

**ARCADIS Avantic** 

# Maintenance Instructions System

For ARCADIS Avantic

Including tests required acc. to IEC 62353
The protocol SPR2-330.832.01.10.XX is required for these instructions

#### **Document Version**

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| 1 | General   | information   |  |
|---|-----------|---|--|
|   | 1.1       | Maintenance Intervals   |  |
|   | 1.2       | Required documents  |  |
|   | 1.3       | Required tools, measurement and auxiliary devices   |  |
|   | 1.4       | Spare parts which may be needed   |  |
|   | 1.5       | Emphasized text   |  |
|   | 1.6       | Safety information and protective measures  1.6.1 General safety information (in existing documents)  1.6.2 General electrical safety information  1.6.3 Radiation safety information  1.6.4 Safety information - risk of infection  1.6.5 Mechanical safety information  1.6.6 Systems equipped with an integrated I.I. laser light localizer  1.6.7 Systems equipped with a single tank laser light localizer |  |
|   | 1.7       | Abbreviation descriptions   |  |
| 2 | Partial n | naintenance   |  |
|   | 2.1       | Partial maintenance activities  |  |
| 3 | Full mai  | ntenance  |  |
|   | 3.1       | Full maintenance activities  3.1.1 Inspection of exterior  3.1.2 Safety Inspection  3.1.3 Maintenance, Operating Values, Functional Inspection, and Maintenance  3.1.4 IQ quick test.  3.1.5 Final work steps / checks in accordance with IEC 62353   |  |
| 4 | Change:   | Changes to previous version   |  |
| 5 |           | List of Work Times  |  |
|   |           |   |  |
| 6 | List of H | azard IDs   |  |

#### 1.1 Maintenance Intervals

There are two types of maintenance: full maintenance and partial maintenance.

Full maintenance includes all of the maintenance steps of a complete maintenance. Partial maintenance only includes the maintenance steps which are of critical importance.

If it is not possible to perform maintenance on the entire system in a single session, partial maintenance can also be performed if the specified maintenance intervals are met.

If national laws or regulations specify more frequent system checks and/or maintenance, this must be observed.

# 1.1.1 Maintenance planning

#### 1.1.1.1 Full maintenance

The first full maintenance for a new system must be performed within 18 months after the system has been handed over to the customer. After that, full maintenance needs to be performed every 24 months. Full maintenance comprises the following maintenance steps:

- Full maintenance activities:
  - » See full maintenance section.



Full maintenance also includes all of the partial maintenance activities. This ensures that the critical maintenance points are performed every 12 months.

#### 1.1.1.2 Partial maintenance

Partial maintenance is always performed in between two instances of full maintenance, initially at 30 months following start-up and every 24 months thereafter. It comprises the following maintenance steps:

- Partial maintenance activities:
  - » See partial maintenance section.

### 1.1.2 Replacement interval for special parts

#### 1.1.2.1 UPS lead gel battery and imaging PC BIOS battery

Initial replace- after 42 months during full maintenance

ment

Thereafter every 48 months during full maintenance

# 1.2 Required documents

General safety guidelines, see system binder TD00-000.860.01...

Main system adjustment instructions
SPR2-330.842.01..

Replacement instructions for the TFT display on hand

**>>** 18" Eizo R11 color display TD00-000.841.15.01...

**»** 18" MVGD 13188 B/W display TD00-000.841.17.01...

Spare parts list

Replacement of parts: SPR2-330.841.01...

Image quality quick test
SPR2-330.820.01..

# 1.2.1 Systems equipped with a laser light localizer

Setting instructionsSPR2-330.815.02..

# 1.2.2 Systems equipped with an I.I. laser light localizer

Installation and setting instructionsSPR2-330.814.02.01...

# 1.3 Required tools, measurement and auxiliary devices



The indicated items are listed in the STC (Service Tools Catalog) unless otherwise stated (the STC is a component of the Spare Parts Catalog) with the exception of items marked with "\*1".



When performing partial maintenance, normally only the tools, measuring instruments, and auxiliary devices marked with "\*2" are required.

