# ARTIS one

## System Owner Manual



SIEMENS Healthineers

# 10 Maintenance

## 10.1 Introduction

Periodic maintenance and routine checks are necessary to ensure safe and satisfactory operation of your system.

Proof of these activities is required by the authorities in some countries.

All legally required tests must be performed at the specified time intervals.

In Germany: constancy test, stipulated under §116 of the Strahlenschutzverordnung (StrlSchV).

This work may be performed only by qualified and authorized service engineers. Qualified in this context means that the engineers have been trained accordingly or have acquired the necessary experience in practice. Authorized means that the engineers have been authorized by the operator of the system to perform maintenance work.

Prior to the first system start-up, we recommend that you name a staff member who will be responsible for ensuring that routine checks and preventive inspection and maintenance work are performed. This employee has to archive all certificates in the "System Owner's Manual" folder.

In addition to our repair service, Siemens Healthineers also offers you a complete range of services for preventive inspection and maintenance of your system. These services can be called on as required or agreed in a flexibly drafted service contract.

If you have not received a quotation from our UPTIME Services service organization, please contact the Siemens Healthineers representative responsible for your facility.

Our medical engineering products are designed for operation under average conditions in accordance with the Operator Manual for a useful life of 10 (ten) years. If the products are operated for longer than this time, additional checks and possibly repairs beyond the usual maintenance procedures may be necessary in order to ensure the functional integrity and operating safety of these products.

Please contact Siemens Healthineers about these measures early enough.

This Maintenance Plan provides information about routine checks and periodic maintenance of your ARTIS one system.

Routine checks:

Normally the system operator entrusts the clinical operating personnel with the task of performing routine checks. These include daily, weekly, and monthly inspections as well as legally required checks as described in the section containing Functional and Safety Checks of the operator manual.

## 10.2 Maintenance Plan

This maintenance plan shows in tabular form the activities which have to be performed by qualified and authorized service engineers in the course of periodic maintenance work. The maintenance work is divided into the following points:

- (→ Page 50 *Safety Checks*)
- (→ Page 52 *Preventive maintenance*)

- (➔ Page 53 *Quality and function tests*)
- (➔ Page 54 *Replacement of safety-relevant parts subject to wear*)

Each table contains an introductory explanation.

You will find detailed working instructions for all maintenance work in the service documentation for this system. These documents are not included in the system shipment.

Maintenance must be performed every 12 months.

## 10.3 Safety Checks

The following checks are intended to ensure the safety of the system. Where appropriate, preventive measures must be adopted or repairs performed. The points to be checked are essentially prescribed by laws and standards.

| Object or Function | Reason | What is checked | Interval (Months) |
|---|---|---|---|
| **General checks** | | | |
| Overall system | Safety of patients and personnel | Visual check of the system (cover panels) for damage and sharp edges | 12 |
| Cables and how cables are laid | Protection of patient and personnel against electric shocks. | Visual check of cables and how cables are laid for safety deficiencies. | 12 |
| Accessories | Safety of patients | Check for safety deficiencies | 12 |
| System radiation protection devices | Protection of patient and personnel against radiation injuries | Check the unit's radiation safety devices and any additional safety devices that may be present (lower body radiation shield, upper body radiation shield, ceiling- mounted radiation shield, etc.), to make sure they are correctly installed and free of damage. | 12 |
| Warning labels | Protection against incorrect operation and thus protection of patients, personnel and unit. | Check for presence of the required warning labels visible to the user for operation of the system. | 12 |
| User interfaces | Protection against incorrect operation and thus protection of patients, personnel and unit. | Check for legibility and operating symbols | 12 |

| Object or Function | Reason | What is checked | Interval (Months) |
|---|---|---|---|
| **Electrical Checks** | | | |
| Electrical safety | Protection of patient and personnel against electric shocks. | • Ground wire resistance measurement<br>• Unit leakage current measurement<br>• Patient leakage current measurement<br>of the complete system per national regulations | 12 |
| **Mechanical Checks** | | | |
| Floor and ceiling mounting | Protection of patients, personnel and unit | Mounting (visual check) | 12 |
| Drives | Ensure power transmission and safety functions | Check for wear, tension, ease of movement and function | 12 |
| System movements (manual) | Safety of the system latching mechanisms | Check of brake holding and end stops | 12 |
| Movable components | Protection of Patients, Personnel and Unit | Cable lead-in, movement behavior and, if applicable, brakes | 12 |
| Accessories | Safety of patients, personnel | Check for functionality and for good condition | 12 |
| User interfaces | Protection against incorrect operation and thus protection of patients, personnel and unit. | Check for completeness | 12 |
| Safety-relevant parts subject to wear | Protection of patients, personnel and unit | Check for functionality and for good condition | 12 |
| **Function Check** | | | |
| Emergency stop devices | Preventing the first malfunction caused by application errors and collapsing patients | Switch-off of system functions after activating the emergency stop device | 12 |
| Control devices and warning indicators | Inform the operator about relevant system conditions and overload situations | The functions of the following displays:<br>• Radiation<br>• Fluoroscopy<br>• X-ray tube load<br>• Block Movements, Block Radiation<br>• Unit movements at the collision limit | 12 |
| System movements (motorized) | Protection of patients, personnel and unit | Safety shutdown of the movements | 12 |
| Collision protection | Prevent damage to unit components | Automatic shutdown of system movements in the collision zone (e.g. ceiling, wall, floor) | 12 |

| Object or Function | Reason | What is checked | Interval (Months) |
|---|---|---|---|
| Function test | Prevent damage to unit components | Final function test of all components | 12 |

## 10.4 Preventive maintenance

The purpose of preventive maintenance is to reduce unforeseen failures to a minimum. Thus the prerequisites for the system to meet the assured characteristics in the long term are created.

