



ARTIS one

Addendum
VA11

1 Important Information

Information for ARTIS one systems with SW-Version VA11A and higher. Be sure to observe the following information when operating your ARTIS one system.

1.1 Safety

WARNING

Non-approved modifications of the system, such as adding hardware components, using spare parts or accessories and installation, maintenance or service activities as well as installation of software or modifying configurations.

Injury of patients or personnel, damage to equipment or wrong diagnosis due to unauthorized hardware or software modifications

- ◆ Only use hardware components or spare parts which are approved by the manufacturer for this specific purpose.
- ◆ Only use accessories which are approved by Siemens Healthineers or accessories compatible with standard interfaces of the system intended for this specific purpose.
- ◆ Do not load any software on the system other than described in the Instructions for Use.
- ◆ Do not change the hardware and software configuration of the system other than described in the Instructions for Use.
- ◆ Installation, maintenance or service activities, as well as modifications of the system environment which may significantly impact the operation of the system, especially in cabling or electrical installation, power supply, climatization or clearances must be performed exclusively by authorized and trained service or installation personnel with the manufacturer's approval.

CAUTION

Operation of magnetic field-emitting devices such as RF ID readers, sponge detection systems and wireless chargers, for example Qi chargers with higher power levels or induction cookers, may interfere with the readout electronics of ARTIS flat detectors.

Compromised image quality due to image artifacts

- ◆ Make sure to keep a distance of at least 2.5 m between magnetic field-emitting devices and the ARTIS flat detector.
- ◆ In case you notice image artifacts, especially with a stripe-like moving pattern, check the exam room for potential sources of magnetic fields and deactivate these or place them at a greater distance from the flat detector.

1.2 Automatic intensity control

The term automatic exposure control is replaced by automatic intensity control in the following sections of the Operator Manual:

- CAREmatic

The term automatic exposure control is replaced by automatic control system in the following sections of the Operator Manual:

- Reducing radiation with CARE
- Checking the image quality
- Scene length and/or measuring field
- Focus

The term automatic exposure control is replaced by automatic intensity control in the following sections of the System Owner Manual:

- Essential Performance
- System including MEGALIX[®] Cat Plus 125/40/90-GW X-ray tube assembly

2 Corrections and additions to the System Owner Manual

The following items replace and supplement the corresponding items in the System Owner Manual.

2.1 Essential Performance

The product complies with test levels of IEC 60601-2- 43/54:2022.

2.2 X-ray generator - pulse time

Pulse time	3.2 ms – 800 ms or continuous mode
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2.3 X-ray generator POLYDOROS ACX

Mode of operation	Continuous operation with intermittent, short time loading (duty cycle controlled by heat unit calculator)
Tube voltage	40 – 125 kV
Tube current	0.5 – 1000 mA with 0.01 mA steps
Output power	1000 mA @ 100 kV, 100 ms nominal electric power 100 kW (according to EN 60601-2-7 and EN 60601-2-54) 800 mA with nominal tube voltage of 125 kV, 100 ms
Pulse frequency	0.5 – 200 P/s or continuous mode
Pulse time	10 – 1000 mA 3.2 ms – unlimited (continuous mode)
Tolerances	kV-accuracy: $\pm 2\%$ Tube current 10 – 1000 mA: mA-accuracy indicated value: $\pm(5\% + 0.1 \text{ mA})$ Tube current 0.5 – 9.99 mA: mA-accuracy indicated value: $\pm(10\% + 0.1 \text{ mA})$ (mA calculated over at least 1.7 ms via mAs/ms of transmitted μA pulses. Cable effects disregarded for the first 1.5 ms of a pulse.)

2.4 Installation data - Generator POLYDOROS ACX

Mains power supply	Wide range input for 3 phase
Conductors	3PH, (N), PE

Nominal voltage	380 V / 400 V / 420 V / 440 V / 460 V / 480 V
Mains voltage tolerance	±10%
Mains voltage frequency	50/60 Hz
Mains voltage frequency tolerance	±3 Hz
Fuse	3 x 60 A
Isolation device	mains circuit breaker
Apparent power consumption (standby)	Standby 5.2 kVA (380 V, 400 V, 420 V, 440 V, 460 V, 480 V)
Apparent power consumption (long-term)	long time 14 kVA (380 V, 400 V, 420 V, 440 V, 460 V, 480 V) (at 4.5 kW continuous X-ray power)
Apparent power consumption (short-term)	short-time 162 kVA (380 V, 400 V, 420 V, 440 V, 460 V, 480 V) (at nominal electric power)

2.5 System including MEGALIX® Cat Plus 125/40/90-GW X-ray tube assembly

	Maximum symmetrical Radiation Field (IEC 60601-2-54) (mm)	300 x 400 (in 1000 mm distance)
Collimator	Quality equivalent filtration	0.9 mm Al at 75 kV/HVL

2.6 Prefiltration

The collimators are equipped with prefilters. There is a permanent filtration and an additional filtration.