|    | Standard tool kit*   | *1/*2 |                              |          |
|----|--|-------|------------------------------|----------|
|    | 1 set of Allen wrenches  | *1/*2 |                              |          |
|    | Spring balance rated for up to 200 N   | *2    | e.g.                         | 04415113 |
| ٠  | Safety tester for leakage current and protective conductor resistance test       |       | SECUTEST SIII+ or equivalent | n.a.     |
|    | DVM  |       | e. g. Fluke 8060A            | 09702101 |
| ٠  | Luminous density measuring device  | *2    | e.g. SPOTMETER for SMfit ACT | 07752848 |
| -  | Densitometer (for available film printer)  | *2    | e.g.                         | 04951286 |
|    | Dynamic test kit   | *2    |                              | 03790156 |
|    | Precision X-ray filter   | *2    |                              | 09900598 |
| -  | Set of resolution tests  | *2    |                              | 02871820 |
|    | Set of radiation filters (10 x 0.3 mm)   | *2    | e.g.                         | 04406120 |
|    | Set of radiation filters   | *2    | e.g.                         | 09798596 |
| •  | 25 mm AL measuring stand, type<br>26765, in accordance with DIN 6868<br>Part 50* | *2    |                              |          |
| or |  |       |                              |          |
| •  | 1.2 mm Cu  | *2    | e.g., from the set of ra-    |          |
|    | plus   |       | diation filters 04406120     |          |
| •  | 17 micrometer Cu strips  | *2    |                              | 01167662 |
| •  | Centering cross (only with Diamentor)  |       | e.g.                         | 09660051 |
| •  | Sealing compound   |       |                              | 02049716 |
| 1  | Special oil Optimol Optipit (for the device lifting column spindle)              |       |                              | 05507525 |

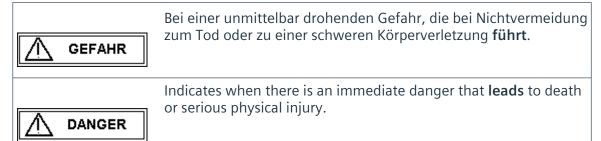
|   | Special oil Slic Pac PTFE                            | 05507517 |
|---|--|----------|
|   | (for the device lifting column slide cyl-<br>inders) |          |
|   | Paint stick, MED white                               | 03444403 |
|   | Paint stick, medical blue                            | 05507087 |
|   | Spray paint, MED white                               | 05507467 |
|   | Spray paint, medical blue                            | 05507046 |
| × | Spray paint, Medium Basic                            | 04004243 |

# 1.4 Spare parts which may be needed

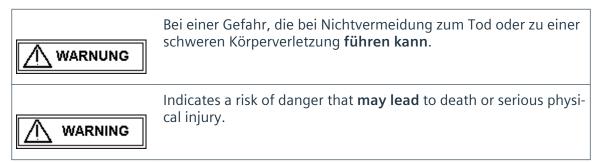
- Cable deflectors for swivel castor large/ARCADIS Avantic stand
- Cable deflectors for wheels small/ARCADIS Avantic stand
- Conductive rubber (basic unit)

# 1.5 Emphasized text

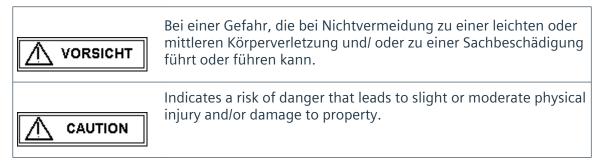
#### Tab. 1 GEFAHR / DANGER



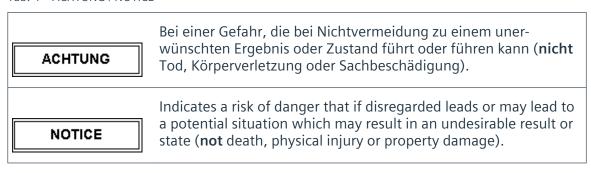
#### Tab. 2 WARNUNG / WARNING



#### Tab. 3 VORSICHT / CAUTION



#### Tab. 4 ACHTUNG / NOTICE



Tab. 5 HINWEIS / NOTE

HINWEIS

Ist als Tipp zu verstehen. Der Anwender muss diese Anweisung nicht unbedingt beachten. Er erfährt jedoch Vorteile, wenn er dies tut.

Should be understood as a tip. The user does not absolutely have to observe these instructions. However, there will be advantages if he does.

# 1.6 Safety information and protective measures

# 1.6.1 General safety information (in existing documents)

# A

#### **WARNING**

Danger of injuries, death or material damage.

Non-compliance can lead to death, injury or material damage.

#### Please observe:

- The product-specific safety information in these instructions,
- » the general safety information in TD00-000.860.01... and
- » The safety guidelines prescribed by your service organization.

# 1.6.2 General electrical safety information



#### **WARNING**

**Electrical safety!** 

Non-compliance can lead to severe injury or even death, as well as material damage!

- » Parts under electrical voltage are accessible when the covers are open. To avoid danger, disconnect the system from the power supply before opening the covers. Pull out the power supply plug.
- If an uninterruptible power supply (UPS) is installed in the system, the voltage output of the UPS must also be deenergized or the voltage output plug must be disconnected.
- » If work steps must be performed using electrical power, the general safety information according to TD00-000.860.01... must be observed.