The effects of different operating conditions (full or partial load operation, temperature, size of dust particles, humidity, gases, vapors) are checked and the condition of parts subject to wear is determined by recording and analyzing characteristic values. Preventive measures must be adopted or repairs must be undertaken as appropriate.

The specified maintenance intervals correspond to the minimum requirements. Compliance with stricter national legislation may be necessary.

| Object or Function | Reason | What is checked | Interval (Months) |
|---|---|---|---|
| Overall system | Preventive measures to avoid<br>• Safety risks<br>• Overheating<br>• Wear and tear<br>• Image artifacts | Check of operating data<br>Check of cables, cable routing and cable connections for damage<br>Cleaning contrast medium, blood, disinfectants from areas not accessible to the customer<br>Inspection and cleaning of coolant and air circulation passageways<br>Inspection and cleaning of optical transmission paths<br>Removal of foreign objects, e.g. positioning aids and injection needles<br>Check of the tolerance limits<br>Check of the movement forces<br>Check of the drive characteristics, acceleration and deceleration movements<br>Measures to ensure that all components move smoothly<br>Check and analysis of points of friction<br>Repairing minor damage | 24 |

## 10.5 Quality and function tests

Quality and function tests are used to check whether the system meets the assured characteristics. Image quality tests determine differences from the original status (e. g. resolution, contrast range, minimum contrast, image signal and, if applicable, check of Digital Subtraction Angiography).

If there are differences, preventive measures must be taken or repairs performed, whenever appropriate.

| Object or Function | Reason | What is checked | Interval |
|---|---|---|---|
| Overall system | Optimum operation on the basis of the specifications listed in the data sheet | Interaction of all system components according to the assured characteristics | 12 months |
| Vacuum components:<br>• X-ray tube assembly | Assuring the system specifications (vacuum components are subject to aging) | Image Quality | 12 months |
| Beam geometry, centering, beam collimation | Observance of the specifications and legal regulations to minimize radiation exposure for the patient and for personnel.<br>(DHHS and country-specific regulations must be observed.) | Centering the central beam onto the center of the image receptor<br>Coincidence of radiation field size and image receptor size or light field size and radiation field size | 12 months |
| Radiation dose | Compliance with specifications and legal requirements to minimize radiation exposure of patient and personnel.<br>(DHHS and country-specific regulations must be observed.) | Check of the dose rate/cutoff dose in<br>• Fluoroscopy (DL)<br>• Acquisition | 12 months |
| Detail recognition | Compliance with specifications and legal requirements.<br>(DHHS and country-specific regulations must be observed.)<br>Ensuring image quality | Resolution during<br>• Fluoroscopy (DL)<br>• Acquisition | 12 months |
| Image contrast | Compliance with specifications and legal requirements<br>Ensuring image quality | Minimum contrast and dynamic range during<br>• Fluoroscopy (DL)<br>• Acquisition | 12 months |
| DSA Device | Compliance with specifications and legal requirements<br>Ensuring image quality | DSA scene: DSA scene; contrast sensitivity, dynamic range, logarithming, subtraction, artifacts | 12 months |
| Image display | Compliance with specifications and legal requirements<br>Ensuring image quality | Brightness and contrast of the configured monitors | 12 months |
| Image Disturbances | Compliance with specifications and legal requirements<br>Ensuring image quality | Image display for intolerable image artifacts for all configured application techniques | 12 months |

| Object or Function | Reason | What is checked | Interval |
|---|---|---|---|
| Dose measuring device | Maintenance of specifications<br>(DHHS and country-specific regulations must be observed.) | Accuracy of the display | 12 months |
| Image documentation systems | Compliance with specifications and legal requirements.<br>(DHHS and country-specific regulations must be observed.)<br>Ensuring image quality | Gray scale reproduction, geometric imaging characteristics, resolution, optical density, artifacts | 12 months<br>(or in accordance with specifications from other manufacturers) |

## 10.6 Replacement of safety-relevant parts subject to wear

| Component | Replacement interval |
|---|---|
| Belt for orbital movement of the C-arm | 10 years |
| BIOS batteries | 2 years |

Apart from that, the system contains no safety-relevant parts subject to wear.

## 10.7 Additional checks

Periodic maintenance of the following components shall be performed by the system owner or qualified and authorized service engineers.

### 10.7.1 Preventive maintenance of cooling circuit water level

We recommend that system operators check the water level of the cooling circuit at least **every three months**.

1 Open the filling gland of the cooling unit.

The water level shall be between the indicated upper and lower limits.

2 Replenish with water (drinking water quality, no distilled water) if cooling liquid is lacking.

Please inform the service technician in case of lacking cooling liquid.

The cooling system may contain residuals of GLYCOSHELL cooling fluid.

This substance is harmful if swallowed.

# 11 Updates / Addenda to Operator Manual

see inserted documents

# 12 Disposal

## 12.1 Equipment disposal

On disposing of the complete system or parts thereof, currently valid environmental legislation must be observed.

Examples of environmentally relevant components are:

- Accumulators and batteries
- Transformers
- Capacitors

For details contact your local customer service representative.

System components hazardous to persons or the environment must be disposed of with care and in compliance with legally binding ordinances.

### For all countries of the EU

For details about take-back and disposal of the product respectively its components or accessories, please contact your local Customer Service or your Siemens Healthineers regional office.

Products bearing this symbol are subject to EC directive 2012/19/EC on waste electrical and electronic equipment (WEEE). This directive determines the framework for the return and recycling of used equipment as applicable throughout the EU.

In the member states of the European Union (EU) Siemens Healthineers will take back and will dispose of the packing material of your system.

ARTIS one is compliant with EC REACH regulation No.1907/2006.

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

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