Instrumentarium Dental Snapshot Intraoral Sensor

Installation & User Manual

INSTRUMENTARIUM

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The original language of this manual is English.

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CE
0537

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1 Introduction

The Snapshot digital intraoral sensor is designed to produce high quality digital X-ray images of teeth and adjacent structures instantly.

To view, enhance, store, send and print images use the CliniView imaging software or another imaging application through the Instrumentarium TWAIN driver.

For taking intraoral images you need the complete system, which consists of:

- Snapshot intraoral sensor
- Intraoral X-ray unit
- Workstation with USB connectivity *)
- CliniView or another imaging application
- Sensor holder and hygienic cover

*) See 6.6 Image Acquisition System Requirements

Before using the sensor read the Warnings and Precautions in this manual.

Read the following manuals to familiarize yourself with the operation of the unit before installing and using it:

- Snapshot User Quick Guide
- Snapshot Installation & User Manual
- CliniView Installation Manual
- CliniView User Manual
- Instrumentarium TWAIN Installation & User Manual

CAUTION! *USA only: Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.*

2 Package contents

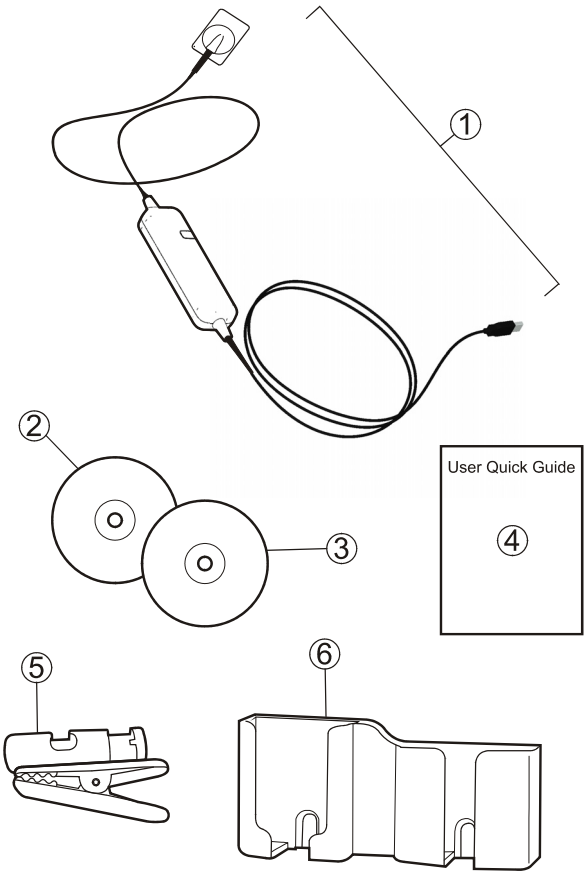
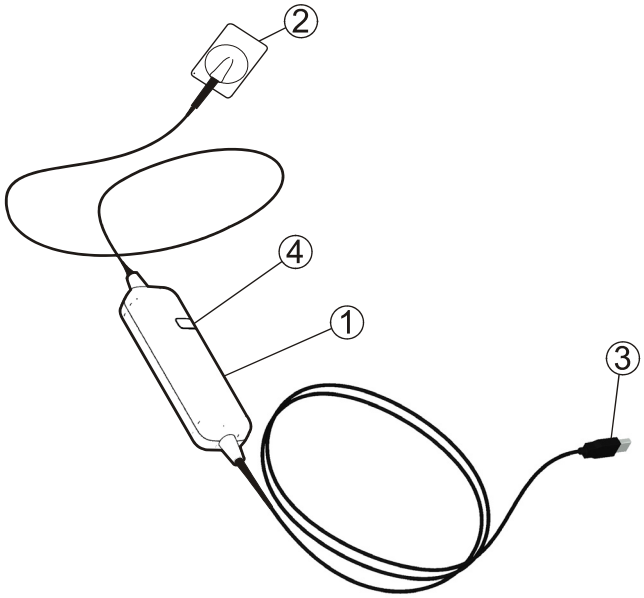


Fig 2.1.

