SensorX

Installation and Operating Instructions

$C \epsilon$ **0297** **Rx**Only

AIR TECHNIQUES
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Contents

Appendix

⚠ Important information

1 About this document

These installation and operating instructions are an integral part of the unit.

ⓘ Air Techniques shall not be held liable and offers no guarantees of the safe and smooth operation of this unit if you fail to comply with notes and instructions contained in these Installation and Operating Instructions.

The German version of the installation and operating instructions is the original manual. All other languages are translations of the original manual. These operating instructions are valid for the following SensorX versions:
Item number:
– G9510A (2121100021)
– G9520A (2121100022)

1.1 Warnings and symbols

Warnings
The warning notes in this document highlight possible injury to persons or damage to machinery.
They are marked with the following warning symbols:

⚠ General warning symbol

The warnings are structured as follows:

⚠ **SIGNAL WORD**
Description of type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between different levels of danger:
– **DANGER**
   Direct danger of severe injury or death
– **WARNING**
   Possible danger of severe injury or death
– **CAUTION**
   Risk of minor injuries
– **NOTICE**
   Risk of extensive material/property damage

EN-US

Miscellaneous symbols

These symbols are used in the document and on or in the unit:

🛈 Note, e.g. specific instructions regarding the efficient use of the unit.

REF Part number

SN Serial number

MD Medical device

HIBC Health Industry Bar Code (HIBC)

C€xxxx CE labeling with the number of the notified body

Rx Only Caution: By virtue of Federal Law, the device may only be sold to dentists or bought on behalf of a dentist.

EC REP Authorized EU representative

▲ Manufacturer

Distributor

Date of manufacture

Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).

Take note of the accompanying electronic documents.

Refer to Operating Instructions.

Wear hand protection.

Use a mask.

Wear eye protection.

Wear protective clothing.

Do not reuse

Protection class II

Type BF applied part

Lower and upper temperature limits

Lower and upper atmospheric pressure limits

Lower and upper humidity limits

1.2 Copyright information

All electronic drawings, processes, names, software, and appliances mentioned here are protected under copyright.
Printing or copying these Installation and Operating Instructions, including excerpts thereof, may only be carried out with the written approval of Air Techniques.

2 Safety

The unit has been developed and designed appropriately such that hazards are largely excluded if the unit is used in accordance with its Intended use.
Therefore, please note the following.
Despite this, the following residual risks can remain:

– Personal injury due to incorrect use/misuse
– Personal injury due to mechanical effects
– Personal injury due to electric shock
– Personal injury due to radiation
– Personal injury due to fire
– Personal injury due to thermal effects on the skin
– Personal injury due to lack of hygiene, e.g. infection

2.1 Intended purpose (CE)

Intended purpose (CE)

The intraoral sensor converts x-rays into digital image information and provides it to a dental software.

Contraindications

None.

Intended use (CE)

The intraoral sensor is used to generate intraoral X-ray images in conjunction with an intraoral X-ray unit. Hygienic protective covers must be used.
Only those accessories or parts specifically mentioned in the Installation and Operating Instructions may be used with the device.
The device must only be cleaned and disinfected using the disinfectants and cleaning agents that are listed in the Installation an Operating Instructions.

Improper use (CE)

Any other usage or usage beyond this scope is deemed to be improper.
The intraoral sensor is not suitable for monitoring patients over a long-term period.

2.2 Intended use (FDA)

Indications for use

The intraoral sensor is intended to convert X-ray photons into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

Intended use (FDA)

The intraoral sensor is used to generate intraoral X-ray images in conjunction with an intraoral X-ray unit. Hygienic protective covers must be used.
Only those accessories or parts specifically mentioned in the Installation and Operating Instructions may be used with the device.
The device must only be cleaned and disinfected using the disinfectants and cleaning agents that are listed in the Installation an Operating Instructions.

Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damage resulting from improper usage. In such cases, the user/operator will bear the sole risk.
The intraoral sensor is not suitable for monitoring patients over a long-term period.

2.3 General safety information

The sale or prescription of this device by a medical practitioner is subject to the restrictions of the applicable Federal Acts. The device may be used only under permanent supervision by a dentist or licensed medical practitioner.

RxOnly Caution: By virtue of Federal Law, the device may only be sold to dentists or bought on behalf of a dentist.

› Comply with the guidelines, laws, rules and regulations applicable at the site of operation when you use this unit.
› Prior to each use, check the function and proper condition of the device.
› Do not convert or modify the unit.
› Comply with the Installation and Operating Instructions.
› Make the Installation and Operating Instructions always available to the operator in the vicinity of the device.

2.4 Specialist personnel

Operation

Persons operating the unit must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

Units for commercial use may not be operated or used by:

– People lacking the necessary experience and knowledge

– People with reduced physical, sensory or mental capabilities

– Children

Installation and repairs

› All installation, resetting, alteration, expansion, and repair work must be carried out either by Air Techniques personnel or by a suitably qualified person approved by Air Techniques.

2.5 Protection from electric shock

› Working on the unit, comply with all the relevant electrical safety regulations.

› Never touch the patient and unshielded plug connections or metallic parts of the device at the same time.

› Immediately replace any damaged cables or plugs.

Comply with the EMC rules concerning medical devices

› The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the unit is operated in any other environment, potential effects on the electromagnetic compatibility must be taken into account.

› Do not use the device near HF surgical devices and MRI equipment.

› Keep a minimum distance of 30 cm between the device and other electronical devices.

› Note that cable lengths and cable extensions have effects on electromagnetic compatibility.