The additional filtration of 0 / 0.1 / 0.2 / 0.3 / 0.6 / 0.9 mm Cu is defined in the acquisition protocol and set automatically by the system.

The additional filtration is indicated in the acquisition parameters (**mm Cu**).



0.2 mm Cu additional filtration is more than 1 mm Al + 0.1 mm Cu required for paediatric applications.



The 0.8 mm Al in the filter wheel position 0.0 mm Cu is regarded as the permanent filtration and not used for additional filtration.

2.7 Image acquisition

MTF (modulation transfer function) at 1 lp/mm	0.5 lp/mm: 80% typical (according to IEC 62220-1-3) 1 lp/mm: 59% typical (according to IEC 62220-1-3) 1.5 lp/mm: 41% typical (according to IEC 62220-1-3) 2.7 lp/mm: 17% typical (according to IEC 62220-1-3)
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2.8 Patient table

Table length	284.5 cm
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2.9 Injectors and IVUS

At present, the following injectors have been approved:

- ACIST CVI
- Guerbet® Illumena
- MEDRAD® Avanta
- MEDRAD® Mark 7 Arterion
- Medtron Accutron® HP-D
- Medtron Accutron® HP

At present, the following systems have been approved for IVUS:

- Volcano IVUS s5i
- AVVIGO Guidance System II
- AVVIGO+ Guidance System
- Boston Scientific iLab Polaris Multi-Modality Guidance System

For operation, technical description, models, and technical data, please see the documentation supplied by the manufacturer.

2.10 Weight of accessories to be attached to the patient table

Accessory / component	Maximum weight
Arm rest	2.5 kg
Arm holder	3.3 kg

Accessory / component	Maximum weight
Body module EAS Card	5.8 kg
Catheter tray, foot-end	6.5 kg
Goose neck tablet holder	0.83 kg
Handgrip	0.5 kg
Hand grips with supports	2.2 kg
Head pad, flat	0.3 kg
Head pad, deep	0.4 kg
Head Wedge	0.4 kg
Head-end holder with rails	1.7 kg
Instrument tray	3.6 kg
Set of body straps	0.3 kg
Spacer rail	4.7 kg
Infusion bottle holder	1.3 kg
Anesthetic arm (Anesthetic screen holder)	1.0 kg
Plugable element 57cm UKS	2.2 kg
Pluggable element, 27cm short	1.0 kg
L body pr. W .joint+swiiveling elem	12 kg
Radialis Armboard small	2.8 kg
Board Radialis wire set	0.5 kg
Lower body radiation protection: Small lead rubber leaf	1.3 kg
Lower body rad. prot. CARD/NEU-RO	17.4 kg
Lower body rad. prot. IR	20.5 kg
Shoulder supports	1.3 kg

2.11 Declaration of immunity and emission compliance

The product complies with following test levels of IEC 60601-1-2:2020

Additional test:

Immunity test	Basic EMC standard or test method	Compliance level
Proximity magnetic fields	IEC 61000-4-39:2017	134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m

2.12 Battery replacement

Batteries within the system, for example, UPS or BIOS batteries, are checked in regular intervals during maintenance.



Batteries must only be replaced by qualified service personnel.

Batteries must be disposed of with care and in compliance with legally binding ordinances.

3 Corrections and additions to the Operator Manual

The following sections replace and supplement the corresponding sections in the Operator Manual.

3.1 Operator manuals on the Internet

All operator manuals for your system are available online as PDF files in the **Document Library**:



- doclib.siemens-healthineers.com

For detailed information, see: (→ Page 9 *Accessing the operator manuals on the Internet*)

Accessing the operator manuals on the Internet



The operator manuals for your system are available electronically on the Internet.

- ✓ You have the correct name and version of your system (medical device) at hand.
- 1 In a browser window, enter the following URL:
doclib.siemens-healthineers.com
If you are visiting this site for the first time, you will need to register and apply for an account.
- 2 Follow the instructions given on the website. After logging on, you will find further support in the **Medical Imaging & Healthcare IT** document category.
- 3 Search and filter for the required document.