1. Snapshot intraoral sensor
2. Imaging application CD
   CliniView (includes software and manuals)
3. Snapshot CD (TWAIN driver, Snapshot manuals)
4. User Quick Guide
5. Sensor Cable Clip
6. Wall mount set

2.1 Sensor main parts



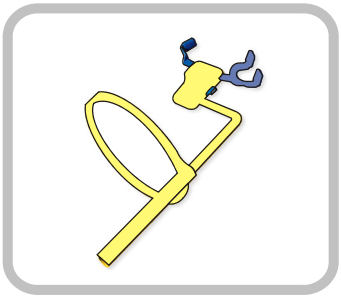
1. Snapshot Unit
2. Sensor
3. USB connector
4. Indicator lights
   - Orange: Standby
   - Green: Ready for image capture
   - Blinking: Image transfer

2.2 Accessories for the sensor

NOTE! *Ordering information for the Instrumentarium Dental accessories in chapter 6.7.*

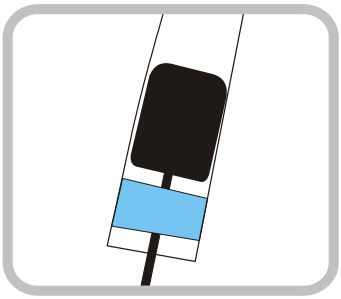
Sensor holders

Use sensor holders together with Snapshot for easier and more accurate patient positioning and for reducing the number of retakes.



Hygienic covers

Protect the sensor with a hygienic cover when using it. Use only proper covers provided by Instrumentarium Dental.



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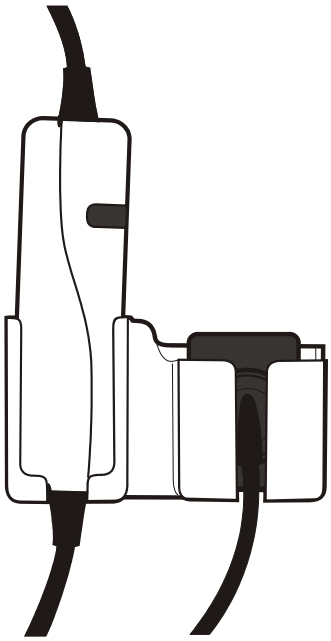


Wall Mount set

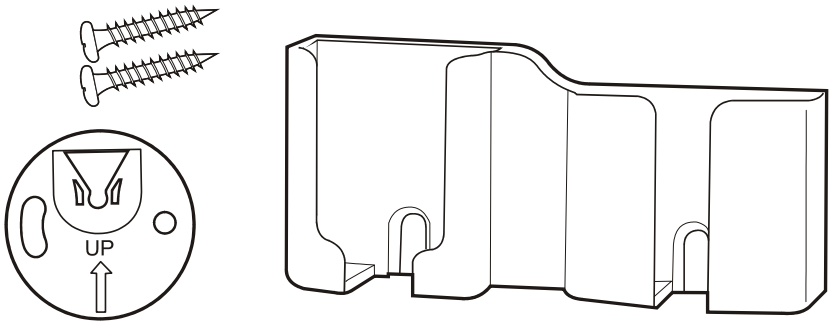
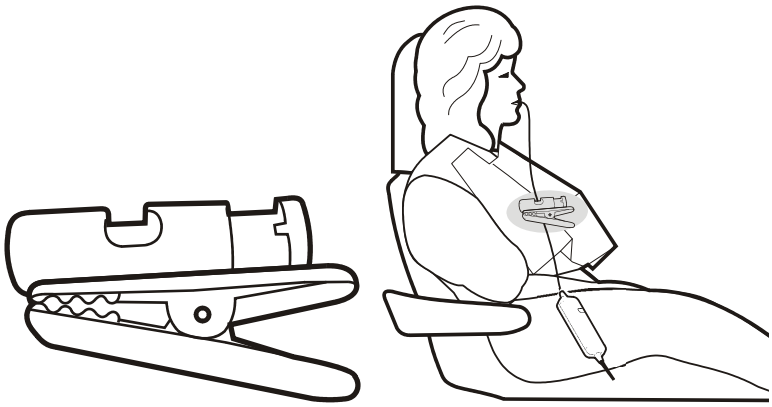


Fig 2.2. Wall mount set

The Wall mount ensures a safe and convenient place to store the sensor when not in use. Install the wall mount rack directly on the wall with screw provided or use the adapter for detachable installation.