› No maintenance measures are required to maintain the basic EMC safety.

⚠ **NOTICE**

Negative effects on the EMC due to non-authorized accessories

› Use only Air Techniques accessories or accessories approved by Air Techniques.

› Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

⚠ **NOTICE**

Erroneous operation mode due to use immediately adjacent to other devices or with other stacked devices

› Do not stack the unit together with other devices.

› If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

⚠ **NOTICE**

Reduced performance features due to insufficient distance between unit and mobile HF communication devices

› Keep at least 30 cm distance between the unit (including parts and cables of the unit) and mobile HF communication devices (wireless units) (including their accessories such as antenna cables and external antennas).

2.6 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3.

The unit meets the requirements according to IEC 60601-1-2:2014.

2.7 Notification requirement of serious incidents

The operator/patient has to report any serious incident related the product to the manufacturer and the competent authority of the Member State, in which the operator and/or patient is established/resident.

2.8 Only use genuine parts

> Only use accessories and optional items specified or approved by Air Techniques.
> Only use original working parts and spare parts.

ⓘ Air Techniques accepts no liability for damage resulting from the use of non-approved accessories, optional items or any parts other than original spare and wear parts.

The use of non-approved accessories, optional items or non-genuine wear parts / replacement parts (e. g. mains cable) can adversely affect the electrical safety and EMC.

2.9 Transport

Only the original packaging ensures optimum protection for the unit during transport.
If necessary, the original packaging for this unit can be ordered from Air Techniques.

ⓘ Air Techniques cannot be held responsible for any damage resulting from transport in unsuitable packaging, even during the warranty period.

> Only transport the unit in its original packaging.
> Keep all packaging away from children.

2.10 Disposal

Disposal of the units, electronic circuitry and PSPs must be accomplished only at the appropriate facilities for recovery and recycling. Make sure to dispose of such items in accordance with current federal, national, state and local government rules and regulations.

2.11 Protection from cybersecurity threats

The unit is to be connected to a computer that can be connected to the Internet. Therefore, the system needs to be protected from threats from the Internet.

> Use antivirus software and update it regularly. Look for evidence of possible virus infection and, if applicable, check with the antivirus software and remove the virus.
> Perform regular data backups.
> Provide access to units only to trustworthy users, e.g. by means of user name and password.
> Make sure that only trustworthy contents are downloaded. Install manufacturer-authenticated software and firmware updates only.

📄 Product description

3 Overview
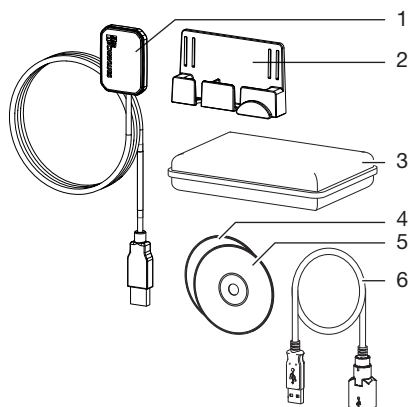
1 Sensor
2 Sensor holder
3 Hygienic protective covers in box
4 Data carrier for imaging software
5 Calibration data carrier
6 USB extension cord

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

SensorX Size #1 . . . . G9510A

– SensorX Size #1, Sensor
– Calibration data carrier
– Sensor holder
– Adhesive pad
– Velcro strip
– Cable holder
– USB extension cord, 1 m
– Hygienic protective covers (qty. 100)
– Imaging software VisionX
– Imaging software DBSWIN
– Installation and Operating Instructions

SensorX Size #2 . . . . G9520A

– SensorX Size #2, Sensor
– Calibration data carrier
– Sensor holder
– Adhesive pad
– Velcro strip
– Cable holder
– USB extension cord, 1 m
– Hygienic protective covers (qty. 100)
– Imaging software VisionX
– Imaging software DBSWIN
– Installation and Operating Instructions

3.2 Accessories

The following items are required for operation of the device, depending on the application:

ⓘ The hygienic protective covers are not sterile at the time of delivery.

Hygienic protective covers Size #1
(qty. 100) G9550
Hygienic protective covers Size #1
(qty. 500) G9551
Hygienic protective covers Size #2
(qty. 100) G9554
Hygienic protective covers Size #2
(qty. 500) G9555

3.3 Optional items

The following optional items can be used with the device:
2D X-ray test phantom G8795

Sensor holder G9556
USB Extension (1 m) G9557

3.4 Consumables

The following materials are consumed during operation of the unit and must be reordered separately:

Hygienic protective covers Size #1
(qty. 100) G9550

Hygienic protective covers Size #1
(qty. 500) G9551

Hygienic protective covers Size #2
(qty. 100) G9554

Hygienic protective covers Size #2
(qty. 500) G9555

4 Technical data

4.1 SensorX Size #1

Electrical data		
Nominal voltage	V DC	5
Nominal current	mA	100

Classification	
Medical Device Class	IIa
FDA classification (CFR Title 21)	II

General technical data		
Dimensions W x H x D	mm in	27.4 x 39.0 x 6.3 1.08 x 1.54 x 0.25
Cable length, sensor	m in	2.5 98.43
Max USB cable extension	m in	1 39.37
Computer connection		USB 2.0 Compatible with USB 3.0

Sensor characteristics		
Active sensor size W x H	mm in	20 x 30 0.79 x 1.18
Min. pixel size	µm	19
Max. no. of pixels		1050 x 1580
Theoretical resolution	LP/mm	26.3
Sensor type		CMOS
Scintillator		Structured CsI scintillator on fibre-optics