#### CAUTION

Electrical voltage!

Non-compliance can result in material damage!

When working on the system, ESD regulations must be observed.

# 1.6.3 Radiation safety information



#### **WARNING**

#### X-ray radiation!

Non-compliance can lead to illness, irreversible damage to body cells and the genotype, severe injury and even death!

When work is performed on the system during which radiation must be released, all radiation protection directives and all rules for radiation protection prescribed by your service organization must be observed.

#### Please observe:



- » Use available radiation protection devices.
- » Wear radiation protection clothing (lead apron).
- » Stay as far away as possible from the radiation source.
- » Release radiation only if necessary.
- Set the radiation activity as low as possible. (low kV and mA values, short radiation time)
- » Release radiation for as short a time as possible.
- Checks requiring the release of radiation are identified by the radiation warning symbol shown on the left.

# 1.6.4 Safety information - risk of infection



#### **WARNING**

Risk of infection due to pathogens!

Non-compliance can lead to severe injury and even death.

- » This product can be contaminated by infected blood or other bodily fluids.
- » Avoid all contact with blood or other bodily fluids!
- Strictly observe the safety guidelines prescribed by your service organization, to prevent infectious diseases during customer service calls.

# 1.6.5 Mechanical safety information

# A

#### **CAUTION**

Risk of burns from hot parts or components!

If not observed, minor to more severe burns, especially on the hands, can occur.

Parts and components (e.g., power components, cooling fins, electromagnetic brakes) that can exceed 50 degrees Celsius during operation are accessible after the covers are opened. To avoid burns, switch the system off prior to touching parts or components and allow at least 5 minutes for cooling.



#### **CAUTION**

Risk of injury from mechanical parts!

If not observed, minor to more severe injury, especially to the hands, can occur.

- After the covers are opened, parts such as flat plugs, threaded bolts, cut-off cable ties and component edges are exposed, and if care is not taken, they can cause crushing, scrapes and cuts to the skin, particularly to the hands.
- » Perform the required work with special care and attention to detail.
- » If necessary, wear work gloves.

# 1.6.6 Systems equipped with an integrated I.I. laser light localizer



#### **CAUTION**

Laser emissions!

This product contains lasers of the class 1M.

Disregarding safety precautions can lead to bodily injury, especially to the retina of the eye, resulting in irreversible damage to vision.

» Follow the safety guidelines prescribed by your service organization. When working with the laser light localizer, do not look into the laser beam directly with optical instruments.

# 1.6.7 Systems equipped with a single tank laser light localizer



## **CAUTION**

Laser emissions!

This product contains class 2 lasers. (USA: class 2 laser).

Disregarding safety precautions can lead to bodily injury, especially to the retina of the eye, resulting in irreversible damage to vision.

Follow the safety guidelines prescribed by your service organization. When working with the laser light localizer, do not look directly into the laser beam.



Laser emissions!

There is no direct hazard to the eye (blinking reflex). Nevertheless do not look directly into the laser beam.

# 1.7 Abbreviation descriptions

| Abbrev. | Description   |
|---------|---|
| SI      | Safety Inspection   |
| SIE     | Electrical Safety   |
| SIM     | Mechanical Safety   |
| PM      | Preventive Maintenance  |
| PMP     | Periodic Preventive Maintenance                               |
| PMA     | Preventive Maintenance Adjustments                            |
| PMF     | Preventive Maintenance, Operating Value Check, Function Check |
| Q       | Quality Check   |
| QIQ     | Image Quality   |
| QSQ     | System Quality Check  |
| SW      | Software Maintenance  |

The steps identified by these abbreviations are part of the maintenance protocol and should be checked off upon completion.

## 2.1 Partial maintenance activities

# 2.1.1 Mechanical Safety

**SIM** C-Arm

Perform all C-arm movements, checking for play in the bearings and bearing noises.

**SIM** Foot brake

 Check the braking effect of the foot brakes of the ARCADIS Avantic stand and monitor trolley on a flat surface.



It is not necessary to measure and document the braking force of the foot-activated brake.

#### **SIM** Angulation brake



Using the spring scale, check whether the angulation brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for ARCADIS Avantic).

#### **SIM** Orbital Brake



 Using the spring scale, check whether the orbital brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for ARCADIS Avantic).

#### **SIM** Horizontal lift brake



 Using the spring scale, check whether the horizontal lift brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for AR-CADIS Avantic).

#### **SIM** Swing brake



 Using the spring scale, check whether the swing brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for ARCADIS Avantic).

