X-DRS VET Smart

Instructions for Use / CN.000216

Version 1.0, 2024-06

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Imprint

Only instructed and authorised persons may have access to the X-DRS VET Smart

Before working with the X-DRS VET Smart, the user manual must be read and completely well understood.

Imprint

CE

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Content

1 Specifications

1.1 Intended Use

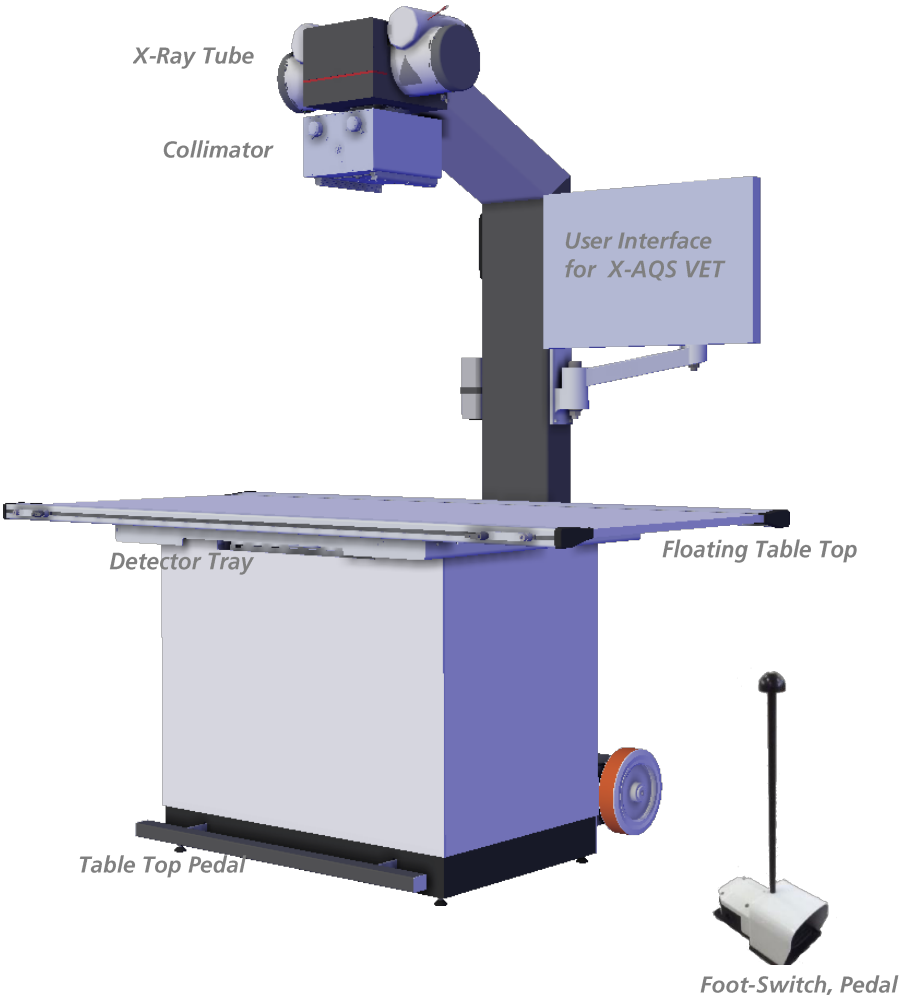
The X-DRS VET Smart is a veterinary medicine radiology station for small animals. The X-ray system consists of a standing unit with an installed X-ray generator, X-ray tube, X-ray detector, collimator, floating tabletop and a support arm holding the All-in-One PC. The system can be used for any X-ray imaging of a recumbent animal to investigate the skeleton, chest and abdomen.

WARNING – Predictable Misuse

Any use of the X-ray system for purposes other than those specified hereinabove is prohibited - it may result in serious personal injury and/or property damage.

It is prohibited to use the X-DRS VET Smart for human medical applications!