4.2   SensorX Size #2

Electrical data		
Nominal voltage	V DC	5
Nominal current	mA	100

Classification		
Medical Device Class		IIa
FDA classification (CFR Title 21)		II

General technical data		
Dimensions W x H x D	mm in	33.1 x 44.7 x 6.3 1.30 x 1.76 x 0.25
Cable length, sensor	m in	2.5 98.43
Max USB cable extension	m in	1 39.37
Computer connection		USB 2.0 Compatible with USB 3.0

Sensor characteristics		
Active sensor size W x H	mm	26 x 36 1.02 x 1.42
Min. pixel size	μm	19
Max. no. of pixels		1368 x 1896
Theoretical resolution	LP/mm	26.3
Sensor type		CMOS
Scintillator		Structured CsI scintillator on fibre-optics

4.3   Electromagnetic compatibility (EMC)

ⓘ The information on electromagnetic compatibility (EMC) applies to both SensorX Sensor Size #1 and Size #2.

Electromagnetic compatibility (EMC) Interference emission measurements	
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Group 1, Class B

Electromagnetic compatibility (EMC) Interference immunity measurements on cover	
Immunity to interference by discharge of static electricity IEC 61000-4-2:2008 ±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant

Electromagnetic compatibility (EMC)
Interference immunity measurements on cover

Immunity to interference by high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010 3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Compliant
Immunity to interference by near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 See Table on immunity to interference table by near fields of wireless HF communication devices.	Compliant

Immunity levels with respect to near fields of wireless HF communication devices

Radio service	Frequency band MHz	Test Level V/m
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE bands 1, 3, 4, 25 UMTS	1700 - 1990	28
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

Electromagnetic compatibility (EMC)
Interference immunity measurements SIP/SOP

Immunity to interference by discharge of static electricity IEC 61000-4-2:2008 ±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant

4.4 Ambient conditions

Ambient conditions during operation		
Temperature	°C °F	10 - 35 +50 to +95
Humidity	%	< 80
Air pressure	hPa	750 - 1160
Height above sea level	m ft	< 2000 < 6562

Ambient conditions during storage and transport		
Temperature	°C °F	-20 to +60 -4 to +140
Humidity	%	10 to 95
Air pressure	hPa	750 - 1160
Height above sea level	m ft	< 16000 < 52493

4.5 Model identification plate

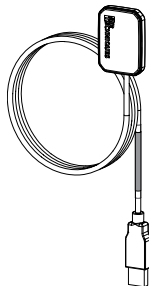The model identification plate is located on the sensor cable and on the case.

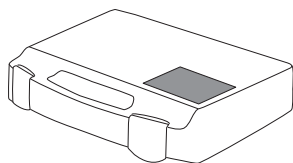*Fig. 1: Model identification plate on the sensor cable*

Fig. 2: Model identification plate on the case

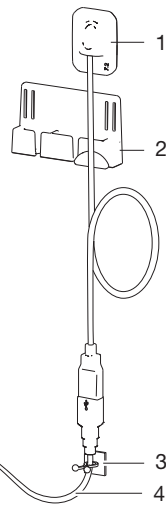| REF	Order number/type number
SN	Serial number

5 Function

Fig. 3: SensorX

1 X-ray sensor
2 Sensor holder
3 Cable holder
4 USB extension cord

The X-ray sensor is connected to the computer via the sensor cable, and if required, the USB extension cable.

The sensor is to be fitted with a hygienic protective cover and to be placed in the mouth of the patient. It is activated via an imaging software (e. g. DBSWIN).

During the X-ray procedure, the X-rays are received by the scintillator (luminescent material) installed in the sensor and are converted into beams of light. These light beams are recorded by the sensor as image information, digitalized and transmitted to the computer. If an error occurs during the transmission, the image information is sent again.

No further X-ray image can be recorded during data transmission.

The application part BF in accordance with IEC 60601-1 is the X-ray sensor.

⚙ Installation

6 Requirements

6.1 Installation/setup room

❯ The unit may only be used in a room that has been set up specifically for this purpose (e. g. an x-ray room). Do not use outdoors.

❯ Do not expose the unit to direct sunlight or heat.

❯ The setup room may not contain any major interference fields (e. g. strong magnetic fields). They could cause malfunction in the unit.

6.2 Monitor

The monitor must meet the requirements for digital X-ray with a high light intensity and wide contrast range.

Strong ambient light, sunlight impinging directly onto the monitor and reflections can make it more difficult or even impossible to perform a diagnosis based on the X-ray images.

6.3 System requirements

The system requirements of the software being used to operate the device must always be met during its operation.

It is recommended to use the latest version of the software.

If third-party software is being used to operate the device, compliance with its system requirements must be assured.

The following additional system requirements must also be met:

Interface:	USB 2.0 USB 3.0
Total maximum cable length:	USB: 5 m
Software:	VisionX 2.4.10 or higher (order number: E7300) VisionX Connect version 3.0 or higher DBSWIN 5.17 or higher (order number: E7200A), VistaEasy, Image Bridge

> For the system requirements of the computer systems, visit the download area at www.airtechniques.com (document no. E7201).

