ScanX Swift 2.0

XPS07.1A...

EN-US Installation and Operating Instructions

Rx Only

equipped for life®

2144100140L29 G8802 2305V005

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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 apply to:
ScanX Swift 2.0, Article number: G8800 (2144100510 / XPS07.1A1)

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

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

LOT Batch name

HIBC Health Industry Bar Code (HIBC)

Model number

CE mark

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.

Disconnect all power from the unit.

Do not reuse

DC current


Non-ionizing electro-magnetic radiation


Warning – risk of dangerous electric voltages


Warning - laser beams


This way up / store and transport in an upright position


Keep dry


Stacking limits

Lower and upper humidity limits

Lower and upper temperature limits

Lower and upper atmospheric pressure limits


Fragile, handle with care


Keep away from sunlight during storage

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 Unauthorized modification

Pursuant to Part 15.21 of the FCC rules, any changes or modifications to this equipment not expressly approved by the manufacturer may cause, harmful interference and void the FCC authorization to operate this equipment.

2.2 Intended use (FDA)

ScanX Swift 2.0 - XPS07.1A...

Indications for use

The ScanX Swift 2.0 is intended to be used for scanning and processing digital images exposed on Phosphor Storage Plates (PSPs) in dental applications.

Barrier envelope

Disposable Barrier Envelopes are intended to be used as a disposable barrier for Air Techniques Phosphor Storage Plates. This device is non-sterile and intended for single patient use only.

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.

$\mathbf{Rx}_{\text{Only}}$ 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.

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 FCC note

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a

particular installation. If this equipment 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.

Module Compliance FCC

The device contains the RFID module with the following ID:

– FCC ID: 2ATTE-2144100082

– IC ID: 25412-2144100082

This module has been tested and found to comply with the following requirements for Modular Approval.

– Part 15.225 - Operation within the band 13.110 - 14.010 MHz.

– Part 2.1046 - Measurements required: RF power output

Antennas

This radio transmitter has been approved by the FCC and ISED to operate with the antenna types listed below with the maximum permissible gain indicated.
Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Radio	Antenna Type	Frequency
NFC	Loop	13,56 MHz

RF exposure statement

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

2.7 ISED Statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with ISED's (Innovation, Science and Economic Development Canada's) licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

RF exposure statement

Caution: Exposure to Radio Frequency Radiation

1. To comply with the Canadian RF exposure compliance requirements, this device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.
2. To comply with RSS 102 RF exposure compliance requirements, a separation distance of at least 20 cm must be maintained between the antenna of this device and all persons.

2.8 Essential performance characteristics

The ScanX Swift View 2.0 unit does not have any essential performance characteristics as set out in IEC 60601-1 (EN 60601-1) section 4.3.
The unit meets the requirements according to IEC 60601-1.
The unit meets the requirements according to IEC 60601-1-2:2014.

2.9 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.

2.10 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.

2.11 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.
- Do not expose the unit to any strong vibrations or shocks.

2.12 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.

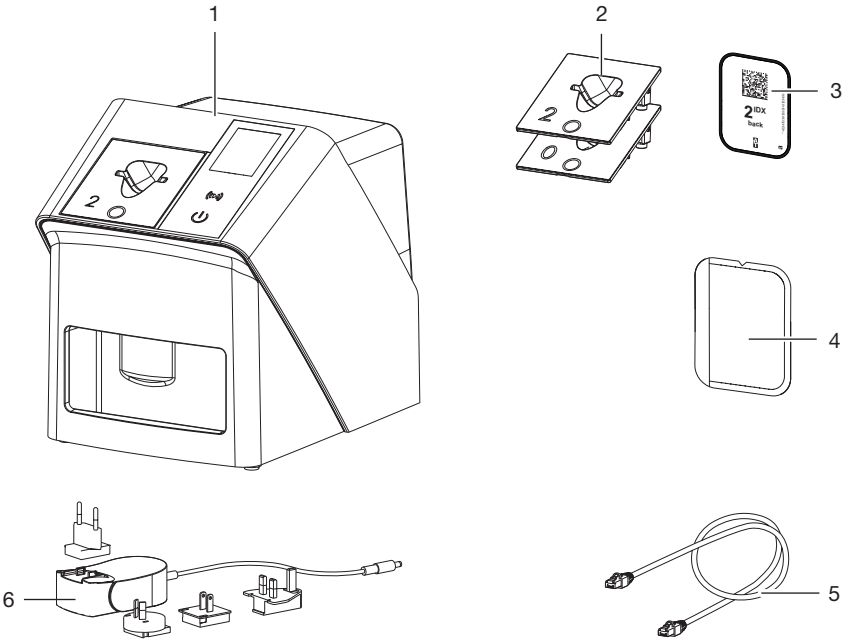
2.13 Protection from cybersecurity threats

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 ScanX Swift 2.0 PSP scanner
2 Plate guides (S0 and S2)
3 Phosphor storage plate IDX
4 Barrier envelope
5 Network cable (3 m)
6 Power supply unit with country-specific adapter

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):

ScanX Swift 2.0

Phosphor storage plate scanner G8800A

- ScanX Swift 2.0 Basic unit
- Power supply
- Network cable (3 m)
- Cover of device ports
- Voucher for VisionX imaging software
- Plate guides:
  - Size 0
  - Size 2 (mounted to the device)
- Phosphor storage plates IDX:
  - Size 0
  - Size 2
- Barrier envelopes:
  - Size 0
  - Size 2
- Barrier films
- Phosphor storage plate cleaning wipes
- Dust cover
- Quick Start Instructions

3.2 Accessories

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

Phosphor storage plates (PSPs)

- Phosphor storage plate IDX Size 0
- Phosphor storage plate IDX Size 1
- Phosphor storage plate IDX Size 2
- Phosphor storage plate IDX Size 3
- Phosphor storage plate IDX Size 4

Barrier envelopes

- Barrrier Envelope S0
- Barrrier Envelope S1
- Barrrier Envelope S2
- Barrrier Envelope S3
- Barrrier Envelope S4

3.3 Optional items

The following optional items can be used with the device:

Wall bracket G8820

Network cable (5 m) G8595

Plate guide storage rack G8819

Commissioning and intraoral constancy tests

2D X-ray test phantom G8795

3.4 Consumables

The following materials are consumed during operation of the device and must be re-ordered:

Cleaning and disinfection

PSP cleaning wipes (50 pieces) B8910

Barrier envelopes

Patented, easy-to-open barrier envelope, size 0 (100 pcs.) 73248-0

Patented, easy-to-open barrier envelope, size 1 (100 pcs.) 73248-1

Patented, easy-to-open barrier envelope, size 2 (300 pcs.) 73248-2

Patented, easy-to-open barrier envelope, size 2 (1000 pcs.) 73248-2k

Patented, easy-to-open barrier envelope, size 3 (100 pcs.) 73248-3

Patented, easy-to-open barrier envelope, size 4 (50 pcs.) 73248-4

3.5 Wear parts and spare parts

Phosphor storage plates (PSPs)

Phosphor Storage Plate Pack IDX,
Size #0
Phosphor Storage Plate IDX S0 (2 pcs.)
Barrier Envelope S0 (1000 pcs.) G8240-0

Phosphor Storage Plate Pack IDX,
Size #1
Phosphor Storage Plate IDX S1 (2 pcs.)
Barrier Envelope S1 (1000 pcs.) G8240-1

Phosphor Storage Plate Pack IDX,
Size #2
Phosphor Storage Plate IDX S2 (2 pcs.)
Barrier Envelope S2 (1000 pcs.) G8240-2

Pack of phosphor storage plates IDX,
Size #3
Phosphor storage plate IDX Size 3
(2 pieces)
Barrier envelope Size 3 (1000 pieces) . G8240-3

Pack of phosphor storage plates IDX,
Size #4
Phosphor storage plate IDX Size 4
(2 pieces)
Barier envelope Size 4 (1000 pieces) . . G8240-4

Plate guides

Plate guide S0 (1 piece) G8813
Plate guide S1 (1 piece) G8814
Plate guide S2 (1 piece) G8815
Plate guide S3 (1 piece) G8816
Plate guide S4 (1 piece) G8817