1.2 Components & Sizes



X-Ray Monobloc

Technical Specifications

Generator model	**PSG-HRS32**
Power input	**3,52kVA**
Supply voltage	**230 V**
Frequency	**50/60 Hz**
Range in kV (in 1 kV steps)	**40 to 125 kV**
Range in mA (in 25 mA steps)	**10 to 400 mA**
Minimum mAs	**0.1 mAs**
Maximum mAs	**320 mAs**
Small focal point	**0.6 mm**
Large focal point	**1.2 mm**

Permissible mAs Values

Maximum kV, mA, ms, small focus – Scale R20

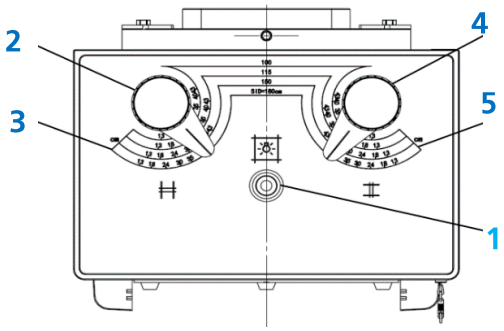
kV / mA	40	50	60	70	80	90	100	110	120	125
10										
11									2200	2200
12,5								2200	2000	2000
14							2200	2000	1800	1800
16						2200	2000	1800	1600	1600
18					2200	1800	1600	1600	1400	1400
20				2200	2000	1600	1600	1400	1250	1250
22			2200	2000	1800	1600	1400	1250	1100	1100
25			2000	1800	1600	1400	1250	1100	1000	1000
28		2200	1800	1600	1400	1250	1100	1000	900	900
32		2000	1600	1400	1250	1100	1000	900	800	800
36	2200	1600	1400	1250	1100	900	800	800	710	710
40	2000	1600	1250	1100	1000	800	800	710	630	630
45	2000	1400	1100	1000	800	710	710	630	560	560
50	1600	1250	1000	900	800	710	630	560	500	500
56	1400	1100	900	800	710	630	560	500	450	450
63	1250	1000	800	710	630	560	500	450	400	400
71	1100	900	710	630	560	500	450	400	360	360
80	1000	800	630	560	500	400	400	360	320	320
90	800	710	560	500	400	360	320	320	280	280
100	800	630	500	450	400	320	320	280	250	250
110	710	560	450	400	360	320	280	250	220	220
125	630	500	400	360	320	280	250	220	200	110
140	560	450	360	320	280	250	220	140		
160	500	400	320	250	250	220	50			
180	400	320	280	250	220					
200	400	320	250	220	50					

Maximum kV, mA, ms lage focus – Scale R20

kV / mA	40	50	60	70	80	90	100	110	120	125
10										
11									2200	2200
12,5								2200	2000	2000
14							2200	2000	1800	1800
16						2200	2200	1800	1600	1600
18					2200	1800	2000	1600	1400	1400
20				2200	2000	1600	1600	1400	1250	1250
22			2200	2000	1800	1600	1600	1250	1100	1100
25			2000	1800	1600	1400	1400	1100	1000	1000
28		2200	1800	1600	1400	1250	1100	1000	900	900
32		2000	1600	1400	1250	1100	1000	900	800	800
36	2200	1600	1400	1250	1100	900	800	800	710	710
40	2000	1600	1250	1100	1000	800	800	710	630	630
45	1600	1400	1100	1000	800	710	710	630	560	560
50	1600	1250	1000	900	800	710	630	560	500	500
56	1400	1100	900	800	710	630	560	500	450	450
63	1250	1000	800	710	630	650	500	450	400	400
71	1100	900	710	630	560	500	450	400	360	360
80	1000	800	630	560	500	400	400	360	320	320
90	800	710	560	500	400	360	320	320	280	280
100	800	630	500	450	400	320	320	280	250	250
110	710	560	450	400	360	320	280	250	220	220
125	630	500	400	360	320	280	250	220	200	200
140	560	450	360	320	280	250	220	200	180	180
160	500	400	320	280	250	220	200	180	160	160
180	400	320	280	250	220	180	160	160	140	140
200	400	320	250	220	200	160	160	140	125	125
220	360	280	220	200	180	160	140	125	110	110
250	320	250	200	180	160	140	125	110	100	100
280	280	220	180	160	140	125	110	100		
320		200	160	140	125	110	71			
360		160	140	125	110					
400		160	125	110	71					

Collimator with Filter tray

1	Switch for visible Light Field
2	Adjustment of transverse Edge
3	Skala/SID transverse
4	Adjustment of longitudinal Edge
5	Skala/SID longitudinal