7 Installation

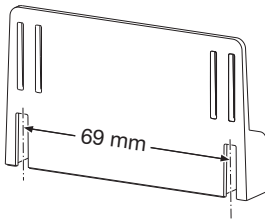## 7.1 Fitting the sensor holder

The sensor holder and the cable holder can be secured to the wall or treatment unit using either the adhesive pad or screws and dowel.
The sensor holder can also be fitted to the lamp stand using the Velcro strip.
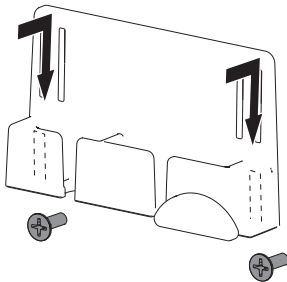
Fastening the sensor holder with screws

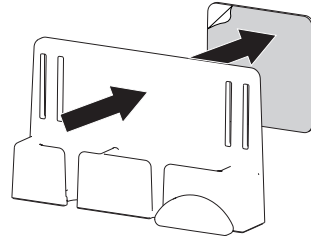ⓘ Use screws and dowel which are suited to the base surface.

› Screw the screws into the wall with the same spacing as between the slits. Insert the screw only to the extent such that the screw head can be hooked into the slits.
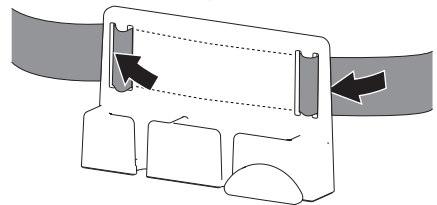

› Place the sensor holder on the screw heads from above.
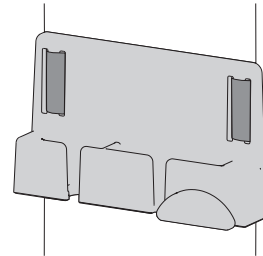

Fastening the sensor holder with the adhesive pad

Fastening the sensor holder using the Velcro strip

› Thread the Velcro strip into the sensor holder.

› Fasten the sensor holder with the Velcro strip.

7.2 Electrical connection

Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

› Only connect units when there can be no question of danger to operator or to patient.
› Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
› If it is not completely clear from the data sheet of the unit that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the relevant manufacturer) to verify that the setup is safe.

› When connecting the unit to other devices, e. g. a PC system, comply with the requirements set out in section 16 of IEC 60601-1 (EN 60601-1).

› When setting up the PC system in the vicinity of the patient:
Only connect components (e.g. computer, monitor, printer) that comply with the standard IEC 60601-1 (EN 60601-1).

› When setting up the PC system outside of the vicinity of the patient:
Connect components (e.g. computer, monitor, printer) that comply at least with the IEC 60950-1 (EN 60950-1) standard.

Connecting the device to a computer

> ⚠ **NOTICE**
> **Damage to the sensor**
>
> The interior parts of the sensor can be damaged by mechanical forces.
>
> › Do not drop the sensor.
> › Do not subject the sensor to any pressure.
> › Do not fold, clamp or crush the cable.
> › Do not carry the sensor by the cable.

› Connect the USB plug of the sensor cable to a free port on the computer.

› If necessary, extend the cable by 1 m using the enclosed USB extension cable.
Further extensions are not permitted.

> ⓘ The USB extension can also be used if the device needs to be plugged in and unplugged regularly and the USB port on the computer is not easily accessible. This protects the USB connection on the computer.

> ⓘ The unit has no main power switch. Therefore, it is important that the USB connection on the PC and, if necessary, the socket outlet for the power supply, are easily accessible and that the appliance can be unplugged if necessary.

7.3 Installation with VisionX

Install the additional component

If the additional component of the unit was not installed along with the installation of the imaging software, it can be installed later on.

› Place the data carrier of the imaging software in the drive or run the installation file.
The Start menu opens.

› If the Start menu does not open automatically, run the file *Start.exe*.

› Select the installation language you require.

› Accept the License Agreement.

› Select the required components.

› Select the *SensorX* unit.

› Follow the further instructions given by the installation wizard.

Installing the calibration data

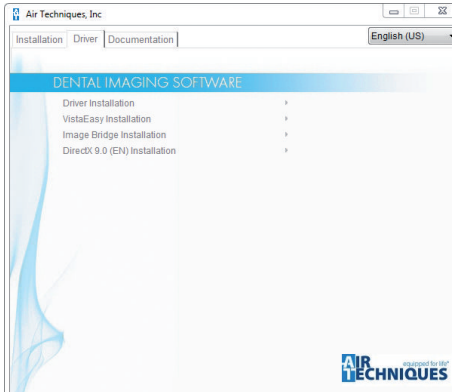> ⓘ Every sensor requires the individual calibration data stored on the enclosed data carrier.

› Insert or plug the enclosed data carrier in the drive.
The data carrier starts automatically and the calibration data are installed.

› If the data carrier fails to start automatically, run the *setup.exe* file.

7.4 Installation with DBSWIN

Installing the driver(s)

› Close all programs.

› Insert or plug the enclosed DBSWIN data carrier in the drive.
The start window opens.

› If the data carrier fails to start automatically, run the *CD_Start.exe* file.

› Select the required language.

› Select the *Drivers* tab.

› Click *Driver Installation*.
› Click *OK* to confirm.
  The *Driver Setup* installation wizard opens.
› Follow the instructions of the installation wizard.

Installing the calibration data

ⓘ Every sensor requires the individual calibration data stored on the enclosed data carrier.

› Insert or plug the enclosed data carrier in the drive.
  The data carrier starts automatically and the calibration data are installed.
› If the data carrier fails to start automatically, run the *setup.exe* file.

8 Commissioning and first start-up

⚠ **NOTICE**

Short circuit due to the build up of condensation

Strong temperature fluctuations can damage the unit.

› Start-up the unit only once it has equilibrated to room temperature.
› Do not expose the unit to strong temperature fluctuations (heating max. 3 °C/min). Exception: Standard heating from room temperature approximately 20° C to body temperature approximately 37 °C during application.