4 Technical data

4.1 Phosphor storage plate scanner (XPS07.1A...)

Electrical data of the device		
Voltage	V DC	24
Max. current consumption	A	1.25
Output	W	< 30
Type of protection		IP20
Electrical data of the power supply unit		
Nominal input voltage	V AC	100 - 240
Frequency	Hz	50/60
Nominal output voltage	V DC	24
Max. output current	A	1.25
General technical data		
Dimensions (W x H x D)	mm	211 X 249 X 258
	in	8.31 X 9.80 X 10.16
Weight	kg	approx. 5.1
	lb	approx. 11.24
Pixel size (selectable)	µm	12.5 - 50
Max. theoretical resolution	Line pairs/mm (Lp/mm)	approx. 40
Network connection		
LAN technology		Ethernet
Standard		IEEE 802.3u/IEEE 802.3ab
Data Rate	Mbit/s	100/1000
Connector		RJ45
Type of connection		Auto MDI-X
Type of cable		≥ CAT5e
Ambient conditions during operation		
Temperature	°C	+10 to +35
	°F	+50 to +95
Relative humidity	%	20 - 80
Air pressure	hPa	750 - 1060
Elevation above sea level	m	< 2000
	ft	< 6562

Ambient conditions during storage and transport		
Temperature	°C	-20 to + 60
	°F	-4 to +140
Relative humidity	%	10 - 95
Air pressure	hPa	750 - 1060
Classification		
Medical Device Class (MDR)		I
FDA classification (CFR Title 21)		II
Laser class (unit) in accordance with IEC 60825-1:2014		1
Laser source		
Laser class in accordance with IEC 60825-1:2014		3B
Wavelength λ	nm	639
Output	mW	<12
Technical data of the RFID module		
Frequency	MHz	13.56
Modulation		ASK
Electromagnetic compatibility (EMC) Interference emission measurements		
High-frequency emissions in accordance with CISPR 11		Group 1 Class B
Interference voltage at the power supply connection CISPR 11:2009+A1:2010		Conforms
Electromagnetic interference radiation CISPR 11:2009+A1:2010		Conforms
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		Conforms
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		Conforms

Electromagnetic compatibility (EMC) Interference immunity measurements on cover	
Immunity to interference by near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 See Table on immunity levels with respect to near fields of wireless HF communication devices	Conforms

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 on supply input	
Immunity to interference by rapid transient bursts – AC voltage grid IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition frequency	Conforms
Immunity to interference, surges IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Conforms

Electromagnetic compatibility (EMC) Interference immunity measurements on supply input	
Immunity to interference, line-conducted disturbances induced by high-frequency fields – AC voltage grid IEC 61000-4-6:2013 3 V 0.15 - 80 MHz 6 V ISM frequency bands 0.15 - 80 MHz 80 % AM at 1 kHz	Conforms
Immunity to interference due to voltage dips, short interruptions and voltage fluctuations IEC 61000-4-11:2004	Conforms

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	Conforms
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1 kV 100 kHz repetition frequency	Conforms
Immunity to conducted disturbances, induced by radio-frequency fields – SIP/SOP ports IEC 61000-4-6:2013 3 V 0.15 - 80 MHz 6 V ISM frequency bands 0.15 - 80 MHz 80 % AM at 1 kHz	Conforms

4.2 Phosphor storage plate

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

Ambient conditions during operation		
Temperature	°C	18 - 45
	°F	64 - 113
Relative humidity	%	< 80

Ambient conditions during storage and transport		
Temperature	°C	< 45
	°F	< 113
Relative humidity	%	< 80

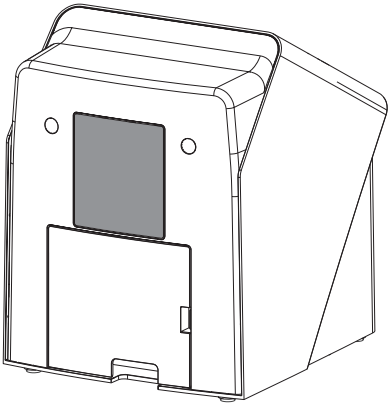
Dimensions of phosphor storage plates		
S0	mm	22 x 35
	in	0.87 x 1.38
S1	mm	24 x 40
	in	0.94 x 1.57
S2	mm	31 x 41
	in	1.22 x 1.61
S3	mm	27 x 54
	in	1.06 x 2.13
S4	mm	57 x 76
	in	2.24 x 2.99

4.3 Barrier envelope

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

4.4 Model identification plate

The type plate is located on the back cover of the device.



REF Order number
SN Serial number

4.5 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant guidelines of the European Union. This equipment conforms to all relevant requirements.

4.6 Simplified declaration of conformity

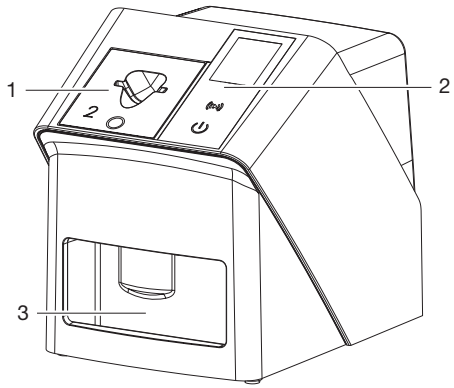
ScanX Swift View 2.0 - XPS07.2A...

The manufacturer hereby declares that the device satisfies the requirements of, among others, Directive 2014/53/EU.
The full text of the EU declaration of conformity can be viewed online in the Download Center:

https://qr.duerrdental.com/conformity

5 Function

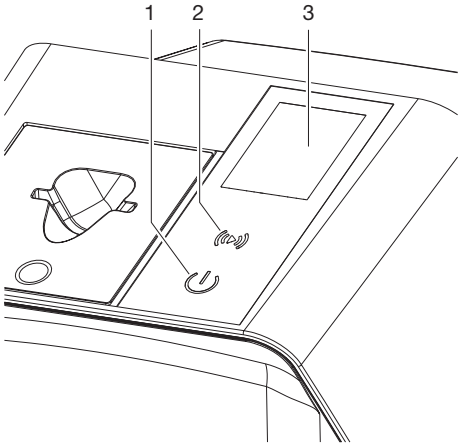
5.1 Phophor storage plate scanner



1 Plate guide
2 Control elements and display
3 Collection tray

The phosphor storage plate scanner is used to scan image data stored on a phosphor storage plate and transfer the data to the imaging software (e.g. VisionX) on a computer.
The transport mechanism guides the phosphor storage plate through the device. The phosphor storage plate is read using a laser inside the scanner unit. The scanned data is converted into a digital image and transferred to the imaging software.
After scanning, the phosphor storage plate runs through the erasure unit. Image data still held on the phosphor storage plate is erased with the aid of bright light.
The phosphor storage plate is then ejected for re-use.

Operating elements



1 On/off switch
2 Confirmation key
3 Display

On/off switch

The On/Of button indicates different states of the device:

- Device off
  Press the On/Off button to start the device.
- The device starts up or is ready for use
  The start screen is displayed as soon as the device is ready for use.

Confirmation key

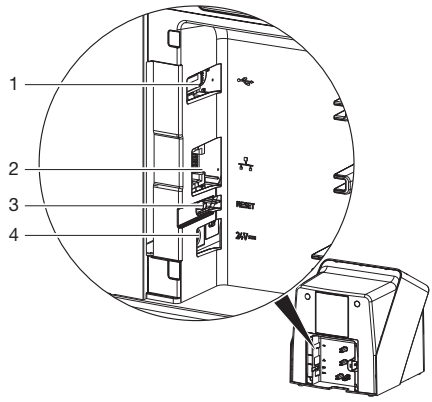
The confirmation key is used to acknowledge messages on the display. The key flashes when a message is displayed that needs to be acknowledged.

Display

The display shows information that is made available by the imaging software.

Connections

The connections are located on the rear of the unit, underneath the cover.

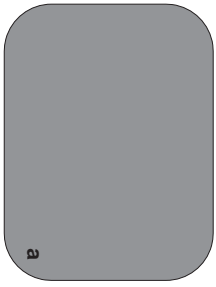


1 USB port (additional accessories)
2 Network connection
3 Reset button
4 Connection for power supply unit

5.2 Phosphor storage plate

The PSP stores X-ray energy, which is re-emitted in the form of light after excitation by the laser. This light is then converted into image information in the phosphor storage plate scanner.
The PSP has an active side and an inactive side. The PSP must always be exposed on the active side.
When used properly, a PSP can be exposed, read and erased several hundred times provided there is no mechanical damage. The PSP must be replaced if there are any signs of damage, e.g. if the protective layer is damaged or there are visible scratches that could interfere with the diagnostics.