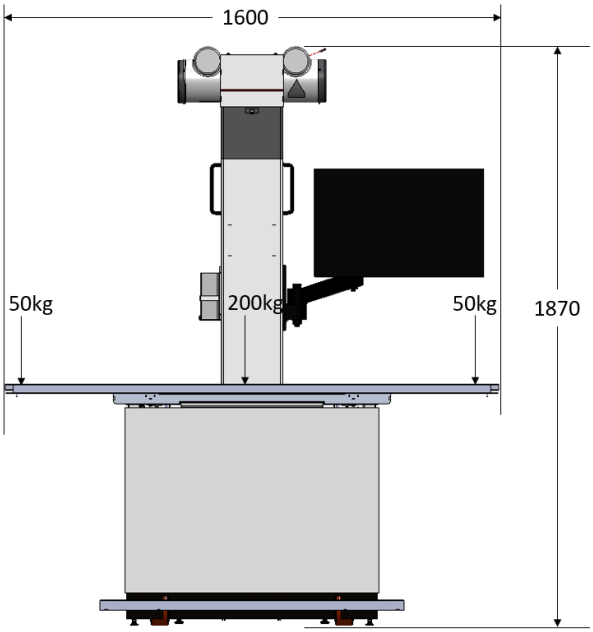
Possible recommended Detector Panel Types

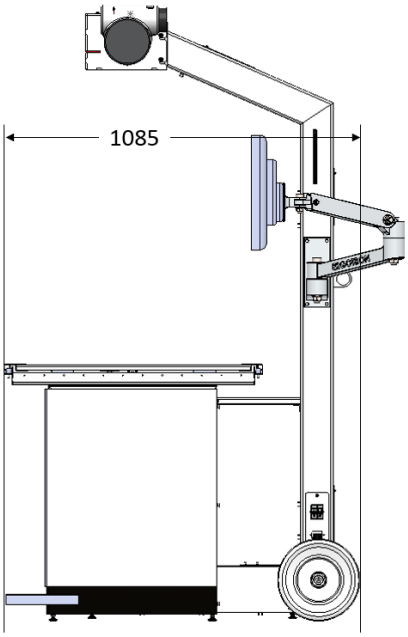
Detector Panel Name	Pixel Size	Format
X-DR XL	139 µm	43 x 43 cm

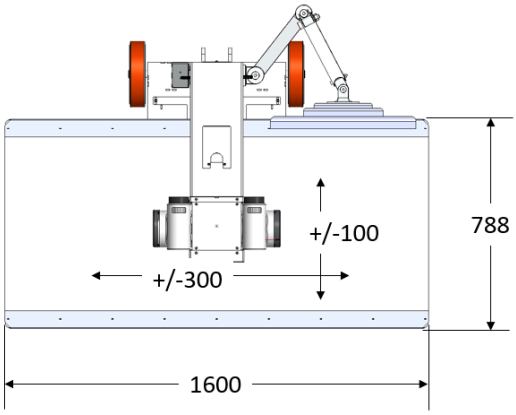
WARNING! Risk of Clamping

Pay attention by closing the Detector-Tray.
Do not clamp the fingers between tray and Table cover!

Overview







WARNING!

Possible breaking of tabletop or tilting of the unit!

Do not sit on the tabletop!
Note the maximum table load on the edges of 50 kg!

Specifications

X-AQS Vet Software (Exposure, Admin & Diagnosis)

The X-AQS Vet-Software will be operated by the attached All-in-One PC as Interface.

The exposure will also be triggered by the Foot Switch / Pedal.

The X-AQS Veterinary Software is intended for veterinary use only.

The software supports the following veterinary processes:

a) Management of patients and keepers

b) Creation and execution of orders

- for X-ray
- on other modalities
- Transfer and import of images from other modalities

c) Diagnosis of the images supported with

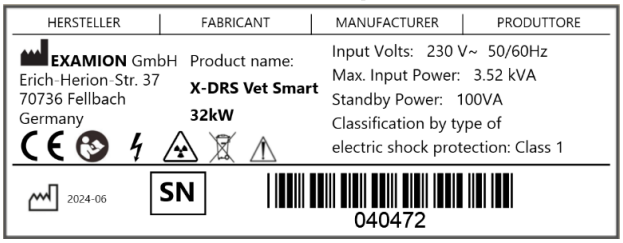
- measurement
- image optimisation
- Viewing and reporting settings

d) Archiving and transfer of diagnoses

A detailed Online-Manual for the X-AQS Vet – Software you will find on the Exit-Screen after mouseclick on X-Button and click on the button "HELP"