› Before starting every time, check the entire system for damage.
› Perform and document safety checks in accordance with national regulations (VDE 0751-1, IEC 60601-1).
› Carry out and document an acceptance test in accordance with national regulations.

The unit supports the following imaging programs:
– VisionX manufactured for Air Techniques
– DBSWIN manufactured for Air Techniques
– Please inquire about third-party software

ⓘ Always use the current version of the imaging program in the commissioning of the device. Check the version of the enclosed imaging program versus the versions available at www.airtechniques.com.

8.1 Configuring the unit in VisionX

The configuration is done in the settings of the imaging software.

ⓘ For further information, see the Help function of VisionX (E7303).

Requirements:
✓ SensorX is connected to computer.
› Start-up SensorX.
› Click ⚙.
› Click *Devices*.
› Click on the *SensorX* unit in the list.

› Click *Configure*.

Acquisition modes

All acquisition modes that are available on the selected device are listed under *Acquisition mode:*. Once you have selected an acquisition mode from the list, you can implement various settings in the tree directory. They vary depending on the connected device and can depend on the installed firmware version.

Duplicate is used to create a copy of the image acquisition mode.

You can delete the image acquisition mode by clicking on *Delete*.

At least one acquisition mode must always be defined. If only the acquisition mode for this device exists, then it must not be deleted.

Creating an X-ray station

ⓘ To be able to use the sensor in VisionX, an X-ray station with the sensor must be created.

› Click *Create X-ray station...*.
› Under *General*, enter the name of the X-ray station and the information about the operator. The data for the current practice is pre-assigned to the operator information.
› Under *X-ray emitter*, assign the X-ray emitter with which the X-ray images will be created. If the respective X-ray emitter is not included in the list, it needs to be created using *Create X-ray emitter...*.
› Under *Image acquisition device*, select the device with which the X-ray images will be imported.
The selection list contains only the image acquisition devices fitting with the X-ray emitter. If the image acquisition device is not included in the list, the device still needs to be connected to the software.

› At ⤳ or go to the navigation bar and click *X-ray stations*.
The X-ray station will be displayed in the list of X-ray stations.

8.2 Configuring the unit in DBSWIN

The configuration differs depending on the imaging program used:
– DBSWIN: See "Deactivate modules not required in DBSWIN" and "Configuring the device in ScanX Net"
– VistaEasy and third-party software (e.g. Sidexis): See "Configuring the device in ScanX Net"

Deactivate modules not required in DBSWIN

› Start DBSWIN.
› In the *Options menu, select* > *Display Configuration*.
› Click on the *Modules* 🔧 button.
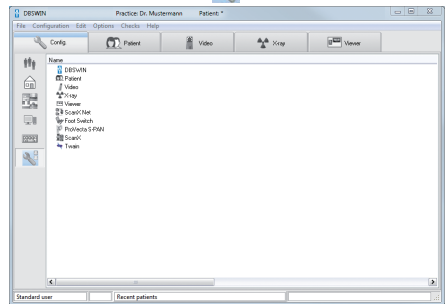
SensorX is controlled by the VistaNet module. In the properties of DBSWIN, the *SensorX* module must be inactive.
If the *ScanX* module is not needed (e.g. for a ScanX Swift View image plate scanner), this module also needs to be inactive.

› Double-click *DBSWIN*.
› Select the *Options* tab.

› Drag the *SensorX* module and if applicable the *ScanX* module with ⟫ into the *Inactive* field.
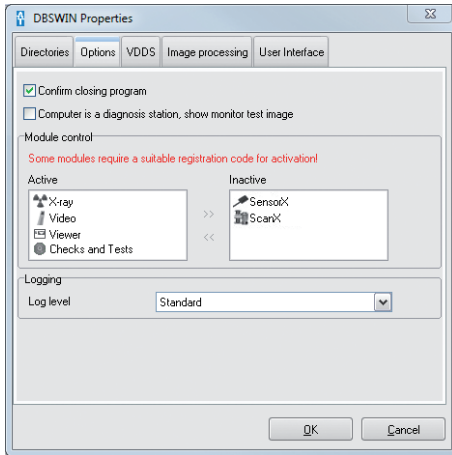
› Restart DBSWIN.

Configuring the device in ScanX Net

› Select *Start* > *All Programs* > *Air Techniques* > *VistaEasy* > *VistaConfig*.
or
In DBSWIN, double-click the *Config.* > *Modules* 🔧 tab followed by *ScanX Net*.

› Activate the connected unit in the *Registered* column.

› Click the *Edit* 📝 button.

› Change the device name (*Designation*) as required.

› Click *Apply* to save the configuration.