Intraoral

Inactive side	Active side
	

Inactive side	Active side
White, with "back", size and manufacturer's information printed on it	Light blue, with positioning aid *a*

Positioning aid *a* is visible on the x-ray image and makes orientation easier during diagnosis.

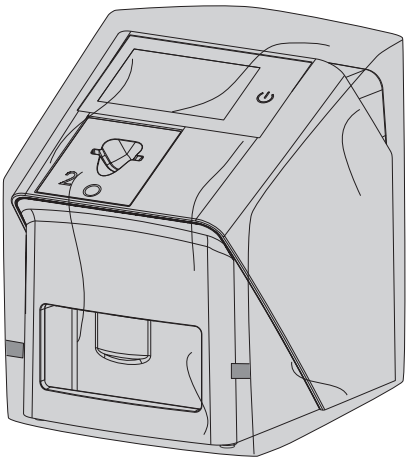
Only use phosphor storage plate IDX with the unit. The unit is unable to read any other types of PSP.

5.3 Barrier envelope

Disposable Barrier Envelopes are intended to be used as a disposable barrier for Air Techniques Phosphor Storage Plates. This device is non-sterile and intended for single patient use only.

5.4 Dust cover

The dust cover protects the device against dust and dirt, for example during extended periods in which the device is not in use.



Installation

Only qualified specialists or persons trained by Air Techniques may install, connect, and commission the unit.

6 Requirements

6.1 Installation/setup room

The room chosen for set up must meet the following requirements:

- Closed, dry, well-ventilated room
- It should not be a room made for another purpose (e.g. boiler room or wet cell)
- Max. light intensity 1000 Lux, no direct sunlight at the place of installation of the unit
- There should be no major fields of interference (e.g. strong magnetic fields) present that can interfere with the proper operation of the unit.
- Ambient conditions correspond to "4 Technical data".

6.2 System requirements

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

6.3 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.

7 Installation

7.1 Setting up the unit

NOTICE

Damage to sensitive components of the unit due to shocks or vibrations

› Do not expose the unit to any strong vibrations or shocks.
› Do not move the unit during operation.

Portable and mobile HF communication appliances can interfere with the effectiveness of electrical medical devices.

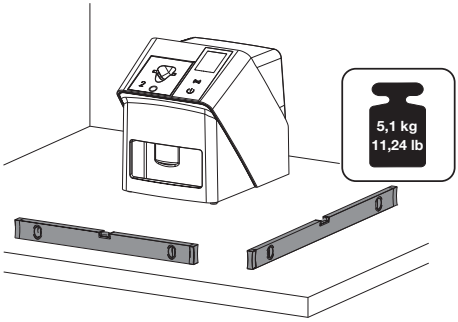
› Do not stack the unit next to or together with other appliances.
› If, however, this unit is operated next to other units or stacked with other units, monitor the unit carefully in the configuration selected in order to ensure normal operation.

The unit can be set up as a tabletop unit or mounted on a wall using the wall bracket.
The load-bearing capacity of the table or wall must be suitable for the weight of the unit (see "4 Technical data").

Setting the unit on a table

To prevent errors when scanning the image data, install the unit so it is not exposed to vibrations.

› Place the unit on a firm, horizontal surface.



Installing the unit with the wall mounting bracket

The unit can be mounted on a wall with the wall mounting bracket (see "3.3 Optional items").

7.2 Electrical connection

Electrical safety when making connections

› Connect the device to a correctly installed power outlet only.
› Do not place non-fixed multi-socket units on the floor. Comply with the requirements in section 16 of IEC 60601-1 (EN 60601-1).
› Do not operate any other systems using the same multiple socket.
› Make sure that none of the electrical cables leading to the unit are under any mechanical tension.
› Before initial start-up verify that the mains supply voltage and the voltage stated on the type plate match (see also "4. Technical data").

Connecting the unit to the mains supply

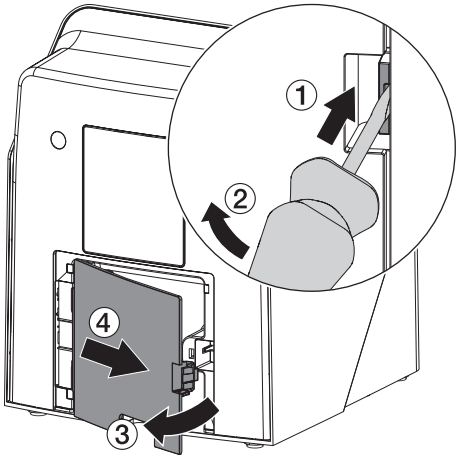
The unit has no main power switch. For this reason, it is important to set up the unit properly such that the plug can be easily accessed and unplugged if required.

Requirements:
✓ Properly installed power outlet close to the unit (observe the max. length of the power cord)
✓ Easily accessible power outlet
✓ Mains voltage matches the information shown on the type plate of the power supply unit

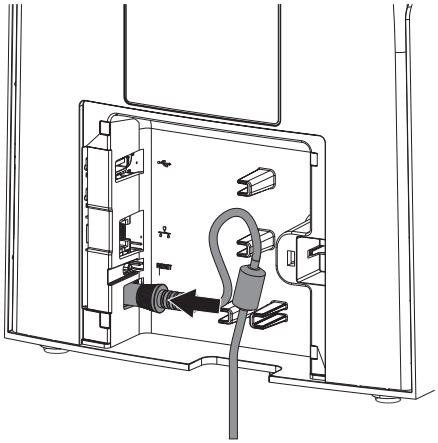
Only the released power supply units may be used:
9000150006 EM1024KR or
9000101790 TR30RDM240

› Attach the matching country-specific mains cable to the power supply unit.

› Remove the cover on the rear of the device using a suitable tool (e.g. slot screwdriver).

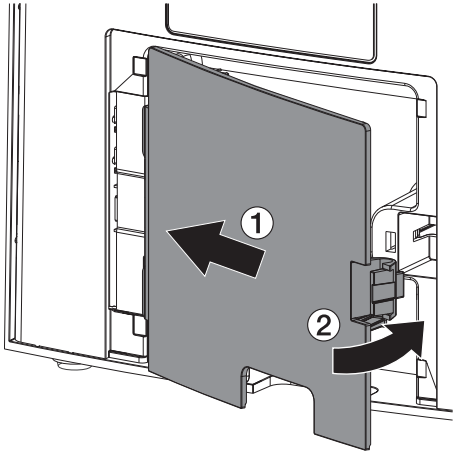


› Plug the connecting plug of the power supply unit into the connection socket of the unit.



› Plug the mains plug into the power outlet.

› Replace the cover.



When operating the device, the cover on the rear must be mounted.

7.3 Connecting the unit to the network

Purpose of the network connection

The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

– Display parameters
– Select operating modes
– Indicate messages and error situations
– Change device settings
– Activate test functions
– Transmit data for archiving
– Provide documents concerning the devices

The unit can be connected to the network with a network cable.

Combining devices safely

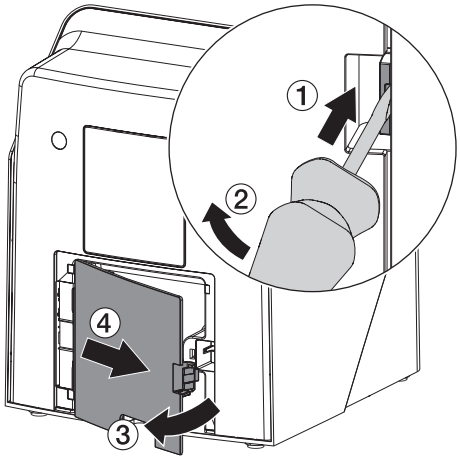
– Safety and essential performance features are independent of the network.
– Faulty manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
– If, e. g., the following changes are made to the network, new risks can arise that require further analysis:
  – Changes in the IT network configuration
  – Connecting additional elements to the IT network
  – Removing elements from the IT network
  – "Update" of devices that are connected to the IT network
  – "Upgrade" of devices that are connected to the IT network
– The data connection utilizes part of the bandwidth of the network. Interactions with other medical devices cannot be completely excluded. Apply the IEC 80001-1 standard for risk assessment.
– The device is not suitable to be connected directly to the public internet.

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).