A wall mount set is included in the sensor sales package. Contact your local sales representative for ordering more sets.

Sensor Cable clip



Use the Cable clip to compensate the weight of the cable when the sensor in use. Attach the clip to e.g. lead apron. A Cable clip is included in the sensor sales package. Contact your local sales representative for ordering more.

3 Installation

3.1 Cliniview Users

1. Install the CliniView software. See instructions in the CliniView manual in the CliniView CD.
2. Connect the Snapshot sensor to the USB port of the computer.
3. The sensor is automatically detected by Windows. All required files are installed from the sensor memory when connected for the first time. Allow the sensor to complete the installation by initiating the image capture the software user interface.
4. The sensor is ready for use. Take a test exposure.

3.2 TWAIN Users

1. Install the Instrumentarium TWAIN driver. See instructions in Instrumentarium TWAIN installation manual in the Snapshot CD.
2. Connect the Snapshot sensor to the USB port of the computer.
3. The sensor is automatically detected by Windows. All required files are installed from the sensor memory when connected for the first time. Allow the sensor to complete the installation by initiating the image capture the software user interface.
4. The sensor is ready for use. Take a test exposure.

3.3 Other software Users

Follow instructions provided with the software.

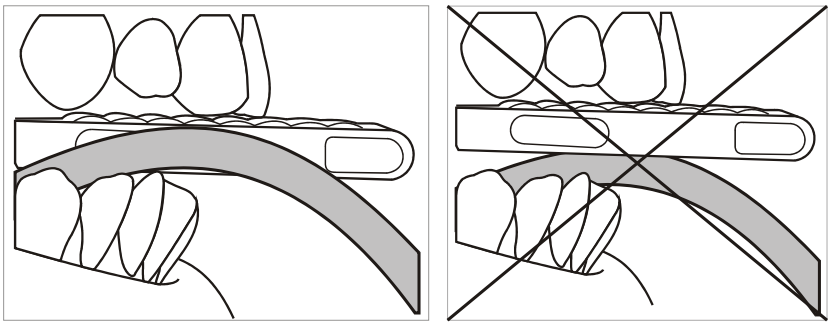
4 Using the Snapshot sensor

4.1 Positioning and exposure

Snapshot sensor type size 1 (S1) is designed for taking anterior, periapical and pedodontic images. The purpose of Snapshot sensor type size 2 (S2) is to capture bitewing and horizontal periapical images.

1. Protect the sensor with a hygienic cover and use an appropriate sensor holder.
   See manufacturer's instructions for details.
2. Start image capturing from the software (see chapter 4.2, Capturing image with the CliniView software or 4.3, Capturing image with the TWAIN driver).
3. Position the sensor.

NOTE! *To prevent the patient biting the sensor cable, lead the cable alongside the holder.*



4. Position the X-ray tube head and make an exposure.

The Snapshot sensor has a wide operating range that allows a use of a fixed exposure value on the X-ray head for typical imaging needs. Use the image processing features of the imaging software to adjust the brightness (and contrast) of the image according to the actual exposure level on the sensor.

Try 0,200 s @ 60kV DC or 0,12 s @ 70kV DC. The exact best value depends on the X-ray tube head (generator type, mA, SSD/cone length) and patient population (children/adult).

For optimized exposure and patient dose you can adjust the exposure settings with the help of the guidance given in chapter 5.4 Recommended exposure values.

4.2 Capturing image with the CliniView software

Single image

1. Start the CliniView software and select the patient.
2. Start image capturing in Cliniview by pressing the **Start intraoral image capturing** button
3. Position the sensor. Select the exposure values and press the exposure button.
4. When finished stop image capturing and save the image.