## 2.1.2 IQ quick test

SIE Image quality (IQ) quick test

- Perform the image quality test according to the ARCADIS Avantic image quality quick test instructions, and record the results of the test.
  - » Also test any other external monitors (if applicable) as well.

# 2.1.3 Final work steps / checks in accordance with IEC 62353

#### 2.1.3.1 General Measurement Notes

According to IEC 62353, the measured values must be compared to the old values. The old values can be seen in the

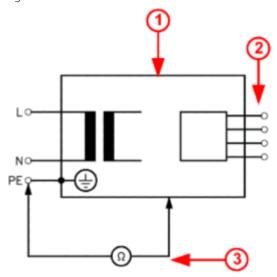
- \* Startup Certificate
- \* old Maintenance Certificate
- \* old Test Certificate per IEC 62353.

If significant differences are found, corrective measures may be necessary.

# Perform the following measurements:

1. Grounding conductor measurement

Fig. 1: Ground wire



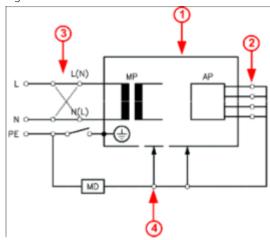
- (1) Medical device
- (2) Application part type B if present
- (3) Measurement instrument
- 2. Device leakage current measurement



Two different methods of measurement can be used.

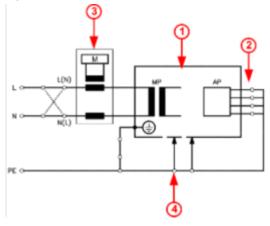
Device leakage current (direct measurement) or (differential current measurement procedure).

Fig. 2: Direct current measurement



- (1) Medical device
- (2) Application part type B if present
- (3) Measurement setup (integrated in measurement equipment)
- (4) Additional connections if present

Fig. 3: Differential current measurement



- (1) Medical device
- (2) Application part type B if present
- (3) Measurement instrument
- (4) Additional connections if present

#### 2.1.3.2 Grounding conductor measurement

Switch off power to the system.

According to IEC 62353, the measured values must be compared to the old values. The old values can be seen in the

- \* Startup Certificate
- \* old Maintenance Certificate
- \* old Test Certificate per IEC 62353.

If significant differences are found or if the measured values exceed 180 mOhms, it may be necessary to initiate corrective measures.

Usually, the problem is that the ground wires are not connected, or incorrectly connected.

#### Test procedure:

Measure between all accessible conductive parts of the components and the plug.
 If using direct current, repeat the measurement with the opposite voltage polarity.
 Both measured resistance values may not exceed the permissible value.



During the protective earth resistance measurement, move flexible power supply cords section-by-section over their entire length to check for any possible wire breaks.

- Varying measured values arising during moving of the power supply cord indicate breakage of the protective earth conductor.
- If necessary, replace the power supply cord.

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If significant differences are found between the old and new values or if the measured values exceed 180 mOhms, it may be necessary to initiate corrective measures.

Usually, the problem is that the ground wires are not connected, or incorrectly connected.

**»** Maximum value:  $0.2 \Omega$  (observe country-specific regulations!)



#### **Exceptions:**

Components with voltage less than/equal to 24 volts

Cover panels that cover electrical components with voltages less than/equal to 24 V.

**SIE** Ground wire status (in milliohms)

#### 2.1.3.3 Device leakage current measurement

#### Prerequisites for device leakage current (direct measurement):

• To prevent measurement errors during direct measurement of the device leakage current, the ME equipment/other equipment must be isolated during the measurement.



#### WARNING

Since the protective earth conductor cannot fulfill its function during direct measurement of the device leakage current, there is a potential hazard to the tester or other personnel during the measurement.

Observe the following safety precautions:

- The leakage current measurement may only be performed after the protective earth test has been passed successfully.
- Access to the ME equipment or other equipment by personnel other than the tester must be prevented (blocking, measurement in a separate room).
- **»** During the measurement, the tester may not touch the ME equipment or other equipment.

#### Prerequisites for device leakage current (direct measurement):

• If the device leakage current is measured according to the differential current measurement procedure, the protective function of the protective earth conductor is maintained. There is no danger for the tester or other persons.

#### Measurement

- Switch on the system.
- Test procedure:
- The device leakage current measurement must be performed twice: First measurement -> L and N at power plug, second measurement -> L and N reversed at power plug.

Limit values in accordance with IEC 62353:

The maximum leakage currents are:

- \* Device leakage current (direct measurement) 0.5 mA
- \* Device leakage current (differential current measurement) 0.5 mA

SIE Device leakage current (in milli A)

#### 2.1.3.4 Function check

**SIE** Perform function check

# 3.1 Full maintenance activities

## 3.1.1 Inspection of exterior

#### **SIM** Damage

Inspect the entire system for damage, such as damage to the housing or paint.