Testing the device

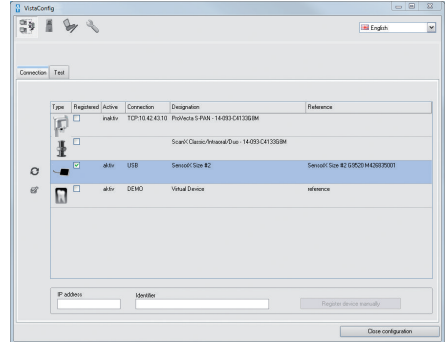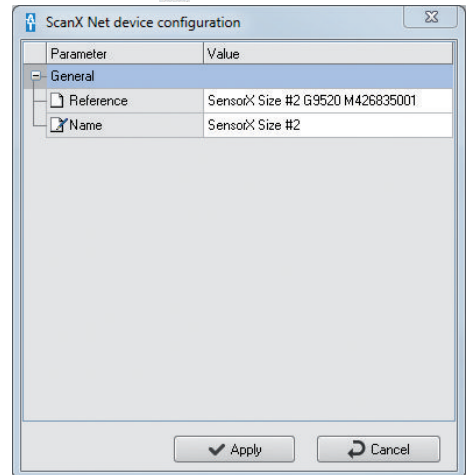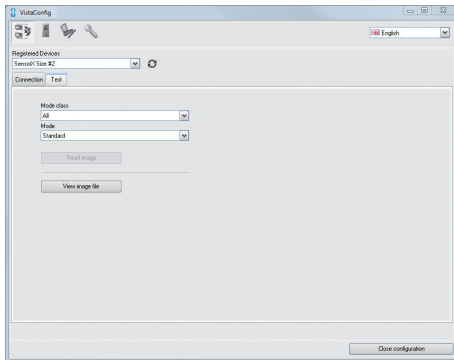An X-ray image can be recorded to test whether the unit has been connected correctly.

> Select the *Test* tab.

> Select the unit from the *Registered Units* list.
> Select the mode.
> Click on *Scan Image*.
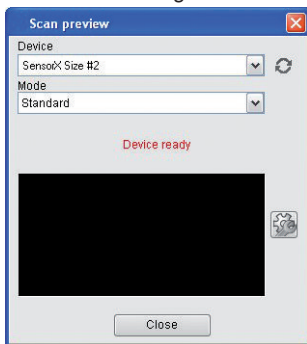
> Record an X-ray image.

8.3 Commissioning tests

The required tests (e.g. acceptance test) must be done in accordance with local rules and regulations.

> Find out which tests are required.
> Carry out testing in accordance with local rules and regulations.

Check image quality

We recommend repeating the test every 3 months. In the event that this requirement deviates from national requirements, please follow and apply the corresponding national requirements.

The image quality test is carried out with VisionX Inspect (see VisionX handbook, order number: E7303 (2110200001).

The following aids are required:

– VisionX Inspect imaging software
– Test phantom for 2D X-rays (see "3.3 Optional items").

Positioning the test phantom

> On the right-hand side of the insertion opening push the sensor as far as it will go into the test phantom. The active side of the sensor must be facing toward the X-ray emitter.

> ⓘ In addition, a small amount of cotton wool wadding can be inserted on the side between the sensor and the test phantom to secure the sensor in position.
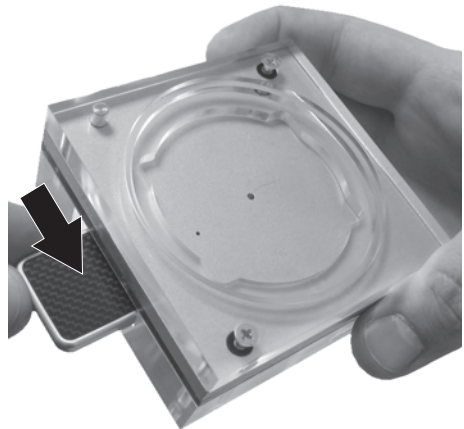
⚠️ **NOTICE**

The test phantom can be damaged if it is dropped.

> Secure the test phantom so that it cannot fall down.
> Alternatively, place the test phantom on a level surface and insert the tube vertically into the centering rings of the test phantom.

> Turn the tube upwards and place the test phantom with the centering rings on the tube.

ⓘ If the test phantom does not fit on the tube, with many manufacturers it is possible to order a tube of the correct size separately.

> Adjust the X-ray parameters (kV, mA, s) on the X-ray unit (use the maxillary molar settings, see "14 Recommended exposure times") and trigger an X-ray image acquisition.

Analysis
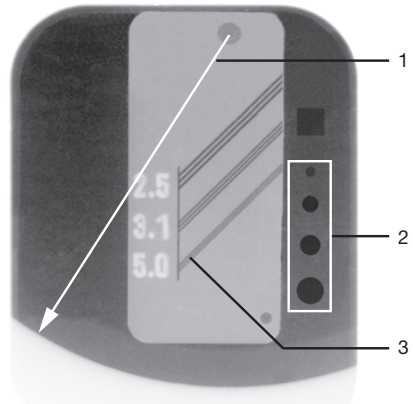
1   Useful radiation field
2   Low contrast
3   High contrast

> Draw a measuring line from the center point of the test image to the edge (boundary between dark/light contrast). The measured result must be less than 30 mm.
The diameter of the useful radiation field (field size at the end of the tube) must not exceed 60 mm.

ⓘ In VisionX Inspect the useful radiation field can be measured with the measuring function in the tool box. (Refer also to the VisionX handbook).

> The four holes (low contrast) must be identifiable.
> At 5.0 LP/mm, the diagonal lines must be clearly distinguishable from each other (high contrast).

Electrical safety checks

> Carry out the electrical safety check according to national law (e. g. in accordance with IEC 62353).
> Document the results.
> Carry out and document the instruction and handover for the unit.

ⓘ A sample handover report is included in the attachment.

👤 **Usage**

9 Operation

⚠️ **CAUTION**

If the sensor is damaged, harmful substances may exit from the unit

> Check the sensor and cable for damage before every use.
> Do not use the sensor if it is damaged.
> Use a right-angle holder.

⚠️ **NOTICE**

Damage to the sensor

The interior parts of the sensor can be damaged by mechanical forces.

> Do not drop the sensor.
> Do not subject the sensor to any pressure.
> Do not fold, clamp or crush the cable.
> Do not carry the sensor by the cable.