Using a template

- To take several images of the same patient you can use a template. Click the template button before starting image capturing.
- Choose a template and set as default some of the ready templates. Alternatively add or edit your own template.

Adjusting an image

- Images can be adjusted with a variety of image adjustment tools. See CliniView manual for details.
- For quick adjustment you can use modality specific adjustment buttons.

4.3 Capturing image with the TWAIN driver

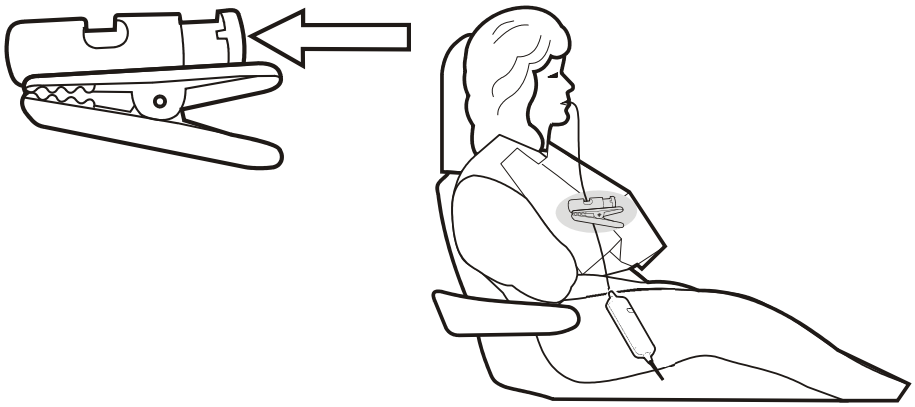
1. Launch the Instrumentarium TWAIN application from your image capture application.
2. In TWAIN user interface select **Capture Snapshot**.
3. Message ‘Ready for exposure’ is shown on the display.
4. Position the sensor. Select the exposure values and press the exposure button.

5 Tips and hints

5.1 Handling and using

Use the Sensor Cable Clip to avoid loose Snapshot unit to force down the sensor from patient's mouth.

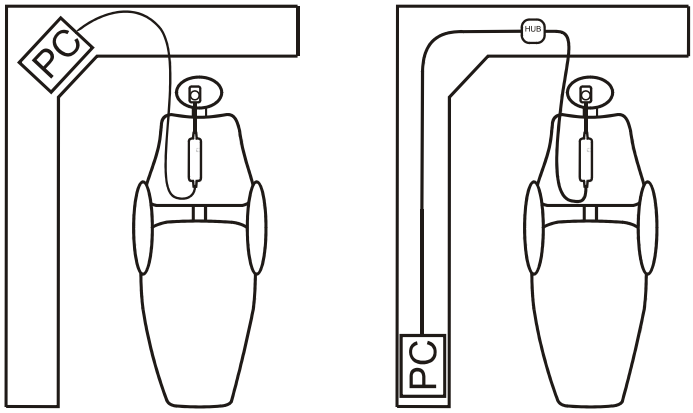
1. Press the clip button to attach the cable to the clip.
2. Attach the clip to e.g. lead apron.



- Use 'Safely remove hardware' function in the icon tray when disconnecting the Snapshot.
- Do not disconnect the Snapshot before the image is displayed on the screen.
- To prevent the patient biting the sensor cable, lead the cable alongside the holder.

5.2 Setting up the operatory

The sensor cable is 3 m long. If it is not enough, use a powered active USB hub as an extension.