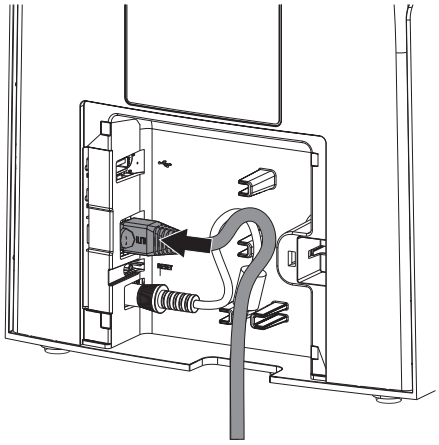
› Only connect units when there can be no question of danger to operator or to patient.
› Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
› If it is not completely clear from the data sheet of the unit that such connections can be safely made 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.
› Comply with the specifications of IEC 60601-1 (EN 60601-1) when connecting the appliance with other appliances, e.g. a PC system, both in and outside the patient environment.
› Only connect peripheral units (e.g. computer, monitor, printer) that conform at least to the requirements set out in the standards IEC 60950-1 or EN 62368-1.
› The connected computer must conform to EN 55032 (class B) and EN 55024.

Connecting the unit via the network cable

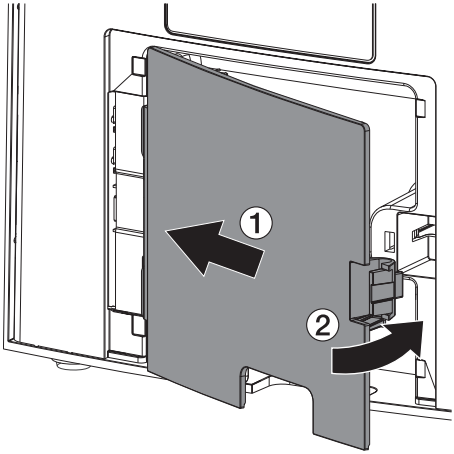
› Remove the cover on the rear of the device using a suitable tool (e.g. slot screwdriver).



› Plug the enclosed network cable into the network socket of the device.



› Replace the cover.



When operating the device, the cover on the rear must be mounted.

8 Commissioning and first start-up

NOTICE

Short circuit due to the build-up of condensation

› Do not switch on the unit until it has warmed up to room temperature and is dry.

The unit supports the following imaging programs:

– VisionX made by Air Techniques
– VisionX Connect
– Third-party software on request

Always use the latest version of the imaging program and ScanX Service Tool when commissioning the device.

8.1 Configuring the network

Network configuration

Various options are available for network configuration:

✓ Automatic configuration via DHCP.
✓ Automatic configuration via Auto-IP for direct connection of device and computer.
✓ Manual configuration.

› Configure the network settings of the device using the software or, if applicable, the touch screen.
› Check the firewall and release the ports, if applicable.

Network protocols and ports

Port	Purpose	Service
1900 UDP	Device identification	
80 TCP	Device identification	
438 TCP	Unit data	
22 TCP	Diagnosis	SSH
n/a	Check that the device is switched on	ICMP / ping

When the unit is first connected to a computer, it applies the language and time settings of the computer.

8.2 Configuring the unit

Use the ScanX Service Tool for configuration.

› To start the Service Tool via VisionX : Select ⚙ > *Devices* > *Configuration* > *Service* > *Service-Tool*.
Alternatively: Launch the Service Tool via the Windows Start menu:
Start > *VisionX Service-Tool* > *VisionX Service-Tool*
› Mark the connected unit in the list.

If the connected device is not included in the list, check if the device is switched on and connected to the network. Then click *Find again*.

› Click *OK*.
If connection fails, an error is displayed.
› Select workflow *001 Initial start-up*.
› Follow the instructions provided by the service tool.

Entering a permanent IP address (recommended)

To reset the network settings, keep the unit reset key pressed for 15 - 20 seconds while switching on.

› Select *Network settings*.
› Change *Use DHCP* to *off*.
› Enter the IP address, subnet mask and gateway.
› Click *Save changes*.
The configuration is saved.

8.3 Security settings

Communication between imaging software and device is always encrypted. At the time of delivery, communication is protected by a default password: 123456. If the security requirements are more extensive, this password needs to be changed in the settings of the imaging software. For more information, please refer to the manual of the imaging software.

8.4 Testing the device

You can scan an X-ray image to check if the unit is properly connected.

› Open VisionX.
› Create an X-ray station for the connected unit.
› Log-in the demo patient (patient ID: DEMO0001).

› Select the acquisition type (e. g. Intraoral).
› To scan a PSP, see "10 Operation".

8.5 X-ray unit settings

A setting of 60 kV is preferred provided it can be set on the X-ray unit.
The standard exposure values for F-speed film (e. g. Kodak Insight) can be used.

The following table shows the standard values for the exposure time and the dose area product of an phosphor storage plate for an adult patient.
The information regarding the elimination time and does area product referred to the use of a VistaIntra as an X-ray device.
µGy = image receiver dose
$mGycm^2$ = dose area product

	DC radiator, 7 mA, tube length 20 cm						
	Without X-ray field limitation			X-ray field limitation 2x3		X-ray field limitation 3x4	
	60 kV	µGy	$mGycm^2$	60 kV	$mGycm^2$	60 kV	$mGycm^2$
Incisor	0.08 s	459	14.6	0.08 s	3.1	0.08 s	6.2
Premolar	0.12 s	715	21.9	0.12 s	4.6	0.12 s	9.3
Molar	0.17 s	1021	31.1	0.17 s	6.6	0.17 s	13.2
Bitewing	0.18 s	1080	32.9	0.18 s	7.0	0.18 s	14

	DC radiator, 6 mA, tube length 30 cm						
	Without X-ray field limitation			X-ray field limitation 2x3		X-ray field limitation 3x4	
	70 kV	µGy	$mGycm^2$	70 kV	$mGycm^2$	70 kV	$mGycm^2$
Incisor	0.13 s	530	11.8	0.13 s	2.5	0.13 s	5.0
Premolar	0.18 s	730.8	16.4	0.18 s	3.4	0.18 s	6.9
Molar	0.25 s	1024	22.8	0.25 s	4.8	0.25 s	9.6
Bitewing	0.27 s	1107	24.6	0.27 s	5.2	0.27 s	10.4

› Check and adjust the specific X-ray unit in accordance with the standard values.

8.6 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.

Acceptance check

The 2D X-ray test phantom, and possibly the corresponding test phantom holder as well, is required for acceptance tests with the PSP and sensor as receivers.

› Before commissioning the unit, the acceptance test of the X-ray system must be carried out in accordance with national regulations.
The constancy tests, which must be carried out at regular intervals by the surgery personnel, are based on the results of the acceptance test.

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 Correct use of phosphor storage plates

WARNING

Risk of cross contamination when not using the barrier envelope or when using the barrier envelope more than once

- Do not use an phosphor storage plate without a barrier envelope.
- Do not re-use the barrier envelope (disposable item).

CAUTION

Image data on the phosphor storage plate is not permanent

The image data is altered by light, natural X-ray radiation and scattered X-ray radiation. This will lead to a reduction in diagnostic information and clarity.

- Read the image data within 30 minutes of exposure.
- Never handle exposed phosphor storage plates without the barrier envelope.
- Do not subject an exposed phosphor storage plate to X-ray radiation before and during the scanning process. Do not X-ray during the scanning process if the unit is in the same room as the X-ray tube.
- Phosphor storage plates must only be read using a phosphor storage plate scanner that is approved by Air Techniques.

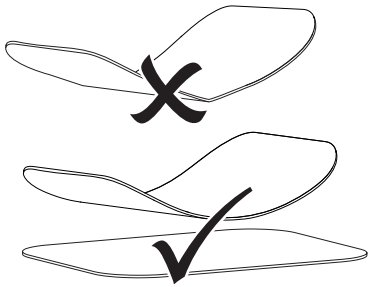
CAUTION

Phosphor storage plates (PSP) are toxic

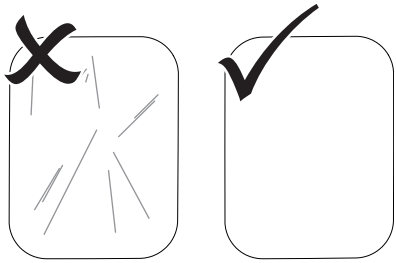
PSPs that are not used with a barrier envelope can lead to poisoning when placed in the mouth or swallowed.

- Only place PSPs in the patient's mouth in a barrier envelope.
- Do not swallow the PSP or parts of it.
- If the PSP or parts of it have been swallowed, consult a specialist doctor immediately and remove the PSP.
- If the barrier envelope was damaged in the patient's mouth, rinse the mouth thoroughly with copious amounts of water. Do not swallow the water in the process.