See X-AQS Vet User Manual

1.6 Product Labelling



Sign	Significance
	**Observe the directive for WEEE (Waste Electrical and Electronic Equipment)**
	**The instructions for use must be read and understood.**
	**Warning of risks to health of operator**
	**Warning sign: Ionising Radiation**
	**Certified regarding the EU-Regulations:** 2014/35/EU: Low Voltage Directive 2014/30/EU: Electromagnetic Compatibility, EMC 2011/65/EU: Hazardous substances in electrical and electronic equipment, RoHS
	**Manufacturer**
	**Fabrication Date**
	**Serial Number**

2 Safety

2.1 Safety and Warning Signs

Icons	Signification
	**Before working with the X-DRS VET Smart System, the instructions for use must be read and understood.**
	**Note to avoid system damage, restrictions or other notes**
	**Warning of risks to health of operator**
	**Warning sign: High voltage**
	**Warning sign: Ionising Radiation**
	**Warning sign: Electromagnetic Interference**
	**Warning sign: Risk of Clamping**

Safety and warning signs in this manual

2.2 Precautions for Use – Operating Limitations - Restrictions

To ensure safety and successful acquisitions, read the manual carefully before working with the system. All instructions and notes must be followed and adhered to.

The X-ray system may only be operated by personnel qualified to use an X-ray system on the animals, instructed in the use of the X-DRS VET Smart System, and who have read and understood the user manual.

Before the X-ray system is used, the user must ensure that all safety features are in working order.

Electromagnetic Influences

Since the X-DRS VET Smart uses a great deal of power, it may not be possible to exclude all electromagnetic interference. Even though the X-ray system complies with the relevant standards, it is recommended to not set up any other sensitive equipment close to the X-ray system. Furthermore, it is advisable to set up the X-ray system at a sufficient distance from other devices that may generate large fields of electromagnetic interference (e.g. magnetic resonance equipment).

Radiation Protection

With this X-ray system, X-rays are produced for the purpose of veterinary imaging.
X-rays pose an increased risk to the operating and maintenance personnel as well as to the patient.

Uninvolved persons should not be in the radiation area of this X-ray system and should be sent away. All statutorily required protections for operators must be used.

During the imaging procedure, all persons have to be protected against X-radiation.

For operating the X-ray system, only specially trained personnel may be employed who possess the necessary knowledge.

In order to prevent incorrect exposures, the imaging procedure (Appendix 2) is to be followed strictly. In particular (but not limited to), the parameter settings must be entered in the X-ray journal before exposure.

National laws, in particular (but not limited to) those regarding dose monitoring and shielding, must be observed.

Electrical Safety

The X-ray system may only be opened by authorized and qualified technical personnel.

The X-ray system may only be operated in **X-ray protected rooms** that meet the requirements of the country-specific installation standards.

The X-ray system is not suitable for use in flammable mixtures of solvents, disinfectants and anaesthetics with air or in flammable mixtures of anaesthetics with oxygen or nitrous oxide.

Safety Information – High Voltage!

To generate X-rays, the X-ray tube is supplied with life-threatening high-voltage during exposure. All high-voltage elements (high-frequency X-ray generator, high voltage cables and X-ray tube) are not hazardous to humans, if the following is observed:

- The covers that provide access to the high-frequency X-ray generator must not be removed under any circumstances.
- The tube cover must be firmly screwed to the X-ray tube and must not be removed under any circumstances.
- Injured cables may not be used under any circumstances. Injured cables must be replaced immediately by an authorized service partner.

WARNING!

The X-ray system must not be connected to the power mains using an extension power cord or a multiple power socket!

Danger of Clamping

When positioning the tabletop, mechanical parts are moved. Due to their large mass, considerable mechanical forces can arise. In case of careless or improper manipulation of the tabletop, in particular, the following dangers occur:

Danger of injury: There is a risk of crushing for operating personnel and animals between parts of the X-ray system and objects in the vicinity on the one hand and on the other hand when holding on to certain areas of the table! There is a risk for operating personnel and animals to bump into the table!

Danger of damage: Parts of the X-ray system and objects in the vicinity (e.g. walls, X-ray beds, etc.) may be damaged by the floating tabletop!

Due to the design of the X-ray system, injury by crushing, particularly of the fingers, is prevented in the best possible way. Where this is technically not possible, a warning sign is attached. The operator must ensure that during the positioning process, nobody is holding onto the marked points or is in the area of the moving parts!