# 3.1.2 Safety Inspection

### 3.1.2.1 Mechanical safety

**SIM** Covers

- Remove the covers from the ARCADIS Avantic stand and monitor trolley.
- Check the covers for mechanical damage.

**SIM** Cable deflectors

Inspect the cable deflectors on the stand and on the monitor trolley and replace them if necessary.

SIM I.I. removable grid - mechanics

Check to make sure the I.I. removable grid is properly secured.

**SIM** I.I. laser light localizer mechanics (if present)

- Check the label on the I.I. laser light localizer for completeness.
- Inspect the I.I. laser light localizer for mechanical damage.
- Install the I.I. laser light localizer on the I.I. and ensure that it locks into place and is seated properly.
  - When doing this, pay special attention to the tension band and its closure.
- Check the I.I. ring for damage and make sure it is screwed in all the way.
- Open the battery compartment and check for leaking batteries.
  - If battery acid has leaked out but the battery contacts are not oxidized:
    - Wear moisture-proof gloves (plastic or latex disposable gloves).
    - Remove the old batteries (if they are still there).
    - Wipe out the battery compartment with a absorbent cloth (paper towel).
    - Afterwards, wipe it out again with a fresh, slightly damp cloth.
    - Dispose of the contaminated cloths and gloves.
    - Insert new batteries and close the battery compartment.
  - If batteries have leaked and the battery contacts have oxidized:
    - We recommend replacing the I.I. laser light localizer.
      Even when the battery contacts are cleaned well, the oxidation usually progresses.

- If you want to try to remove the oxidation residue and battery acid anyway:
  - Wear moisture-proof gloves (plastic or latex disposable gloves).
  - Remove the old batteries (if they are still there).
  - Remove the oxidation residue from the battery contacts with a small file.
  - Wipe out the battery compartment with a absorbent cloth (paper towel).
  - Afterwards, wipe it out again with a fresh, slightly damp cloth.
  - Dispose of the contaminated cloths and gloves.
  - Insert new batteries and close the battery compartment.

**SIM** I.I. laser light localizer function (if present)

- Check the function of the laser diodes.
- Make sure the laser diodes automatically shut off after approx. 1 minute.
- Check the adjustability of the laser light compartments at the center of the single-tank cover.

SIM Laser light localizer, close to tube - mechanics (if present)

- Check the label of the integrated laser light localizer for accuracy and legibility.
- For systems equipped with the I.I. attachment (delivered until March 2006):
  - Check the I.I. attachment of the laser light localizer for mechanical damage.
  - Check the I.I. ring for damage and make sure it is screwed in all the way.
  - Place the I.I. attachment of the laser light localizer on the I.I. Make sure it locks into place and is seated properly.

**SIM** Integrated laser light localizer, close to tube - function (if present)

- Check the function of the laser diodes.
- Make sure the laser diodes automatically shut off after approx. 5 minutes.
- When laser light localizer is present, delivered until March 2006:
  - Check the accuracy of the laser light localizer with the I.I. attachment. See Setting Instructions RXR2-130.032.01....
  - If needed, adjust the laser light compartments with the I.I. attachment. See Setting Instructions RXR2-130.032.01....
- When laser light localizer is present, delivered in or after April 2006:
  - Check the function of the laser diodes.
  - Check the adjustability of the laser light fan beams centered on the image intensifier.

SIM C-Arm

 Perform all C-arm movements, checking for slackness of the bearings and bearing noises.

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#### **SIM** Foot brake

 Check the braking effect of the foot brakes of the ARCADIS Avantic stand and monitor trolley on a flat surface.



It is not necessary to measure and document the braking force of the foot-activated brake.

#### **SIM** Angulation brake



Using the spring scale, check whether the angulation brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for ARCADIS Avantic).

#### **SIM** Orbital Brake



 Using the spring scale, check whether the orbital brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for ARCADIS Avantic).

#### SIM Horizontal lift brake



 Using the spring scale, check whether the horizontal lift brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for AR-CADIS Avantic).

#### **SIM** Swing brake



 Using the spring scale, check whether the swing brake reaches the required braking value when in braked state (values: see Replacement of Parts manual for ARCADIS Avantic).

#### **SIM** Wheels and castors

- Move ARCADIS Avantic straight on a flat surface.
- Evaluate the straight and quiet movement of the ARCADIS Avantic.
- Replace any defective wheels.

#### **SIM** Lifting column for basic unit



There may not be any additional weight on the C-Arm, e.g. lead aprons or other covers, during these checks and adjustments.