- Phosphor storage plates are flexible like X-ray film. However, the phosphor storage plates should not be bent.



- Do not scratch the phosphor storage plates. Do not subject the phosphor storage plates to pressure from hard or pointed objects.



- Do not soil the phosphor storage plates.
- Protect the phosphor storage plates against sunlight and ultraviolet light.
  Store phosphor storage plates in a barrier envelope of the correct size.

- Phosphor storage plates will be pre-exposed on exposure to natural radiation and stray x-ray radiation. Protect erased and exposed phosphor storage plates from X-ray interference.
  If the phosphor storage plate has been stored for longer than one week, erase the phosphor storage plate prior to use.
- Do not store phosphor storage plates under hot or moist conditions. Note the ambient conditions (see "4 Technical data").
- When used properly, phosphor storage plates can be exposed, read and erased several hundred times provided there is no mechanical damage.
  Replace the phosphor storage plate if there are any signs of damage, e.g. if the protective layer is damaged or there are visible scratches that impair the quality of the diagnosis.
  Also replace the phosphor storage plate if the RFID tag is damaged or becoming detached.
- Phosphor storage plates that have a production or packaging defect will be replaced by Air Techniques in the same quantity. Claims can only be accepted within 7 working days after receipt of the goods.
- Clean phosphor storage plates properly (see "11 Cleaning and disinfection").

10 Operation

CAUTION

Image data on the phosphor storage plate is not permanent

The image data is altered by light, natural X-ray radiation and scattered X-ray radiation. This will lead to a reduction in diagnostic information and clarity.

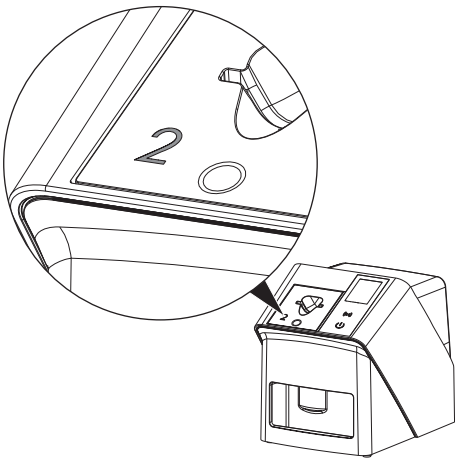
- Read the image data within 30 minutes of exposure.
- Never handle exposed phosphor storage plates without the barrier envelope.
- Do not subject an exposed phosphor storage plate to X-ray radiation before and during the scanning process. Do not X-ray during the scanning process if the unit is in the same room as the X-ray tube.
- Phosphor storage plates must only be read using a phosphor storage plate scanner that is approved by Air Techniques.

10.1 Switch the device on

› Tapping the On/Off switch ⏻ turns on the device.
The On/Off button lights up briefly and the device starts up.
As soon as the device is ready for use the On/Off button is blue and the start screen is displayed.

10.2 Replacing the plate guide

The device can read phosphor storage plates in the sizes S0 to S4. The matching plate guide is needed for each size of phosphor storage plate. The size of the phosphor storage plate is marked on the plate guide.



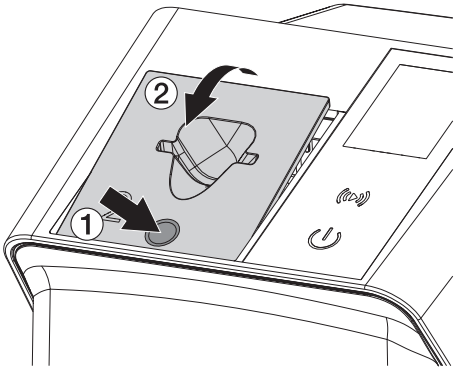
CAUTION

Loss of image information and equipment damage if the wrong plate guide is used

› Always use the plate guide of the correct size for the PSP being used.
› Before each scanning process, compare the phosphor storage plate size with the markings on the plate guide.

The plate guy can be switched at any time. To prevent a loss of image quality do not switch the plate guide during a scanning process.

› Use your finger to press the indentation while tilting the plate guide toward the front at the same time.



› Insert the plate guide from above.

10.3 X-ray

The workflow is described using an IDX S2 phosphor storage plate as an example.

Only use phosphor storage plate IDX with the unit. The unit is unable to read any other types of PSP.

Required accessories:
– PSP
– Barrier envelope of the same size as the PSP

WARNING

Risk of cross contamination when not using the barrier envelope or when using the barrier envelope more than once

› Do not use an phosphor storage plate without a barrier envelope.
› Do not re-use the barrier envelope (disposable item).

WARNING

Danger from the re-use of products intended for single use

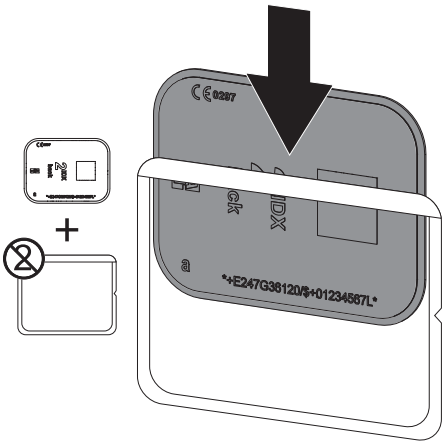
Single-use article is damaged after use and cannot be reused.

› Dispose of single-use articles after use.

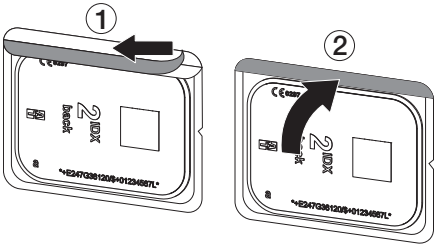
Preparing the X-ray

✓ The phosphor storage plate has been cleaned.
✓ The phosphor storage plate is not damaged.
✓ The adhesive film sticks to the inactive side of the phosphor storage plate. If the adhesive film peels off, replace the phosphor storage plate.
› If using it for the first time or if it has been stored for over a week: erase the phosphor storage plate (see "10.5 Erasing the phosphor storage plate").

› Completely slide the phosphor storage plate into the barrier envelope. The white (inactive) side of the phosphor storage plate must be visible.



› Pull off the adhesive strip, fold down the flap and close the barrier envelope tightly by pressing together firmly.



Taking the X-ray image

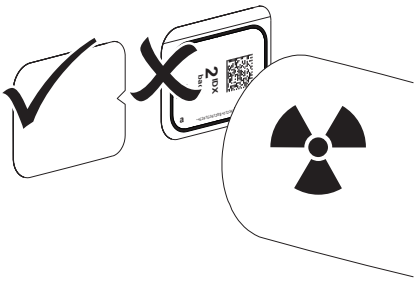
NOTICE

Damage to the phosphor storage plate (PSP) caused by a sharp-edged holding system

› Only use holding systems that do not damage the barrier envelope or the PSP.
› Do not use holding systems with sharp edges.

Wear hand protection.

› Place the phosphor storage plate in the barrier envelope into the patient's mouth.
In doing this, make sure that the active side of the phosphor storage plate faces the X-ray tube.



› Set the exposure time and setting values on the X-ray unit (see "8.5 X-ray unit settings").
› Record an X-ray image.

Result:
The image data must be scanned within 30 minutes.

Preparing for scanning

CAUTION
Light erases the image data on the phosphor storage plate
› Never handle exposed phosphor storage plates without the barrier envelope.

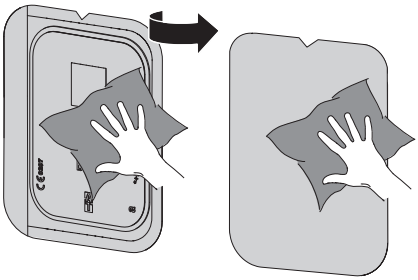
Wear hand protection.

› Remove the phosphor storage plate with the barrier envelope from the patient's mouth.

WARNING
Contamination of the unit
› Clean and disinfect the barrier envelope before removing the PSP.

› In the event of heavy soiling, e. g. from blood, dry clean the barrier envelope and protective gloves, e. g. wipe with a clean cellulose cloth.

