTS	
Electrical safety	IEC 60950 for office use or IEC/ISO 60601-1 (medical PC)
Processor	Pentium® 600MHz or better (Windows 2000)
	Pentium® 600MHz or better (Windows XP)
Hard disk	10 GB
CD-ROM	Yes
Keyboard	Yes
Mouse	Yes
USB port	Yes
Accessories	Audiocard and speakers optional
Operating system	Windows® 2000 Windows® XP (SP2) See Microsoft Windows System Requirements
Main memory (RAM)	Windows® 2000 and XP: 256 MB or more
Monitor	15” or bigger
Archive	CD-R DAT Iomega® Jazz® MOD
WLAN network adapter	IEEE 802.11 b compatible (built in, USB, access point or equivalent)

6.7 ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

These Electromagnetic Compatibility tables according to IEC 60601-1-2 Ed 2 in chapter 7.5 consists of:

WARNING!

When used Sigma M adjacent to other equipment such configuration should be carefully observed to ensure that electromagnetic interference (EMI) does not degrade performance.

The use of Sigma M attached to Instrumentarium Dental Focus x-ray, as presented in this user manual, has been verified by the manufacturer.

WARNING!

USE LIMITATION: External components: The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM.

WARNING!

Portable and mobile RF communications equipment can affect the system.

The Sigma is suitable for use in the specified electromagnetic environment. The purchaser or user of the Sigma should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment
Radio-Frequency Emissions CISPR11	Group 2	The Sigma M must emit electromagnetic energy in order to perform it's intended function. Nerby electronic equipment may be affected.
Radio-Frequency Emissions CISPR11	Class B	The Sigma is suitable for use in all establishments, including domestic establishments 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	IEC 61000-3-2 Class A	The Sigma is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The Sigma is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 6.1 Electromagnetic emissions IEC 60601-1-2 Ed 2.

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter	**150KHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
Equation	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
Rated Maximum Output Power of Transmitter (watts)	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

Table 6.2 Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2 Ed 2.

Sigma M is suitable for use in the specified electromagnetic environment. The purchaser or user of Sigma M should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/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 is that of a typical commercial and/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 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T)	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T)	Mains power quality is that of a typical commercial and/or hospital environment. If the user of Sigma M requires continued operation during power mains interruptions, it is recommended that Sigma M be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 6.3 Electromagnetic immunity IEC 60601-1-2 Ed2

Sigma M is suitable for use in the specified electromagnetic environment. The purchaser or user of Sigma M should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6	3 V150 kHz to80 MHz	[V_1] 3 V	Portable and mobile RF communications equipment are used no closer to any part of Sigma M, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RFIEC 61000-4-3	3 V/m80 MHz to2,5 GHz	[E_1] 3 V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe Sigma M to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Sigma M.

**Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V_1] V/m.

The Recommended Separation Distances are listed on page 21.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 6.4 RF immunity of non-life-support equipment or system IEC 60601-1-2

7 Appendix 1, Sigma M products and accessories

A Sigma M system (with the exception of the PC) is assembled using the following parts:

Products	
Part no.	Description
900003	Sigma M sensor size 1 (Type S1): – USB electronics with battery – Sigma M charger – Wall mount set – USB-cable, 3m – CliniView software CD – Manuals – Sensor ID sticker – Mounting magnet
900004	Sigma M sensor size 2 (Type S2): – USB electronics with battery – Sigma M charger – Wall mount set – USB-cable, 3m – CliniView software CD – Manuals – Sensor ID sticker – Mounting magnet

The following accessories are approved parts:

Accessories	
Part no.	Description
55042	Sigma M hygienic covers (500 pcs)
200382	Sigma M Charger, EUR
200383	Sigma M Charger, USA
5169795	Rechargable Battery
5169703	Mounting Magnet
200245	Wall Mount set
200162	Sigma M Sensor holder starter kit Size 1 - Bitewing holder 1 pc - Posterior holder (UR/LL) 1 pc - Posterior holder (UL/LR) 1 pc - Periapical holder (UR/LL) 1pc - Periapical holder (UL/LR) 1 pc - Endo holder (UR/LL) 1 pc - Endo holder (UL/LR) 1 pc - Positioning ring 1 pc

Accessories	
Part no.	Description
200163	Sigma M Sensor Holder Starter Kit Size 2 - Bitewing holder 1 pc - Posterior holder (UR/LL) 1 pc - Posterior holder (UL/LR) 1 pc - Periapical holder (UR/LL) 1pc - Periapical holder (UL/LR) 1 pc - Endo holder (UR/LL) 1 pc - Endo holder (UL/LR) 1 pc - Positioning ring 1 pc
200333	Bitewing Refill S1 Refill Pack, 10 pcs
200335	Posterior S1 Refill pack, 10 pcs
200337	Periapical S1 Refill Pack, 10 pcs
200338	Endo S1 Refill Pack, 10 pcs
200334	Positioning ring Refill Pack, 5 pcs
200339	Bitewing S2 Refill Pack, 10 pcs
200340	Posterior S2 Refill pack, 10 pcs
200330	Super-Bite Senso Holders (KerrHawe) - Super-Bite Senso Anterior 2 pcs - Super-Bite Senso Posterior 2 pcs
200331	Kwik-Bite Senso Holders (KerrHawe) - Kwik-Bite Senso 4 pcs
200332	Endo-Bite Senso Holders (KerrHawe) - Endo-Bite Senso Anterior 2 pcs - Endo-Bite Senso Posterior 2 pcs

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INSTRUMENTARIUM

Sigma M

User Manual, English

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