We highly recommend using the sensor with a right-angle holder. This prevents positioning errors and protects the sensor against mechanical damage (e.g. through an alarmed patient biting the sensor).
Operating the sensor with DBSWIN or via VistaEasy, you can generate X-ray images in two acquisition modes:
– Standard (26.3 LP/mm)
– Low resolution (13.15 LP/mm)

The transmission time is just a few seconds depending on sensor size and settings.

9.1 Taking an X-ray image

Check before every use:
✓ The sensor and cable are not damaged.
✓ The sensor and cable have been cleaned and disinfected.

🧤 Wear hand protection.

> Start the computer.
> Start the imaging software.
> Select the desired image mode.
> Make SensorX ready for image acquisition in the imaging software.

⚠️ **WARNING**

Danger of cross contamination when not using the hygienic protective cover or when using the hygienic protective cover more than once

The materials used for the hygienic protective cover are not suitable for reprocessing. This can result in malfunctions, leaks and material failure.

> Do not use the unit without the hygienic protective cover.
> Do not re-use the hygienic protective cover (disposable item).

> Push the hygienic protective cover (see "3.2 Accessories") over the sensor.
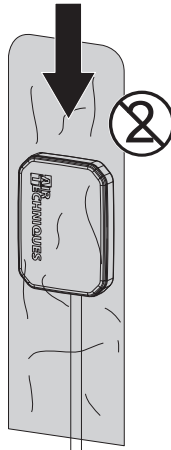
❯ If you use the right-angle technique, make sure to use a fitting right-angle holder. The right-angle holder must not damage the hygienic protective cover.

❯ Set the exposure values on the X-ray unit (see "14 Recommended exposure times").

❯ Place the sensor with the right-angle holder in the patient's mouth.
Make sure that the active (white) side of the sensor faces the X-ray unit when you do this.

❯ Trigger the X-ray image.
The image is automatically transferred to the imaging software. No further X-ray image can be taken during data transmission.

10 Cleaning and disinfection

When cleaning and disinfecting the unit and its accessories, comply with national directives, standards and specifications for medical products as well as the specific specifications for dental practices or clinics.

⚠ **NOTICE**

The use of unsuitable agents and methods can damage the unit and accessories

❯ Only use the disinfection and cleaning agents specified or approved by Air Techniques and the EPA.

❯ Comply with the operating instructions of the disinfectants and cleaning agents.

Wear hand protection.

10.1 Clean and disinfect the accessories

The sensor holder surface, the cable and the USB connector can be disinfected with disinfectant wipes.

› Wipe the surface with a soft, lint-free cloth soaked in disinfectant or with a disinfection wipe. Comply with the operating instructions of the disinfectant.

11 Reprocessing

11.1 Risk analysis and classification

A risk analysis and classification of medical devices that are common in dentistry must be performed before they are reprocessed by the operator. Comply with all national directives, standards and specifications such as e.g. the "Guidelines for Infection Control in Dental Health-Care Settings from the Centers for Disease Control and Prevention".

Accessories of the medical device are also subject to reprocessing.

Classification recommendation based on proper use of the product: **Semi-critical A**

Semi-critical medical product:

A medical product which comes into contact with mucous membrane or pathologically changed skin.

The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

11.2 Reprocessing procedures

Perform the reprocessing procedure after each patient treatment and according to the reprocessing procedure:

– Pre-cleaning and manual cleaning in accordance with AAMI TIR 30

– Manual disinfection in accordance with USFDA (21 CFR sections 58, 201, 211 and 820)

Important information!

The reprocessing instructions in accordance with FDA Guidance "Reprocessing Medical Devices in Health Care Settings - Validation Methods and Labeling" have been independently tested by the manufacturer for the preparation of the device and its components for their reuse.

The person conducting the reprocessing is responsible for ensuring that the reprocessing is performed using equipment, materials and personnel that attains the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person conducting the reprocessing are the responsibility of the member of staff performing the reprocessing.

Frequent reprocessing has little effect on the components of the device. The end of the product life cycle is mainly influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The validation of the reprocessing method was performed based on the assumption that, in the worst case scenario, a hygienic protective cover could be damaged while it is being applied or during use.

In accordance with IEC 80601-2-60, the applied part of the SensorX is limited to a length of 80 mm, starting at the sensor edge, opposite from the cable. For this reason, only the applied part was considered during the validation of the reprocessing method.

The reprocessing procedure was validated as follows:

– **Pre-cleaning**
  – Lint-free disposable wipe
– **Manual cleaning**
  – Monarch disinfection wipes (Air Techniques)
– **Manual disinfection**
  – Monarch disinfection wipes (Air Techniques)

11.3   General information

› Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilization of medical devices as well as the specific specifications for dental practices and clinics.

› When selecting the cleaning and disinfectant agents to be used, the information provided (see "11.5 Manual cleaning, disinfection and drying") must be followed.

› Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning agent and disinfectant.

› Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.

› Only use disinfectants that are aldehyde-free and display material compatibility with the product.

› Only use freshly-produced solutions.

› Only use distilled or de-ionized water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. Legionella bacteria).

› Use clean, dry, oil- and particle-free compressed air.

11.4   Preparation at the operating location

Wear hand protection.

Wear eye protection.

Use a mask.

Wear protective clothing.

› Clean the hygienic protective cover (with integrated sensor) with a disinfection wipe.

› Carefully pull off the hygienic protective cover and discard it.

› Clean the device for 1 minute with a lint-free disposable wipe soaked in cold tap water until no more dirt or contamination can be seen.