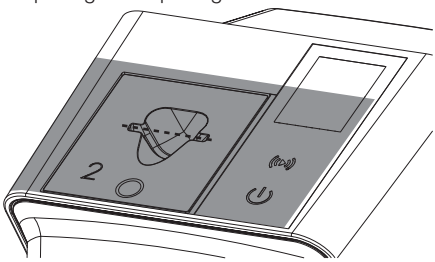
› Disinfect the barrier envelope and protective gloves with a suitable disinfection wipe; see "11 Cleaning and disinfection").
Alternatively, use a spray disinfectant on a soft, lint-free cloth.



› Allow the barrier envelope and phosphor storage plate to dry completely.

NOTICE
Powder from the protective gloves on the PSP damages the unit during scanning
› Completely clean all traces of the protective glove powder from your hands before handling the PSP.

› Take off the protective gloves and disinfect your hands.
› Apply the barrier film to the device.
Doing so make sure that the opening in the middle of the barrier film coincides with the opening of the plate guide.



10.4 Scanning the image data via a computer

Starting the phosphor storage plate scanner and software

The reading-out process is described using the VisionX imaging software.
For further information regarding the use of the imaging software, refer to the relevant manual.

› Start VisionX.
› Select the patient.
› Select the corresponding image type in the menu bar.
› Select the unit.
› Set the acquisition mode.
Recording starts immediately.
› If ScanManager is enabled, select the X-ray job on the touch screen of the unit.

Result:
The touch screen will display an animated visual symbol requesting insertion of the phosphor storage plate.

Insert the phosphor storage plate only once the bar above the animation is green.
Do not insert another phosphor storage plate as long as the bar of the animation is blue.

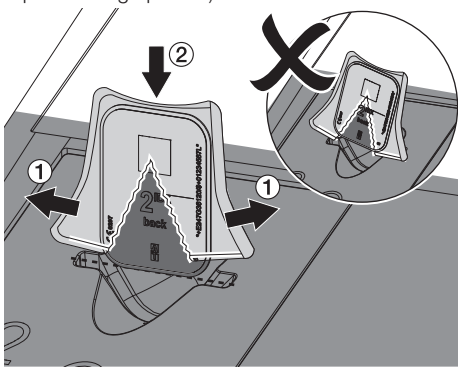
Scanning the PSP

Observe the information on the display.
When feeding in the phosphor storage plate, make sure that it is correctly assigned to the right patient.

› Tear the barrier envelope lengthwise at the notch.
› Place the barrier envelope containing the phosphor storage plate in the plate guide such that it is aligned in the middle and straight. The opened side of the barrier envelope faces down, the inactive side of the PSP faces the operator.

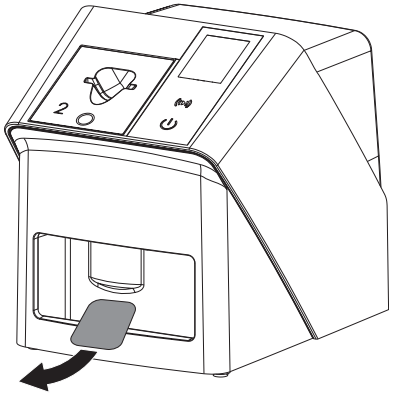
The device recognizes automatically if the phosphor storage plate was fed in wrong orientation (active side toward the user) and displays a message to this effect on the touchscreen. Turn over the phosphor storage plate (in active site toward the user)and feed it in again immediately.

› The phosphor storage plate must not be pushed out of the barrier envelope before placing it against the plate guide. Otherwise there is a risk that image information could be erased by ambient light (see "9 Correct use of phosphor storage plates").



› Slide the phosphor storage plate out of its barrier envelope downwards into the device until the phosphor storage plate is automatically drawn in.
The barrier envelope is held in place by the plate guide and is not transported into the unit. Make sure to insert only the phosphor storage plate, and not the barrier envelope, into the unit.
The image data is automatically transmitted to the imaging software.
After it has been scanned, the phosphor storage plate is erased and drops into the collection tray.
› Remove the empty barrier envelope.

› Remove the phosphor storage plate and prepare to take a new X-ray.



› Peel the barrier film and discard it.

› If applicable, scan any more phosphor storage plates that need to be scanned.
After the last phosphor storage plate click *Finish image acquisition*.

10.5 Erasing the phosphor storage plate

The image data is erased automatically after scanning.
The special *ERASE* mode only activates the erasure unit of the phosphor storage plate scanner. No image data is scanned.
The phosphor storage plate needs to be erased using the special mode in the following cases:

– The first time the phosphor storage plate is used or if it is stored for more than one week.
– Due to an error, the image data on the phosphor storage plate has not been erased (software error message).

› Select the special *ERASE* mode in the software.

› Insert the phosphor storage plate (see "Scanning the PSP").

10.6 Switching the unit off

› Tap the On/Off switch ⏻ to turn the device Off.
The On/Off button lights up briefly and the device powers down.
As soon as the unit has shut down it switches off completely.

After switching off the unit, wait 10 seconds before switching the unit on again.

› In case of malfunction, a hard power-down of the unit can be done. For this purpose, tap the On/Off button for 5 seconds ⏻.
In response, the unit powers down immediately.

Using the dust cover

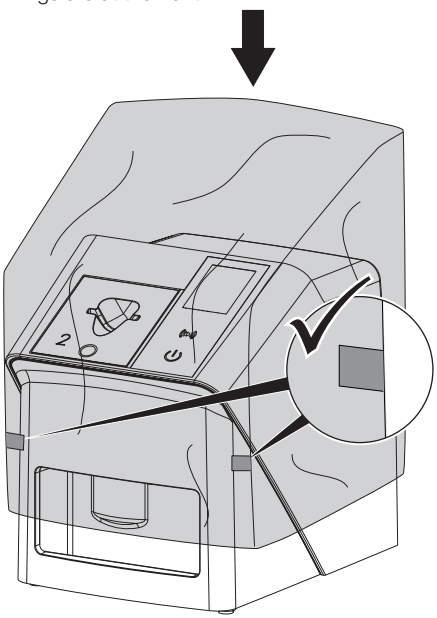
The dust cover protects the device against dirt and dust during extended periods in which it is not used.

WARNING

Danger of suffocation

› Store the dust cover out of the reach of children.

› Pull the dust cover over the device until it is completely covered. Make sure that the markings are at the front.



› Store the dust cover in a clean place when it is not in use.

11 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.

11.1 Phophor storage plate scanner

Surface of the unit

The plate guide needs to be removed prior to cleaning and disinfection (see "10.2 Replacing the plate guide").

For cleaning and disinfection of the plate guide, see "Plate guide".

The surface of the unit must be cleaned and disinfected if it is contaminated or soiled.

NOTICE

Liquid can cause damage to the unit

› Do not spray the unit with cleaning agents or disinfectants.
› Make sure that liquid penetrates into the unit.

› Remove any soiling with a soft, lint-free cloth that has been dampened with cold tap water.
› Disinfect the surfaces with a disinfectant wipe. Alternatively, use a spray disinfectant on a soft, lint-free cloth. Comply with the operating instructions of the disinfectant.

Plate guide

The plate guides can be cleaned and disinfected with a wipe disinfection.

NOTICE

Heat damages the plate guide

› Do not subject plate guide to steam sterilization.

› Remove any soiling from both sides of the plate guide with a soft, damp, lint-free cloth.
› Disinfect the plate guide using a disinfectant wipe. Alternatively, use a spray disinfectant on a soft, lint-free cloth. Comply with the operating instructions of the disinfectant.
› Allow the plate guide to completely dry before using it.

11.2 Barrier envelope

› Clean the Barrier Envelope after being removed from the patient's mouth with a disinfectant wipe, such as Air Techniques Monarch Surface Wipes.
› Allow the Barrier Envelope to completely dry prior to ejecting the PSP.

11.3 Phosphor storage plate

Cleaning and disinfectant wipes are unsuitable for the cleaning of phosphor storage plates and may damage them.
Only use a cleaning agent that is compatible with the materials:
Air Techniques recommends the PSP Cleaning Wipes (see "3.4 Consumables"). Only this product has been subjected to material compatibility testing by the manufacturer.

NOTICE

Heat or humidity damage the phosphor storage plate

› Do not sterilize the phosphor storage plate with steam.
› Do not disinfect the phosphor storage plate by immersion.
› Only use cleaning agents that are compatible with the materials.

› Soiling on both sides of the phosphor storage plate should be cleaned off with a soft, lint-free cloth before each use.
› Remove persistent or dried soiling with the phosphor storage plate cleaning cloth. Comply with the instructions for use of the cleaning cloth.
› Allow the phosphor storage plate to completely dry before using it.

