 Via Roma, 45 21057 Olgiate Olona (VA)	Project Name: X-MIND unity	XMu - Installation check list All. 9 a PR 7.5.3_1
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INSTALLATION CHECK LIST

X MIND unity data	
SN _____	UDI _____
Facility name	_____
Facility address	_____
State/province	City _____
Nation	Zip code _____
Facility phone number	E-mail _____



PLEASE NOTE

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After the completion of the installation of the X-MIND unity, the installer technician MUST fill in the form contained in this document to certify that the device has been correctly installed.

The Installation Checklist Form must be completely filled in all the details, stamped and signed by the installer technician and must be sent by e-mail to de Götzen S.r.l.: imaging.italysupport@acteongroup.com

de Götzen S.r.l. reserves the right to reject the filled *Installation checklist Form* if not correct or complete in each part or with any test not passed: in these cases, or **if the form has not been sent to de Götzen, any kind of right of the user will be automatically off, including any kind of responsibility of the manufacturer. Any future claims and/or complaint will be considered null and void.**

Make 3 copies of the filled in form:

- One for de Götzen (soft copy)
- One for the User (keep it with the device documentation)
- One for the Dealer (installer technician)



PLEASE NOTE

If you encounter problems that don't allow to correctly pass the tests or you have any doubt for the correct installation of the equipment, contact immediately your referring technician or the manufacturer: imaging.italysupport@acteongroup.com

Since the authorized installer technician is in charge to perform the installation and tests of the X-MIND unity, he/she has the full responsibility of the correct installation of the equipment.




PLEASE NOTE

Carry out the following operations while XMIND UNITY is OFF and disconnected from mains supply (MAINS SWITCH is OFF)

Check	Pass	Fail	Check Description
WALL MOUNTING (ONLY)	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that the wall support is adequate, the system is properly installed to the wall and anchors screws are properly tighten.
MOBILE VERSION (ONLY)	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that the pantograph arm is properly fixed to the column and its rotation is limited by the two screws (small angle). Ensure that the wheels are fixed and the brakes work properly.
MOBILE VERSION (ONLY)	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that the metal pin in F2 is replaced with the provided fuse.
LABELS CHECKING	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that all the labels on the system are available and properly attached: for each label check the serial number is the same one reported on the documents.
SYSTEM ROTATING PARTS	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that all rotating parts have a functioning mechanical stop to avoid cables twisting.
SYSTEM STABILITY	<input type="checkbox"/> P	<input type="checkbox"/> F	Check that all the movements are smooth and no forcing. Check that the system maintains the position without further movements after releasing it.

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COVERS INSTALLATION	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that all the enclosures and covers are properly installed (including all the screw caps) and not damaged. Make sure the bottom slide cover of the bracket is properly installed.
ELECTRIC INSTALLATION	<input type="checkbox"/> P	<input type="checkbox"/> F	Please indicate length and section of power cord from Mains Switch to X-MIND UNITY power terminals. The cable shall respect the requirement explained in paragraph REQUIREMENTS OF THE ELECTRIC LINE of the Installation Manual. LENGTH (m): _____ CONDUCTOR SECTION (mm2): _____
GROUNDING	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that the grounding is connected properly (refer to paragraph ELECTRICAL CONNECTIONS of the Installation Manual.
GROUNDING CONTINUITY	<input type="checkbox"/> P	<input type="checkbox"/> F	Check electrical continuity between the ground terminal and aluminum filter inside the tubehead cone: to perform this test is required to use a multimeter in continuity mode with buzzer sound enabled. The test is passed if the multimeter emits sound.
USER INFORMATION	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that the Operator has received the whole documentation provided with the system and the necessary information in order to operate the system according to safety measures.



PLEASE NOTE

Carry out the following operations while XMIND UNITY is OFF but connected to mains supply (MAINS SWITCH is ON).


VOLTAGE INPUT	<input type="checkbox"/> P	<input type="checkbox"/> F	Ensure that the supply voltage is compatible with the power supply requirements (100 - 240 V AC ; 50/60Hz). Ensure supply voltage stability. Write down the measured power voltage value at L/N terminal. WARNING - CAUTION This part is live (mains voltage) also when the mains switch of UNITY is OFF: be careful when perform this test. Voltage measured [V AC]: _____
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PLEASE NOTE

Carry out the following operations while XMIND UNITY is ON and connected to mains supply (MAINS SWITCH is ON).

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POWER SWITCH FUNCTIONING	<input type="checkbox"/> P	<input type="checkbox"/> F	Verify that the power switch is properly functioning and that the power indicator is lit on the control panel.
EXPOSURE TEST	<input type="checkbox"/> P	<input type="checkbox"/> F	Make one exposures using below parameters: - X-RAY tube Voltage: 65 kVp - X-RAY tube Current: 7 mA - Time: 2 s and verify the exposure is perfectly performed without error messages.

ONLY FOR US installation

Fill out report of assembly (Form FDA 2579)	<input type="checkbox"/> P	<input type="checkbox"/> F	The report must be filled out to certify that the medical equipment was assembled according to the instructions provided by the manufacturer, and meets the requirements of the applicable Federal standards contained in 21 CFR 1020.30 through 1020.33. Reports must be filed with FDA's Center for Devices and Radiological Health (CDRH) within 15 days of completion of the assembly.
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ADDITIONAL NOTES

Commissioning performed in accordance with installation manuals and any specific safety controls implemented in the country without detection of defects.
The unit including all accessories and documents, in accordance with the manuals, were given in the correct state.
The undersigned confirms to have the technical knowledge required for the installation.

DATE _____

INSTALLATION TECHNICIAN SIGNATURE _____

NAME AND SURNAME: _____

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