3 Operating

3.1 Start and Preparation for Work

When the X-DRS VET-Smart is switched on, the system remains in standby mode and waits for communication with the X-AQS VET software. The circuit breaker on the right-hand side of the device must be active before the system can be switched on via the acquisition PC. The internal capacitors are already charged in this state,

Start of the Acquisition-PC

- When the acquisition PC is switched on, the X-ray generator is simultaneously switched ready for operation. The LED display on the tube head signals this state.
- The control PC starts the EXAMION Desktop. The X-AQS software is started manually from this programme.
- Check the function of the detector (connection).
- Check the function of the collimator.
- Select X-Ray as the recording device.
- Prepare radiation protection.

See X-AQS Vet User Manual

3.2 Preparing Acquisition Order

The Orders will be managed and administrated in the X-AQS VET Software. See the detailed descriptions in the IFU of X-AQS VET.

Crucial steps:

- See that in X-AQS Vet the Device X-Ray is choosen.
- Select the patient vis Patient- or Holder-Screen and START.
- Choose the Species.
- Choose the Organ and START.
- *Or alternatively: select an already set order from the worklist.*
- The Exposure Screen with the Exposure-Scheme starts.

3.3 Acquisition

Adjustment of Exposure geometry and parameters:

- Modify the Exposure parameters if necessary.
- Set the patient on the table if possible as proposed on Exposure Screen.
- Start the Collimator light field.
- Move the tabletop after step on the Table Top Pedal.

Indication of readiness via status bar:

Ready for Scan	System is ready for Exposure
…	Action required or wait for readiness
Exposure …	Exposure in the process / start of Exposure is not possible

Triggering the Exposure with the Footswitch Pedal

- See in Status Bar if the System is "READY".
- Press the pedal down (and hold the status) to start the first step (preparation).
- After a few seconds, the display changes to indicate that the system is ready to emit the X-rays.
- **Press the pedal further down (and hold the status) to trigger the second step (for X-ray).**
  A signal tone sounds during the entire recording**. (If the operator releases the pedal during the 2nd step, the recording is stopped).**

If an exposure is aborted by leaving the pedal before the end of exposure the user will see the message:

"X-Ray cancelled by operator"

When the exposure starts and the image data is read out. The "PREVIEW" screen appears.

Preview / Scanning: appears after exposure before the transfer to the VIEWER screen.

The PREVIEW-Screen shows the shot with shutter. The image is sent to the viewer via **SEND** or **DISCARD** or **PARK** (The image is only loaded into the viewer with the other images when the series is complete - or the image can be discarded).

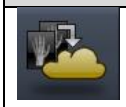
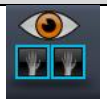
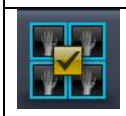
Operating

See X-AQS Vet User Manual

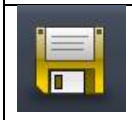
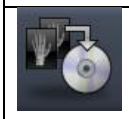
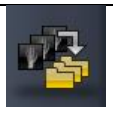
3.4 Preparation for Diagnosis, Archiving or Distribution

By the portal to the viewer, images can be archived, saved for forwarding or loaded into the viewer for reporting.

Forwarding to diagnostis

Icon	Activity	Icon	Activity
	Export the selected Images to the Cloud		Start of Viewer
	Select all		Delete selected Files
	Select none		Load all patient images

Archiv oder Distribution

Icon	Activity	Icon	Activity
	Print		Save in Diagnosis list
	Export the selection to a data carrier		Save all in Diagnosis list
	Sending the selection by e-mail		Save in Archive
	Create a patient CD/DVD		Save all in Archive

3.5 Error Messages

NAME OF ERROR
No Connection to generator
No connection to detector
Emergency stop active
No exposure beep sound during exposure

4 Cleaning & Maintenance

Cleaning

The special surface coating of the Examion X-DRS VET Smart makes it easy to clean. Generally, all that is needed is to wipe the system off with a dry cloth after use. If a cleanser must be used against stronger soiling, use a mild detergent. Do not use a caustic or abrasive cleanser.

Disinfecting

Those parts of the Examion X-DRS VET Smart that come into contact with the animal must be disinfected after each use with a suitable disinfectant. This concerns in particular (but not limited to) the tabletop. Use a clean cloth to wipe the system off with disinfectant.