❯ Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

11.5 Manual cleaning, disinfection and drying

⚠️ **NOTICE**

Damage to the device due to incorrect cleaning and disinfection

- ❯ Only clean the surface of the unit.
- ❯ Only use disinfection and cleaning agents specified or approved by Air Techniques and the EPA.
- ❯ Use combined cleaning agents and disinfectants which do not contain chlorine, solvents, strong bases (pH >11), or oxidizing agents.
- ❯ Do not use any aggressive or abrasive cleaning agents.
- ❯ Only clean the unit using wipe disinfection.
- ❯ Do not clean the unit by submerging or spraying in combination with disinfectant.
- ❯ Do not subject the unit to steam sterilization.

The outer surfaces of the applied part can be cleaned and disinfected manually using cleaning and disinfection wipes.

Cleaning

- ❯ Thoroughly wipe down the outer surfaces for 1 minute with a cleaning wipe.
  Then allow for 1 minute exposure to the agent.
- ❯ Check to make sure that no soiling is visible any longer.

Disinfecting

- ❯ Thoroughly wipe down the outer surfaces for 1 minute with a disinfection wipe.
- ❯ Repeat this step with a new disinfection wipe for 2 minutes.
  This means that the entire disinfection step is performed for 3 minutes.

Final rinse

After the action time prescribed by the manufacturer has expired:
- ❯ Rinse all components under running water for at least 30 seconds (temperature < 35 °C / < 95 °F).

Drying

- ❯ Allow the device to air-dry.
  The device must be completely dry before a new hygienic protective cover is pulled on.

12 Maintenance

The unit is maintenance-free.

? Troubleshooting

13 Tips for operators and service technicians

ⓘ Any repairs above and beyond routine maintenance may only be done by suitably qualified personnel or by one of our service technicians.

13.1 Poor X-ray image

Error	Possible cause	Remedy
No image transmission, despite X-ray image having been triggered	X-ray dose too low	› Correct the exposure values (see "14 Recommended exposure times").
Artifacts in image	Sensor damaged	› Replace the sensor.
X-ray image too dark or too bright	Incorrect exposure time set	› Correct the exposure time (see "14 Recommended exposure times").

13.2 Software error

Error	Possible cause	Remedy
The operating system does not recognize the unit	Another USB device blocks the USB port	› Remove the blocking USB device.
Error code E-0012	The device driver has not been installed correctly	› Re-install the device driver (see installation and configuration manual).
Error code E-0077	Software installation corrupt	› Inform your Service Technician.
Error code E-1001	The unit is not connected	› Connect the unit to the USB port.
	Incorrect sensor size selected in software	› Select the correct sensor size.
	Unit is defective	› Inform your Service Technician.
Error code E-1002	Multiple sensors are connected to the computer at the same time	› Disconnect the sensors not required. Only a single sensor may be connected to the computer at any one time.
Error code E-1008	Sensor connected with over-long or incorrect USB extension	› Only use the USB extension (1 m) included in the scope of delivery.
	The computer USB port is unsuitable for the data rate	› Connect the sensor to a different USB port.
Error code E-0012	The device driver has not been installed correctly	› Re-install the device driver (see installation and configuration manual).

Error	Possible cause	Remedy
Error code E-1020	The current state of the sensor does not permit image creation	› Disconnect and reconnect the USB connection cable.
	Sensor defective	› Inform your Service Technician.
Error code E-1026	Incorrect image mode	› Select a different image mode. › Inform your Service Technician.
Error code E-2006	No image mode selected	› Select the desired image mode.
Error code E-10014	Sensor calibration data not installed	› Install the sensor calibration data (see installation and configuration manual).
Error code E-10016	Sensor calibration data incorrect	› Inform your Service Technician.

Appendix

14 Recommended exposure times

⚠ **CAUTION**

Over-long exposure times can render the X-ray image unusable

> Do not exceed the maximum exposure time of 0.5 s.

The following table lists the exposure times for an adult patient.
The exposure time must be increased by 25% for adult patients with a high bone density.
The exposure time for children must be reduced by 30%.

	DC emitter, 7 mA Tube length 20 cm				DC emitter, 7 mA Tube length 30 cm			
	60 kV	µGy	70 kV	µGy	60 kV	µGy	70 kV	µGy
Upper jaw								
Incisor	0.080 s	605	0.080 s	858	0.160 s	553	0.100 s	478
Premolar	0.120 s	928	0.100 s	1069	0.160 s	553	0.100 s	478
Molar	0.160 s	1243	0.120 s	1276	0.200 s	693	0.125 s	583
Bitewing	0.160 s	1243	0.120 s	1276	0.200 s	693	0.125 s	583
Mandible								
Incisor	0.080 s	605	0.080 s	858	0.160 s	553	0.100 s	478
Premolar	0.120 s	928	0.100 s	1069	0.160 s	553	0.100 s	478
Molar	0.160 s	1243	0.120 s	1276	0.200 s	693	0.125 s	583
Bitewing	0.160 s	1243	0.120 s	1276	0.200 s	693	0.125 s	583

Tab. 1: Exposure time for adult patients

15 Handover record

This document confirms that a qualified handover of the medical device has taken place and that appropriate instructions have been provided for it. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

☐ Visual inspection of the packaging for any damage
☐ Unpacking the medical device and checking for damage
☐ Confirmation of the completeness of the delivery
☐ Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction: **Signature:**

Name and address of the qualified adviser for the medical device:

Date of handover: **Signature of the qualified adviser for the medical device:**

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