11.4 Dust cover

Clean the surface of the dust cover if it is visibly dirty.
› Clean the dust cover with a soft, lint-free cloth that has been moistened with cold tap water.
› Always clean and disinfect the unit before placing the dust cover on it.

12 Maintenance

12.1 Recommended maintenance schedule

Only qualified personnel or personnel trained by Air Techniques is allowed to service the unit.

Prior to working on the unit or in case of danger, disconnect it from the mains.

The recommended maintenance intervals are based on operation of the device for 15 intraoral images per day on 220 working days per year.

Maintenance interval	Maintenance work
Annually	› Visually inspect the device.
	› Check the phosphor storage plates for signs of scratches and change if necessary.
	› Check the belt drives, transport belts and springs, and replace if necessary.
	› Remove dust and dirt from accessible parts.
	› Carry out a system check.
Every 3 years	› Replace the light protection brushes.
	› Change the roller fixtures.
	› Change the drive belt.

Troubleshooting

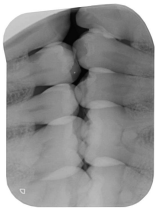
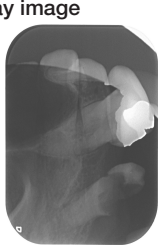
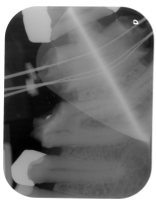
13 Tips for operators and service technicians

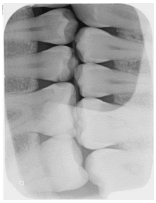
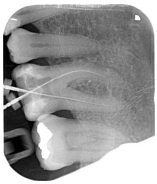
Any repairs above and beyond routine maintenance may only be done by suitably qualified personnel or by one of our service technicians.

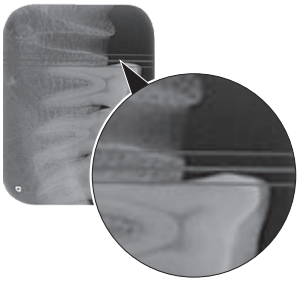
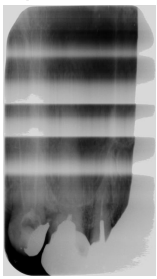
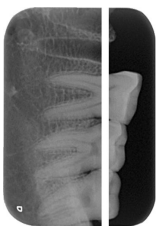
Prior to working on the unit or in case of danger, disconnect it from the mains.

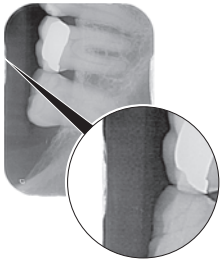
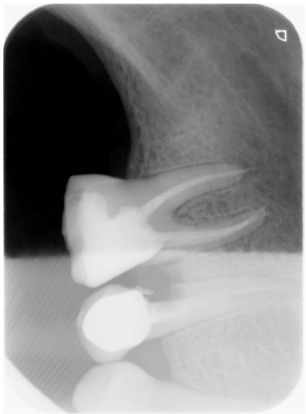
13.1 Poor X-ray image

Error	Possible cause	Remedy
Instead of the X-ray image, the software shows a completely white image or no image	Phosphor storage plate not fed in straight and inactive side was scanned	› Scan the phosphor storage plate again immediately, protecting it against ambient light and making sure you feed it in correctly in the process.
	Image data on the PSP has been erased, e.g. by ambient light	› Always scan the image data of the PSP as soon as possible.
	Fault in the unit	› Contact technician.
	No image data on phosphor storage plate, phosphor storage plate not exposed or not sufficiently exposed	› X-ray tube / check settings of the unit › Expose the PSP.
	X-ray unit is faulty	› Contact technician.
	Incorrect cartridge, barrier envelope was also pushed into the unit	› Use the correct cartridge for the size of phosphor storage plate being used.
Phosphor storage plate drops out of the unit, no image is shown on the monitor and an error message is displayed	IDX phosphor storage plate was not used	› Only use Air Techniques IDX phosphor storage plates.
X-ray image too dark	X-ray dose too high	› Check X-ray parameters.
	Incorrect brightness/contrast settings in the software	› Adjust the brightness of the X-ray image in the software.
X-ray image too bright	Exposed PSP has been exposed to ambient light	› Always scan the image data of the PSP as soon as possible.
	X-ray dose too low	› Check X-ray parameters.
	Incorrect brightness/contrast settings in the software	› Adjust the brightness of the X-ray image in the software.

Error	Possible cause	Remedy
X-ray image only shadowy	The X-ray dose on the PSP was insufficient	› Increase X-ray dose.
	Amplification (HV value) is set too low in the software	› Increase amplification (HV value).
	Unsuitable scanning mode selected	› Select a suitable scanning mode.
	The setting for the threshold value is too high	› Reduce the threshold value.
Top or bottom bulge in the X-ray image 	PSP inserted off-center and at an angle	› Check the error code on the touch screen. › Insert the PSP centrally and straight.
X-ray image is mirror inverted	PSP exposed on the wrong side.	› Insert the PSP correctly in the barrier envelope.
		› Position the PSP correctly.
		› Mind the error message and mirror the X-ray image manually in the imaging software.
Ghosting or double exposure on X-ray image 	PSP exposed twice	› Only expose the PSP once.
	PSP not sufficiently erased	› Check the erasure unit for proper function. › Inform a service technician, if the problem persists.
X-ray image mirrored in one corner 	PSP creased during X-ray exposure	› Do not bend the PSP.

Error	Possible cause	Remedy
Shadow on the X-ray image 	PSP removed from the barrier envelope before scanning	› Do not handle PSPs without a barrier envelope. › Store the PSP in a barrier envelope.
X-ray image cut off, part missing 	A metal part of the X-ray tube is in front of the X-ray beam	› Recording an X-ray image, make sure there are no metal parts between the X-ray tube and the patient.
		› Check X-ray tube.
	Faulty edge masking in imaging software	› Deactivate edge masking.
Software unable to combine the data to make a complete image	The X-ray dose on the PSP was insufficient	› Increase X-ray dose.
	Amplification (HV value) is set too low in the software	› Increase amplification (HV value).
	Unsuitable scanning mode selected	› Select a suitable scanning mode.
	The setting for the threshold value is too high	› Reduce the threshold value.
X-ray image has strips on image	PSP has been pre-exposed, e.g. by natural radiation or stray X-ray radiation	› If the PSP has been stored for more than one week, erase the PSP prior to use.
	Parts of PSP exposed to light during handling	› Do not expose exposed PSPs to bright light. › Scan image data within half an hour after the exposure.
	PSP dirty or scratched	› Clean the PSP. › Replace scratched PSP.
Bright stripes in the scanning window	Too much incident ambient light during the scanning process	› Darken the room. › Turn the unit such that no light is directly incident on the input unit.

Error	Possible cause	Remedy
Horizontal, grey lines in the X-ray image, extending beyond the left and right image edge 	Transport slipping	› Clean the transport mechanism, replace the transport belts if necessary.
X-ray image is stretched lengthwise with bright, horizontal stripes 	Wrong barrier envelope or PSP used	› Only use original accessories.
X-ray image split vertically into two halves 	Dirt in the laser slit (e.g. hair, dust)	› Clean the laser slit.
X-ray image with small bright spots or clouding	Micro scratches on the PSP	› Replace the PSP.

Error	Possible cause	Remedy
Lamination of the PSP detaches at the edge 	Wrong retainer system used	› Only use original PSP and film retainer systems.
	PSP handled incorrectly.	› Use the PSP correctly. › Comply with the operating instructions of the PSP and film retainer systems.
The X-ray image shows a pre-erasure at one end 	After the barrier envelope has been torn open, the phosphor storage plate is pushed out of barrier envelope prior to scanning.	› Do not push out the phosphor storage plate until the torn-off barrier envelope has been placed on the input unit.

13.2 Software error

Error	Possible cause	Remedy
"Too much ambient light"	Unit is exposed to too much light	› Darken the room. › Turn the unit such that no light can directly enter into the entry slot.
"Incorrect power supply unit"	Incorrect power supply unit connected	› Use the enclosed power supply unit.
"Overtemperature"	Laser or erasure unit too hot	› Switch the unit off and allow it to cool.
"Erasure unit fault"	LED defective	› Contact technician.