Safety Information - Disinfection and Cleaning

Do not pour or spray disinfectant or cleanser on the X-ray system! If liquids, especially explosive or flammable liquids, enter the system, it poses a grave danger to humans and the device! The surfaces of the X-ray system may only be disinfected using a cloth moistened with disinfectant.

Daily Checks

The X-ray system must be checked each day before switching it ON according to the table below:

	Check	**Possible remedy**
Monoblock	Check if oil leaks off the Monoblock.	Do not switch ON the X-ray system! Contact your service partner.
System	Check if covers / housings of the components are damaged.	Do not switch ON the X-ray system! Contact your service partner.
Cables	Check if cables are damaged. Check if all plugs are inserted correctly and not loose.	Do not switch ON the X-ray system! Contact your service partner. Plug in the plugs correctly.
Ambient conditions	Check if temperature and humidity are within the prescribed range.	Adjust ambient conditions to prescribed values.

If the inspection of the X-ray system has been carried out according to the above table and no problem has been found, the X-ray system can be switched ON. It is recommended to subsequently carry out the following further checks:

	Check	**Possible remedy**
General	Make a test image, check the test image for: • Image distortion, • Indication of data loss, • Image defects.	Contact your service partner.
Defect pixels, image inhomogeneity	Make a test image (irradiate the entire detector, 70 kV, 2 mAs, no additional absorption plates in the beam path) and check the test image for: • Defect pixels (white or black "missing" pixels or lines) • Image inhomogeneity	Contact your service partner to have the detector recalibrated.

Monthly Checks

	Check	**Possible remedy**
Defect pixels, image inhomogeneity	Make a test image (irradiate the entire detector, 70 kV, 2 mAs, no additional absorption plates in the beam path) and check the test image for: • Defect pixels (white or black "missing" pixels or lines) • Image inhomogeneity	Contact your service partner to have the detector recalibrated.

Informations on EXAMION Maintenance

The maintenance interval for the Examion X-DRS VET Smart is one year.
Quality controls must be carried out in accordance with the applicable national regulations.

Warning - Maintenance and Repairs

Any maintenance or repair work may only be carried out by authorized and qualified technical personnel, otherwise there is a risk of personal injury and / or property damage.

Non-compliance with the prescribed maintenance intervals, the requirements for daily checks or the performance of maintenance and repair work by unauthorized or non-qualified persons will void any possibly existing warranty or damage claims.

Maintenance Intervalls

Interval	Component
Yearly	Entire X-ray system including quality control, especially: - Detector - X-ray generator - Field geometry
Every 3 years	Collimator

If the country-specific regulations require shorter intervals or additional tests, these regulations must be followed.

Maintenance of X-Ray Generator & Collimator

If stricter controls are not stipulated by law, the X-ray generator must be serviced by an authorized service partner at least once a year in accordance with the manufacturer's specifications. The X-ray tube may have to be recalibrated. The X-ray system does not have any components that can be serviced or repaired by the user. In case of malfunction, contact an authorized service partner. The operator is solely responsible for ensuring that all maintenance is carried out on time.

Every three years, the brightness of the collimator must be checked by an authorized service partner. The lamps must be replaced if they no longer reach the prescribed brightness or are defective. The field geometry must be checked and adjusted annually.

Service & Support Contact Info

5 Service & Support, Contact Info

In the event of faults that are not described in the troubleshooting table, contact the service department of **EXAMION GmbH**!

In the event of incorrect operation and system errors, there is a risk of image loss, incorrect diagnosis and increased radiation exposure of the patient or user!

You can reach the service of EXAMION GmbH via the following contact options:

Phone: **+49 711 1200 02 – 0**

Email: support@examion.com

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6 Conformity

The responsible manufacturer of the System is
EXAMION GmbH | Erich-Herion-Straße 37 | 70736 Fellbach | GERMANY.

CE

The product is conform with the following directives:

2014/35/EU	**Low voltage directive**
2014/30/EU	**Electromagnetic compatibility directive**
2011/65/EU	**RoHS directive**

The following standards were applied:

IEC 60601-1-2 Medical electrical equipment-part 1-2: General requirements for basic safety and essential performance collateral standard: Electromagnetic disturbances-Requirements and tests

IEC 60601-1-3 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – collateral standard: radiation protection in diagnostic X-ray equipment.

IEC 60601-2-7 Medical electrical equipment-part 2-7: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators

IEC 60601-2-54 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

IEC 60950-1 Information technology equipment - Safety - Part 1: General requirements