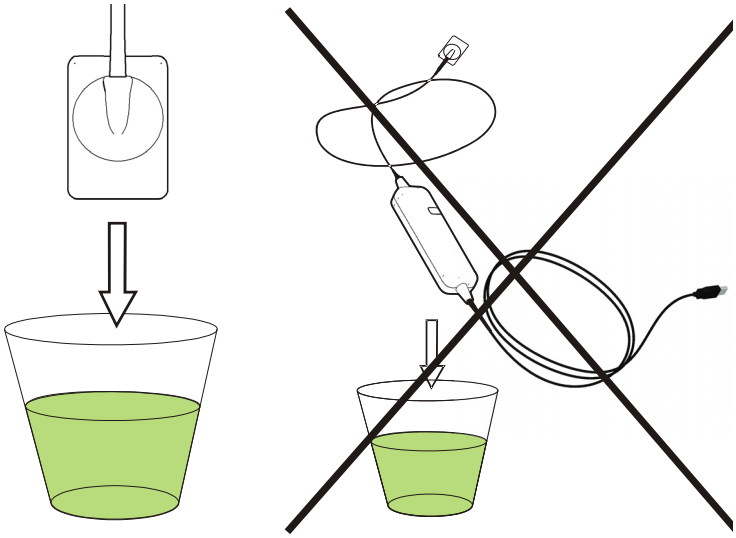
Two sensors of a different size can be simultaneously connected to the PC.

Make sure you do not overload your USB port. Do not connect other device to the HUB. If you have start up problems with the sensor try another USB port at your computer.

5.3 Cleaning

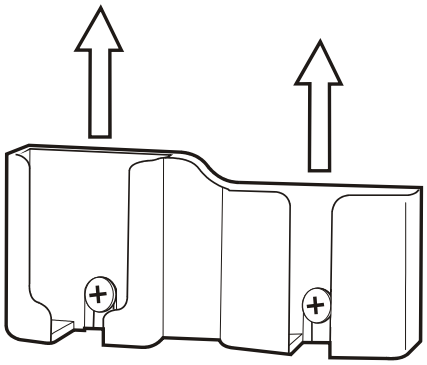
Sensor

Only the CMOS sensor can be immersed in disinfectant solution. Do not immerse the Snapshot unit.



Wall mount set

Remove the whole wall mount set from the wall to clean it properly. If the adapter is used the wall mount can be lifted upwards to detach. If the wall mount is mounted with screws first loose the screws for ½ turn ccw.



5.4 Recommended exposure values

Snapshot recommended exposure times for DC x-ray units*								
	60kV, 7mA				70kV, 7mA			
	9" cone		12" cone		9" cone		12" cone	
	adult	child	adult	child	adult	child	adult	child
Maxillary incisor	0,20	0,10	0,40	0,20	0,10	0,05	0,20	0,10
Maxillary cuspid	0,20	0,10	0,40	0,20	0,10	0,05	0,20	0,10
Maxillary molar	0,32	0,16	0,63	0,32	0,16	0,08	0,32	0,16
Mandibular incisor	0,20	0,10	0,40	0,20	0,10	0,05	0,20	0,10
Mandibular cuspid	0,25	0,10	0,40	0,20	0,125	0,05	0,20	0,10
Mandibular molar	0,25	0,16	0,50	0,25	0,125	0,063	0,25	0,125
Bitewing	0,25	0,16	0,50	0,25	0,125	0,063	0,25	0,125
* For AC units increase exposure time about 30%.								

Snapshot recommended exposure times for DC x-ray units*								
	65kV, 7.5mA				70kV, 8mA			
	9" cone		12" cone		9" cone		12" cone	
	adult	child	adult	child	adult	child	adult	child
Maxillary incisor	0,16	0,10	0,25	0,16	0,10	0,08	0,16	0,10
Maxillary cuspid	0,16	0,10	0,25	0,16	0,10	0,08	0,16	0,10
Maxillary molar	0,20	0,12	0,32	0,20	0,125	0,08	0,20	0,125
Mandibular incisor	0,125	0,10	0,20	0,16	0,10	0,06	0,16	0,10
Mandibular cuspid	0,125	0,10	0,20	0,16	0,10	0,06	0,16	0,10
Mandibular molar	0,20	0,16	0,32	0,20	0,125	0,08	0,20	0,125
Bitewing	0,20	0,16	0,32	0,20	0,125	0,08	0,20	0,125
* For AC units increase exposure time about 30%.								