- Visually inspect the exterior visible part and interior visible part of the lifting column for damage.
- Switch the system on.
- Lubricate the basic unit lifting column.
  - Lubricate the spindle of the lifting column with special oil Optimol Optipit.
  - Lubricate the running surfaces of both slide cylinders (lifting column guide) with special oil -Slic Pac PTFE.

- Electrically move the lifting column over its entire lift range.
  - Listen for noises and check for play in the bearings.
  - The lifting column movement must switch off automatically when the end positions are reached.

#### **SIM** Emergency stop switch

Press the emergency stop switch

The lifting column must not move when the "raise" and "lower" buttons on the main unit control panel are pressed.

Unlock the emergency stop switch by pressing it lightly and turning to the left.
 The basic unit lifting column can be moved again.

#### **SIM** Motorized monitor trolley lifting column (if present)

- Visually inspect the exterior visible part and interior visible part of the motorized monitor trolley lifting column for damage.
- Move the motorized monitor trolley lifting column over its entire lift range.
  - While doing this, note any movement noises and bearing play.
  - The lifting column movement must switch off automatically when the end positions are reached.

#### **SIM** TFT monitor(s)

- Check monitor(s) for damage.
- Check monitor(s) for proper attachment to the monitor trolley.

#### **SIM** SIEMENS logos

- Check all SIEMENS logos to ensure they are affixed securely and in a good physical state.
  - » Replace any SIEMENS logos that are damaged or have protruding edges.

#### **SIM** Warning signs

- Ensure that all required warning labels are attached and in good condition.
  - Replace any illegible labels or markings.

#### **SIM** ID labels

- Ensure that all required ID labels are attached and in good condition.
  - Replace any illegible labels or markings.

#### 3.1.2.2 Electrical safety

#### **SIE** Cables and plugs

Check visible system cables and plugs for damage.

#### **SIE** Fluoroscopy timer

Check: See "Compulsory radiation switch off" section.

SIE Acoustic warning signal

Check: See "Compulsory radiation switch off" section.

SIE Compulsory radiation switch off

Connect the base system to the monitor cart, switch on the system, and wait for it to boot.



- Test the functioning of the audible warning signal and compulsory radiation switch off (if required) according to the country-specific regulations. Also check functioning of the fluoroscopic timer in this process.
- Open local service at the imaging system PC.
- Click <Mainsystem>.
- The the Main System window that is displayed, select the correct system and click <Next>.
- Under <Configuration>, click the <Buzzer> menu.
- Read out and record the configurations saved under "Buzzer settings" and "Blocktime settings".

With the installation of the VC10A SP1 software updates, the possible configurations for the buzzer and block time settings were adapted to the current national standards and regulations and expanded accordingly.

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The online help contains corresponding explanations regarding the functions that can be configured.

Refer to the functions corresponding to the configuration for the acoustic warning signal and mandatory shutdown of radiation.

This information is also published in the system start-up instructions.

- Refer to the functions corresponding to the configurations.
- In accordance with the local configuration, check the the acoustic warning signal function and the mandatory shutdown of radiation function. Also check the fluoroscopy clock function.

**SIE** Check the radiation release switch



- Check the functioning of the hand and foot switches for radiation release.
- Check the cables of the radiation release switches for mechanical damage.
- Move the cables and inspect them for breakage.

**SIE** Radiation indicator



Activate fluoroscopy briefly.

The radiation indicator on the operating part of the ARCADIS Avantic stand and the radiation indicator on the monitor cart must light.

Switch the system off.

**SIE** Iris collimator



- Check the iris collimator and correct it if necessary.
  - Select I.I. full format and activate fluoroscopy briefly.

- The collimator blades must be clearly visible at the edges of the image.
- Select a zoom format and release fluoroscopy briefly.
- The collimator blades must be clearly visible at the edges of the image.

**SIE** Air kerma meter (if present)

Check the air kerma meter and test its accuracy (see Main System Adjustment Instructions SPR2-330.842.01...).

**SIE** Dose area product meter (if present)

• Check the dose-area product meter and the calibration (see Main System Adjustment Instructions SPR2-330.842.01...).

SIE Voltage discharge rubber

 Check the voltage discharge rubber on the ARCADIS Avantic stand and the wheels and castors of the monitor trolley for damage or contamination, and replace or clean them as necessary.

# 3.1.3 Maintenance, Operating Values, Functional Inspection, and Maintenance

#### 3.1.3.1 Maintenance

PMF UPS battery replacement

- The lead gel battery integrated into the UPS has to be replaced for the first time after 42 months, and thereafter every 48 months on a preventive basis.
  - **>>** The replacement procedure is described in the operator manual from the manufacturer as well as in the Replacement of Parts manual SPR2-330.841.01.