Error	Possible cause	Remedy
Imaging software fails to recognize the unit	Unit not switched on	› Switch the device on.
	Connecting cable between unit and computer not correctly connected	› Check the connecting cable.
	Computer does not detect any connection to the unit	› Check the connecting cable. › Check the network settings (IP address and subnet mask).
	Hardware error	› Contact technician.
	The IP address of the unit is being used by another unit	› Check the network settings (IP address and subnet mask) and assign a unique IP address to each unit. › Inform a service technician, if the problem persists.
Error during data transmission between unit and computer. Error message "CRC error timeout"	Connecting cable used is incorrect or too long	› Only use original cables.
Software message: "VisionX has detected that the phosphor storage plate may have been exposed from the wrong side. Please check the orientation and the image quality before making a diagnosis"	The phosphor storage plate was exposed on the back (inactive) side while the X-ray was being taken	› When diagnosing the X-ray image, note that the X-ray image is displayed mirror-inverted.
Error message "E2490"	The connection to the unit was interrupted while the software was still attempting to communicate with the unit	› Restore the connection to the unit. › Repeat the process.

13.3 Fault on the unit

Error	Possible cause	Remedy
Unit does not switch on	No mains voltage	› Check the mains cable and plug connection and replace if necessary.
		› Check the power supply unit. › If the green status LED does not light up, replace the power supply unit.
		› Check the mains fuse in the building.
	On/off switch is defective	› Contact technician.

Error	Possible cause	Remedy
Unit switches off again after a short time	Mains cable or power supply unit plug not inserted correctly	› Check the mains cable and plug connections.
	Hardware defect	› Contact technician.
	Mains supply voltage too low	› Check the mains supply voltage.
Unit not shown in the imaging software	Network cable not plugged in	› Plug-in the network cable.
	No DHCP server connected	› It may take some time for the imaging software to detect the unit. › Update the unit list.
	Faulty network configuration	› Configure the network correctly.
Unit is on, but there is no display on the touch screen	Touch screen initialization fault	› Switch the unit off and on again.
	Touch screen brightness set too dark	› Update firmware. › Increase the brightness of the touch screen.
	Touch screen defective	› Contact technician.
Loud operating noises after switching on lasting for more than 30 seconds	Radiation deflector defective	› Contact technician.
Unit not responding	The unit has not yet completed the startup procedure	› After switching the unit on, wait 20 - 30 seconds for the startup procedure to be completed.
	Unit is blocked by the firewall	› Enable the ports for the unit in the firewall settings.
Phosphor storage plate does not fit into the intake slot	Incorrect cartridge used	› Use the correct cartridge for the size of phosphor storage plate being used.
Barrier envelope slips into intake slot along with the phosphor storage plate	Incorrect cartridge used (too large)	› Use the correct cartridge for the size of phosphor storage plate being used.

Error	Possible cause	Remedy
Network connection has been disconnected	WLAN stick is not inserted	› Insert the WLAN stick into the device.
	Distance to WLAN router too far	› Set up the unit closer to the WLAN router.
	Walls between WLAN router and unit are too massive	› Set up the unit closer to the WLAN router.
	Another WLAN network is affecting the operation of the unit's WLAN network	› Change the frequency range of the WLAN network.
	Connecting cable between unit and computer not correctly connected	› Check the connecting cable.
	IP address of the device is used by another device	› Check the network settings (IP address and subnet mask) and assign a unique IP address to each unit. › Inform a service technician, if the problem persists.
Unit ejects the phosphor storage plate without the image data being transmitted to the imaging software. Error message: "Incorrect phosphor storage plate type inserted"	IDX phosphor storage plate was not used	› Only use phosphor storage plates IDX made by Air Techniques › The ejected phosphor storage plate can be imported on a suitable phosphor storage plate scanner (e.g. ScanX Swift View). Make sure that the phosphor storage plate is protected against ambient light.

13.4 Error messages on the display

Error	Possible cause	Remedy
Error code -1008	Internal connection disrupted	› Update firmware.
Error code 1010	Temperature of unit too high	› Allow the unit to cool down. › Contact technician.
Error code 1022	Subassembly not initialized	› Fault in software, update the software if required. › Contact technician.
Error code 1024	Internal data communication fault	› Switch the unit off and back on again. › Update the firmware. › Darken the room. › Turn the unit so that no light can fall directly into the insertion slot.
Error code 1026	Incorrect acquisition mode	› Select a different acquisition mode › Inform a service technician. › Update the firmware. › Reset the scanning modes to the factory settings via the unit interface or the Imaging Software.
Error code 1100	Permitted time for scan process exceeded	› Contact technician. › Check the belt drive. › Check for blockage, remove PSP from unit.
Error code 1153	Unit fault	› Switch the unit off and on again. › Update firmware.
Error code 1154	Internal data communication fault	› Switch the unit off and on again. › Update firmware.
Error code 1160	Final radiation deflector rotation speed not reached	› Contact technician. › Update firmware. › Replace the radiation deflector subassembly if the problem occurs regularly.
Error code -1171	Fault on laser	› Return the unit for repair.
Error code 1172	SOL sensor timeout Fault on the laser, SOL sensor or pentaprism assembly	› Inform a service technician. › Update the firmware.
Error code 10000	Unit is exposed to too much light	› Darken the room. › Turn the unit such that no light can be directly incident in the entry slot.

Error	Possible cause	Remedy
Error code 10009	Internal communication error warning; unit remains ready for operation	› Update the firmware.
Error code 10017	Unit shuts down	› Wait until the unit has shut down completely
Error code -10027	Plate guide is missing or was taken off	› Insert plate guide.
Error code -10026	Phosphor storage plate exposed on the wrong side	› Insert the PSP correctly in the barrier envelope.
		› Position the phosphor storage plate correctly.
		› Mind the error message and mirror the X-ray image manually in the imaging software.
Error code -10027	Incorrect plate guide used	› Always use the correct plate guide for the size of the phosphor storage plate.
Error code -10028	Incorrect or damaged phosphor storage plate used	› Use an approved phosphor storage plate or check the phosphor storage plate for damage. The phosphor storage plate has been erased.
Error code 2	System error during startup of the unit	› Switch the unit off and back on again. › Update the firmware.
Error code -78	Storage medium (e. g. memory card or memory stick) is full	› Transmit image data to the computer. › Insert an empty storage medium.
	Fault during memory cleanup	› Press and hold the reset button while switching on the unit.
		› Update firmware. › Press and hold the reset button while switching on the unit.
Firmware not running	A firmware update has been carried out	› Switch the unit off and on again.
	Internal communication fault	› Switch the unit off and on again.
Settings (e.g. language) reset after unit restart	Faulty configuration file	› Update the firmware. › Reset the configuration to the factory settings and reconfigure.

Appendix

14 Scanning times

The scanning time is the time required for complete scanning of image data and depends on PSP format and pixel size.
The time to image depends mainly on the computer system used and its work load. Times stated are approximate.

Theoretical resolution (LP/mm)	**40**	**25**	**20**	**10**	**6.7**
Pixel size (µm)	**12.5**	**20**	**25**	**50**	**50**
Intra S0 (2 x 3)	26 s	16 s	13 s	6 s	4 s
Intra S1 (2 x 4)	32 s	20 s	16 s	8 s	4 s
Intra S2 (3 x 4)	32 s	20 s	16 s	8 s	4 s
Intra S3 (2.7 x 5.4)	40 s	25 s	20 s	10 s	5 s
Intra S4 (5.7 x 7.6)	53 s	33 s	27 s	14 s	8 s

15 File sizes (uncompressed)

The file sizes depend on the PSP format and the pixel size. File sizes stated are approximate and have been rounded upwards.
Suitable compression methods can considerably reduce the file size without loss of data.

Theoretical resolution (LP/mm)	**40**	**25**	**20**	**10**	**6.7**
Pixel size (µm)	**12.5**	**20**	**25**	**50**	**50**
Intra S0 (2 x 3)	9.86 MB	3.85 MB	2.46 MB	0.62 MB	0.62 MB
Intra S1 (2 x 4)	12.29 MB	4.80 MB	3.07 MB	0.77 MB	0.77 MB
Intra S2 (3 x 4)	16.27 MB	6.36 MB	4.07 MB	1.02 MB	1.02 MB
Intra S3 (2.7 x 5.4)	19.01 MB	7.43 MB	4.75 MB	1.19 MB	1.19 MB
Intra S4 (5.7 x 7.6)	55.45 MB	21.66 MB	13.86 MB	3.47 MB	3.47 MB

16 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:**

Hersteller / Manufacturer:

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