5.5 Optimizing the sensor performance

The display and its brightness/contrast settings as well as ambient lighting have a great impact on the diagnostic value of a digital image on screen. Use Tools ⇒ Monitor ⇒ test ⇒ Start Check to run a monitor test in the CliniView Software.

Image quality settings

Best clarity requires correct exposure with adequate dose. Make sure that you are using proper exposure settings for your X-ray tube head.

The sensor can operate in two image quality modes. The default mode of operation is standard quality. It provides good performance for most clinical needs. For occasional needs superior quality may be desirable. Then select the high quality mode at the imaging software.

The high quality mode may require slightly higher dose and image processing time. The file size is also larger. On the other hand provides the best possible resolution and most accurate sensor calibration.

Image processing settings

The raw image returned by the sensor is processed in the image viewing software. This processing impacts the image brightness, contrast and sharpness. Best image processing parameters depend on the image data and diagnostic needs. The purpose of the processing is to enhance contrast in the diagnostically interesting areas and filter noise.

The default values for image processing have been determined to satisfy most clinical needs. The user may save new default values if there is a consistent need to adjust every image. In the software user interface there is a possibility to return the factory defaults.

NOTE! *When using the Instrumentarium TWAIN there is typically multiple image processing applied. The default image processing at the application should be minimal to avoid over processing. The average image quality should be superior already at the TWAIN preview window. The daily brightness/contrast adjustment to accommodate patient to patient variation is most conveniently done at the calling application.*

Sensor timing parameters

The sensor timing should not normally be changed.

The sensor time out must be longer than the time normally required for positioning when the sensor is in the ready for image capture. Exceeding the time out time will cause the sensor to go from the ready state to the standby state.

The sensor integration time must be longer than the longest exposure time used.

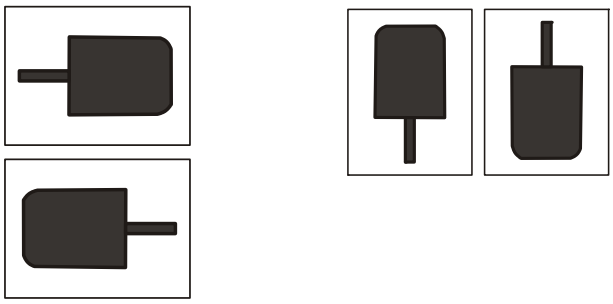
5.6 Using the CliniView software

Refer the CliniView User manual for all CliniView features.

What if image is upside down?

Cause: If you capture images by pressing **Quick intraoral image capturing** button for both left and right side, the other image is upside down.

Remedy: Rotate button can be used to turn the image over. Or use template, which assists you in capturing images sequentially in a specified order and location in the patient's mouth. Go to Template dialog by selecting Image ⇒ Edit template.



What if image capturing buttons are not enabled?

Cause: Patient is not selected.
Remedy: Select patient.

Cause: Snapshot device is not selected.
Remedy: Select devices to be used from Tools ⇒ Installed devices.

5.7 Using the Instrumentarium TWAIN software

Refer the Instrumentarium TWAIN installation and user manual for all features and settings.

At the TWAIN options it is often preferable to select:

1. “Immediately proceed with acquiring a new image”: Snapshot.

   This starts the image capture automatically and thus reducing the number of mouse click required.

2. Under Snapshot Options: "Capture images in the continuous capture mode" (default) to keep the sensor in the capture mode for successive images.

   This allows several image capture in series without touching the keyboard.

6 General information

6.1 Troubleshooting

PC does not recognize USB

Remedy: Remove USB hardware and reconnect. Change USB port if needed. Try using a powered USB HUB to connect the sensor if port change does not help.

Snapshot lights are not lit

Remedy: Remove USB hardware and reconnect. Change USB port if needed. Try using a powered USB HUB to connect the sensor if port change does not help.