3.2 Intended use

ARTIS, as a family of dedicated angiography systems generating fluoroscopic and radiographic X-ray images, is intended for diagnostic imaging, and to support interventional and minimally invasive therapy.

Its use is indicated for image guidance in non-vascular, vascular, cardio-vascular, neuro-vascular, minimal-surgical, and surgical procedures.

The ARTIS one system includes also software options which allow the reconstruction of two-dimensional images acquired with rotational angiography into a three-dimensional image format, as well as options supporting diagnosis, planning, guidance and treatment follow-up.

3.3 Patient target group(s)

The system can be used on all patients, from pediatric to geriatric. Patient weight is limited to the specification of the patient table.

3.4 Language of user interface

The user interface of the ARTIS one system can be configured in one of the following languages:

- German
- English
- French
- Spanish
- Japanese
- Chinese



For each of the above languages, there is an online help system available.

Online help

3.5 Room lighting

According to the German standard DIN 6868-157, the lighting in rooms in which diagnoses are made on image display devices (monitors) must fulfill the following requirements:

- The lighting must be adjustable and glare-free.
- The setting of the illuminance must be reproducible, e.g. dimmer with scale.
- No mirroring or reflections of windows, lights, view boxes, etc. must occur in the operating position of the monitors.

3.6 Protection against electric shock complies with the updated IEC standards

- **Protection class**

Class I: The system belongs to protection class I with a type B applied part according to IEC 60601-1:2020.

- **Power supply**

For all products that are operated within an X-ray system, the power supply must be made through a conductor or other multipole circuit breaker installed on-site.

The room installation must comply with IEC 60364-7-710:2021 or the corresponding national regulations.

3.7 Flat detector

Image acquisition is performed through a flat detector followed by digital image processing and documentation.

- FD pixium 2630S with input field of approx. 26 cm x 29 cm (39 cm Ø)

3.8 Lower body radiation protection



The lower body radiation protection is provided to reduce the scattered radiation in the lower body of the examiner. The lower body radiation protection can be attached to the accessory rails on both sides of the patient table. The lower body radiation protection provides an accessory rail to which the control modules and other accessories can be attached.

Observe the **operating instructions of the manufacturer**.

3.9 Examination lamp

The note "Not available in China" is removed from the Examination lamp chapter of the ARTIS one Operator Manual.

3.10 Injector

The note "Not available in China" is removed from the Injector chapter of the ARTIS one Operator Manual .

3.11 System Messages / Troubleshooting for low water level of tube cooling unit

- ◆ When the message **Tube cooling water level low: Refill as per operator manual** is displayed, check the water level and refill the cooling system if needed.
 - (→ Page 12 *Checking the water level*)
 - (→ Page 12 *Identifying your cooling system*)
 - (→ Page 12 *Refilling the Laird or Klüver cooling system*)
 - (→ Page 13 *Refilling the Lytron cooling system*)
 - (→ Page 13 *Refilling the SMC cooling system*)

Checking the water level






Check the water level of the cooling system at least every three months!

- 1 Open the filling gland of the cooling unit.
The water surface must be clearly visible above the cooling ribs.
- 2 Replenish with tap water or drinking water quality if cooling liquid is lacking.

Identifying your cooling system

One of the following cooling units is installed at your system.

Laird or Klüver	Lytron	SMC
		

Refilling the Laird or Klüver cooling system



- 1 Open the tank.

- 2 Refill the cooling system up to the neck of the tank with tap water preferably with the help of a funnel.
- 3 Close the tank.

Refilling the Lytron cooling system



- 1 Open the tank.
- 2 Refill the cooling system up to the level indicated by the red arrow with tap water preferably with the help of a funnel.
- 3 Close the tank.

Refilling the SMC cooling system



- 1 Open the tank.
- 2 Refill the cooling system up to the neck of the tank with tap water preferably with the help of a funnel.
- 3 Close the tank.



This device bears a CE mark in accordance with the provisions of EU Regulation 2017/745 of April 5, 2017 concerning medical devices and the Council Directive 2011/65/EU of June 8, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The CE marking applies only to Medical Devices which have been put on the market according to the above-mentioned EU Regulation and EU Directive.

Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

Whenever the hardware necessary to run the software is supplied, the CE Mark is provided in accordance with, if applicable, Electro Magnetic Compatibility Directive 2004/108/EC and / or Low-Voltage Directive 2006/95/EC.

Caution: Federal law restricts this device to sale by or on the order of a physician (21 CFR 801.109(b)(1)).

This document was originally written in English.

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