**PMF** Imaging PC BIOS battery replacement

- The Imaging PC BIOS battery has to be replaced for the first time after 42 months, and thereafter every 48 months on a preventive basis.
  - The replacement for ARCADIS Gen2 systems (PC types M450, M460, M470 and M720) is described in the Replacement of Parts manual TD00-400.841.40... (PC Concept), and for the ARCADIS Gen1 systems (PC types M420, M430, M450, and M720) in the Replacement of Parts manual SPR2-330.841.01....

**PMP** System ventilation

• Clean the ventilation slots of the ARCADIS Avantic stand and monitor trolley.

PMP Cleaning the system

- Clean the entire system:
  - Visible cables
  - Exterior surfaces
  - Contact surface of wheels
  - Interior space

3

# 3.1.3.2 Operating Values, Inspection

PMF Event log

Read out and evaluate the system event log.

#### 3.1.3.3 Functional inspection

**PMF** Laser camera connection (if present)

Check the function of the laser camera connection.

**PMF** Check the operating function.

• Check all system operating functions.

**PMF** Monitor display of the iris collimator aperture

- Select I.I. full format.
- Close the iris collimator (X-iris) completely.
- Mark the diameter of the iris collimator aperture displayed on the monitor.
   Release fluoroscopy briefly. The actual diameter of the iris collimator is visible. The
- monitor display previously shown must coincide in position and diameter with the actual iris collimator aperture.
- Open the iris collimator completely.
- Mark the diameter of the iris collimator aperture displayed on the monitor.
- Release fluoroscopy briefly. The actual diameter of the iris collimator is visible. The monitor display previously shown must coincide in position and diameter with the actual iris collimator aperture.
- Select I.I. zoom format.
- Close the iris collimator (X-iris) completely.
- Mark the diameter of the iris collimator aperture displayed on the monitor.
- Release fluoroscopy briefly.

The actual diameter of the iris collimator is visible. The monitor display previously shown must coincide in position and diameter with the actual iris collimator aperture.

- Open the iris collimator completely.
- Mark the diameter of the iris collimator aperture displayed on the monitor.
- Release fluoroscopy briefly.

The actual diameter of the iris collimator is visible. The monitor display previously shown must coincide in position and diameter with the actual iris collimator aperture.

**PMF** PMF Monitor display of the slot diaphragm positions

- Select I.I. full format.
- Completely close the slot diaphragm and rotate the slot diaphragm from its home position.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.







Release fluoroscopy briefly.

The actual position (distance of the blades and angle of rotation) of the slot diaphragm is visible. The monitor display previously shown must correspond in position and angle of rotation with the actual slot diaphragm position.

- Open the slot diaphragm completely and rotate it again.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the blades and angle of rotation) of the slot diaphragm is visible. The monitor display previously shown must correspond in position and angle of rotation with the actual slot diaphragm position.

- Select I.I. zoom format.
- Completely close the slot diaphragm and rotate the slot diaphragm from its home position.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the blades and angle of rotation) of the slot diaphragm is visible.

- The monitor display previously shown must correspond in position and angle of rotation with the actual slot diaphragm position.
- Open the slot diaphragm completely and rotate it again.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the blades and angle of rotation) of the slot diaphragm is visible. The monitor display previously shown must correspond in position and angle of rotation with the actual slot diaphragm position.



Perform this check with the lowest possible kV values so that the front edges of the slot diaphragm plate are effectively visualized.

### 3.1.3.4 Upkeep

#### PMP Upkeep

Entire system: Touch up any paint damage as needed.

# 3.1.4 IQ quick test

SIE Image quality (IQ) quick test

- Perform the image quality test according to the ARCADIS Avantic image quality quick test instructions, and record the results of the test.
  - » Test any additional external monitors (if applicable) as well.

# 3.1.5 Final work steps / checks in accordance with IEC 62353

#### 3.1.5.1 General Measurement Notes

According to IEC 62353, the measured values must be compared to the old values. The old values can be seen in the

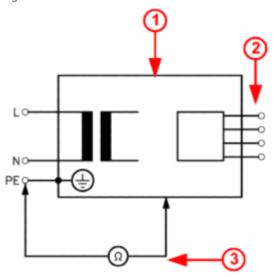
- \* Startup Certificate
- \* old Maintenance Certificate
- \* old Test Certificate per IEC 62353.

If significant differences are found, corrective measures may be necessary.