Images are too grainy and light

Cause: Exposure factors (kV, mA, s) used are too low
Remedy: Increase exposure factors

Cause: Image adjustments have not been performed
Remedy: Adjust the image brightness, contrast and gamma using CliniView software

Images are too dark

Cause: Exposure factors used are too high
Remedy: Decrease exposure factors

Cause: Image adjustments have not been performed
Remedy: Adjust the image brightness, contrast and gamma using CliniView software

Lack of image contrast

Cause: Image adjustments have not been performed

Remedy: Adjust the image contrast using CliniView software

Cause: Exposure factors (kV, mA, s) used are not optimal

Remedy: Increase exposure factors

Images are blurred

Cause: The patient moved
Remedy: Prevent patient movement

Cause: The X-ray source moved
Remedy: Prevent X-ray unit movement or have the unit serviced

Cause: Incorrect integration time
Remedy: Set the integration time in CliniView to be longer than the exposure time

Images are burned out

Cause: Excessive exposure time
Remedy: Set shorter exposure time
Remedy: Change a long cone on the X-ray unit

TWAIN returns colorful image

Cause: The calling application does not support 16-bit image data
Remedy: Select preferred image depth: “By default select 8-bit image transfer” at the TWAIN options.

6.2 Maintenance and service

Service

There are no user serviceable parts.

Cleaning

Use a cloth moistened in mild cleaning solution (soap) or mild disinfectant to clean the Snapshot unit.

Disinfecting the sensor

Only the CMOS sensor can be immersed in disinfectant solution (e.g. Virkon, Cidex). Follow the disinfectant instructions carefully. Do not use aggressive chemicals.

CAUTION! *Do not immerse the Snapshot unit!*

6.3 Main label and symbols

The main label can be found on the USB cable.

Fig 6.1. Main label

	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.
CE 0537	If the unit has CE-marking it is CE-marked according to the Medical Device Directive 93/42/EEC.
	USB connection
	Type BF equipment
IP44	The degree of protection provided by the Snapshot unit. Protected against solid objects over 1mm (tools, wires & small wires). Protected against water sprayed from all directions - limited ingress permitted.
IP67	The degree of protection provided by the sensor. Totally protected against dust. Protected against the effects of immersion between 15 cm and 1m.
	WTS/GK Revised May 30, 2003
	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.

Table 6.1 Symbols

6.4 Warnings and precautions

Do not immerse the Snapshot unit!

If a IEC 60950-compliant (non-medical) PC is used, it must not be brought in to the patient environment.

Find the electromagnetic compatibility tables according to IEC 60601-1-2 Ed 2 in this Instrumentarium Dental Snapshot user manual.

Personal computer should only be connected to grounded outlet.

Inspect periodically the sensors.

Do not sterilize the sensor using autoclave or UV oven.

Make sure that the Ready LED illuminates before making an exposure.

Recommended exposure values are in the user manual.

Any service attempts by unauthorised persons are strictly prohibited.

Use a new disposable hygienic cover for every patient.

Operating temperature range is in the user manual.

To ensure patient safety please observe the following: The PC shall be placed in the same room and outside patient environment (at least 1.5 m from the patient and patient support).

The system leakage current must be checked to meet the limits of IEC 60601-1-1. This must be notified when connecting other equipments to PC.

The system leakage current can be achieved for example by using 60601-1 compliant PC (medical PC) or medical USB HUB or other appropriate isolation method.

6.5 Manufacturer’s liability

When installing the Instrumentarium Dental Snapshot 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 Instrumentarium Dental Snapshot 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.
- The Instrumentarium Dental Snapshot system is installed and used according to the Installation & User Manual for the Instrumentarium Dental Snapshot system
- Maintenance and repairs are performed by a qualified the Instrumentarium Dental Snapshot 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 60601-1-2 Ed 2 in this Instrumentarium Dental Snapshot user manual.

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

6.6 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, XP, Vista 32-bit)
- Hard disk: 10 GB
- CD-ROM: Yes
- Keyboard: Yes
- Mouse: Yes
- USB port: Yes
- USB: 2.0
- Accessories: Audiocard and speakers optional
- Operating system:
  Windows® 2000 (not recommended, not supported by TWAIN 5.0), XP (SP2), Vista 32-bit.
  See Microsoft Windows System Requirements.
- Main memory (RAM): Windows® 2000, XP and Vista 32-bit: 256 MB or more

6.7 Accessories

Accessories	
Part no.	Description
203441	Intraoral sensor hygienic cover size 1 (generic, fits the Snapshot size 1 sensor)
203442	Intraoral sensor hygienic cover size 2 (generic, fits the Snapshot size 2 sensor)
203435	Sensor cable clip (10 pcs)
203357	Wall mount set
5169578	Hygienic covers
200162	Instrumentarium 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
200163	Instrumentarium 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

Instrumentarium Dental Sensor holders (optionally)

- Available separately
- Two sizes
- Consult your local dealer for details

Other holders available from a third party suppliers:

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

KerrHawe Sensor holders (optionally)

- Available separately
- Universal size
- Bitewing, posterior, anterior, endo
- Consult your local dealer for details

6.8 Technical specifications

Trademark	Snapshot
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 UL2601-1:1997 CAN/CSA C22.2 No.601.1-M90 According to IEC 60601-1:1998 +Am1:1991+Am2:1995, CE models marked according to the Medical Device Directive 93/42/EEC (Device classification: II b)
Patient connection:	Applied part: BF-type
Sensor technology:	CMOS
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 XP (SP2) or Vista 32-bit
Operating software:	CliniView, Instrumentarium TWAIN
Full Mouth Series:	FMS, user defined
File sizes:	0,8 MB, uncompressed file,Sensor size 1 1,3 MB, uncompressed file,Sensor size 2
X-ray shield in the sensor:	Lead (Pb)

CE 0537

Dimensions

Outer dimensions:	Snapshot unit:	86 x 25 x 14 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 mm^2
	Sensor size 2:	36,48 x 25,84 mm^2
Sensor shape:	Four rounded corners, two corners with greater radius for better patient comfort in Sensor size 2.	
Sensor type:	Sensor size 1:	SC-I-1-S1
	Sensor size 2:	SC-I-1-S2
	The sensor type is marked on the main label (see chapter Main label for details).	

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

Sensor unit

PC connection:	USB 2.0
USB:	USB 2.0 High speed, 500 mA.
USB cable length:	maximum 3 meters (9,8 feet).
General applied part (sensor):	BF type

Ambient conditions

Snapshot unit

Transportation and storage temperature:	-40°...+60°C (-40F...+158F),
Operating temperature:	+10°...+40°C (+50F...+104F)
Relative humidity (storage):	10-93%
Water tightness:	IP67 (sensor) IP44 (Snapshot unit)

Materials

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

6.9 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

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.

6.10 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 Instrumentarium Dental Snapshot adjacent to other equipment such configuration should be carefully observed to ensure that electromagnetic interference (EMI) does not degrade performance.*

The use of Instrumentarium Dental Snapshot 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 Snapshot is suitable for use in the specified electromagnetic environment. The purchaser or user of the Snapshot 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 Instrumentarium Dental Snapshot 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 Snapshot 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 Snapshot 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 Snapshot 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 6.2 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 6.3 Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2 Ed 2.

Instrumentarium Dental Snapshot is suitable for use in the specified electromagnetic environment. The purchaser or user of Instrumentarium Dental Snapshot 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 Instrumentarium Dental Snapshot requires continued operation during power mains interruptions, it is recommended that Instrumentarium Dental Snapshot 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 6.4 Electromagnetic immunity IEC 60601-1-2 Ed2

Instrumentarium Dental Snapshot is suitable for use in the specified electromagnetic environment. The purchaser or user of Instrumentarium Dental Snapshot 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 Radiated RFIEC 61000-4-3	3 V 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 are used no closer to any part of Instrumentarium Dental Snapshot, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 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 Instrumentarium Dental Snapshot to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Instrumentarium Dental Snapshot.

**Over the frequency range 150 kHz to 80 MHz, field strengths are less than 3 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 6.5 RF immunity of non-life-support equipment or system IEC 60601-1-2

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