#### Perform the following measurements:

1. Grounding conductor measurement

Fig. 4: Ground wire



- (1) Medical device
- (2) Application part type B if present
- (3) Measurement instrument

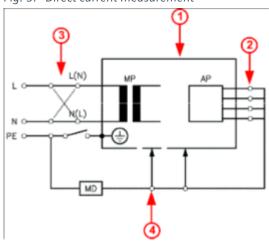
#### 2. Device leakage current measurement



Two different methods of measurement can be used.

Device leakage current (direct measurement) or (differential current measurement procedure).

Fig. 5: Direct current measurement



- (1) Medical device
- (2) Application part type B if present
- (3) Measurement setup (integrated in measurement equipment)
- (4) Additional connections if present

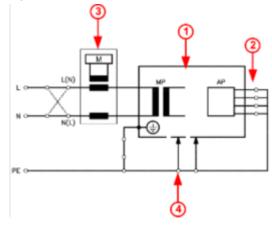


Fig. 6: Differential current measurement

- (1) Medical device
- (2) Application part type B if present
- (3) Measurement instrument
- (4) Additional connections if present

#### 3.1.5.2 Grounding conductor measurement

Switch off power to the system.

According to IEC 62353, the measured values must be compared to the old values. The old values can be seen in the

- \* Startup Certificate
- \* old Maintenance Certificate
- \* old Test Certificate per IEC 62353.

If significant differences are found or if the measured values exceed 180 mOhms, it may be necessary to initiate corrective measures.

Usually, the problem is that the ground wires are not connected, or incorrectly connected.

#### Test procedure:

Measure between all accessible conductive parts of the components and the plug.
 If using direct current, repeat the measurement with the opposite voltage polarity.
 Both measured resistance values may not exceed the permissible value.



During the protective earth resistance measurement, move flexible power supply cords section-by-section over their entire length to check for any possible wire breaks.

- Varying measured values arising during moving of the power supply cord indicate breakage of the protective earth conductor.
- If necessary, replace the power supply cord.



If significant differences are found between the old and new values or if the measured values exceed 180 mOhms, it may be necessary to initiate corrective measures.

Usually, the problem is that the ground wires are not connected, or incorrectly connected.

**»** Maximum value:  $0.2 \Omega$  (observe country-specific regulations!)



#### **Exceptions:**

Components with voltage less than/equal to 24 volts

Cover panels that cover electrical components with voltages less than/equal to 24 V.

**SIE** Ground wire status (in milliohms)

#### 3.1.5.3 Device leakage current measurement

#### Prerequisites for device leakage current (direct measurement):

■ To prevent measurement errors during direct measurement of the device leakage current, the ME equipment/other equipment must be isolated during the measurement.



#### WARNING

Since the protective earth conductor cannot fulfill its function during direct measurement of the device leakage current, there is a potential hazard to the tester or other personnel during the measurement.

Observe the following safety precautions:

- The leakage current measurement may only be performed after the protective earth test has been passed successfully.
- Access to the ME equipment or other equipment by personnel other than the tester must be prevented (blocking, measurement in a separate room).
- **»** During the measurement, the tester may not touch the ME equipment or other equipment.

#### Prerequisites for device leakage current (direct measurement):

• If the device leakage current is measured according to the differential current measurement procedure, the protective function of the protective earth conductor is maintained. There is no danger for the tester or other persons.

#### Measurement

Switch on the system.

- Test procedure:
- The device leakage current measurement must be performed twice: First measurement -> L and N at power plug, second measurement -> L and N reversed at power plug.

Limit values in accordance with IEC 62353:

i

The maximum leakage currents are:

- \* Device leakage current (direct measurement) 0.5 mA
- \* Device leakage current (differential current measurement) 0.5 mA

SIE Device leakage current (in milli A)

#### 3.1.5.4 Function check

**SIE** Perform function check

| Defect | Chapter             | Changes  |
|--------|---------------------|--|
| 288082 | All                 | Electronic report for completion improved              |
| 288082 | Partial maintenance | Final work steps / checks in accordance with IEC 62353 |
| 288082 | Full maintenance    | Final work steps / checks in accordance with IEC 62353 |

The work times given below are approximations. Actual work time for the various tasks (cleaning, for example), will vary from system to system.

Tab. 6 ARCADIS Avantic

| Maintenance step  | Required work time in minutes |
|---|-------------------------------|
| Partial maintenance   | 75                            |
| Visual inspection, external   | 15                            |
| Safety inspection   | 240                           |
| Maintenance inspection, operating value inspection, and functional inspection | 60                            |
| Final result inspection, quality inspection, and general maintenance          | 105                           |

It is not recommended to further subdivide the maintenance beyond the categories of full maintenance and partial maintenance, since this could cause an unnecessary increase in work (because of IEC 62353, for example).

There are no Hazard IDs in this document.

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