



Pre-installation Manual
Hologic 3Dimensions Mobile

Index

1	INTRODUCTION.....	3
2	SYSTEM DESCRIPTION	4
2.1	GANTRY	4
2.2	CONSOLE	5
3	ELECTRIC SPECIFICATIONS	6
3.1	ELECTRIC CLASSIFICATIONS	6
3.2	NETWORK CONNECTION	6
3.3	GROUNDING	6
3.4	NETWORK CONNECTIONS.....	7
3.5	VPN.....	7
3.6	CABLES AND CABLE TRAYS.....	7
3.7	X-RAY LIGHT INDICATOR.....	7
4	CONSTRUCTIONAL FACILITIES	8
4.1	FLOOR	8
4.2	WALLS.....	8
4.3	CONSTRUCTION.....	8
4.4	LOCATION OF MOBILE TRAILER	8
4.5	CENTER OF GRAVITY REFERENCE	9
5	CLIMATE CONDITIONS.....	10
5.1	POWER CONSUMPTION AND HEAT OUTPUT OF THE SYSTEM	10
5.2	HUMIDITY AND TEMPERATURE OF THE ROOM	10
6	X-RAY PROTECTION.....	10
6.1	X-RAY PROTECTION OF THE ENVIRONMENT	10
6.2	X-RAY LIGHT INDICATOR.....	10
7	TRANSPORT ROUTE.....	11
8	SITE LAYOUT SPECIFICATION.....	11
	ATTACHMENT 1: WORK SWITCH	12

1 Introduction

This manual contains product information, specifications and requirements regarding the installation of the Hologic 3Dimensions digital mammographic for mobile units, hereinafter referred to as the 'system'. In this manual Tromp Medical will be referred to as 'TM'. All information in this manual is important and relevant to a successful installation process.

If there are any doubts regarding this pre installation manual, installation, planning or process please contact the project manager of Tromp Medical.

Tromp Medical strongly recommends using experienced contractors who specialize in constructing mobile medical units.

Please note that this system generates x-ray radiation. Client will be responsible for permits that comply with local regulations to use this system.

Disclaimer

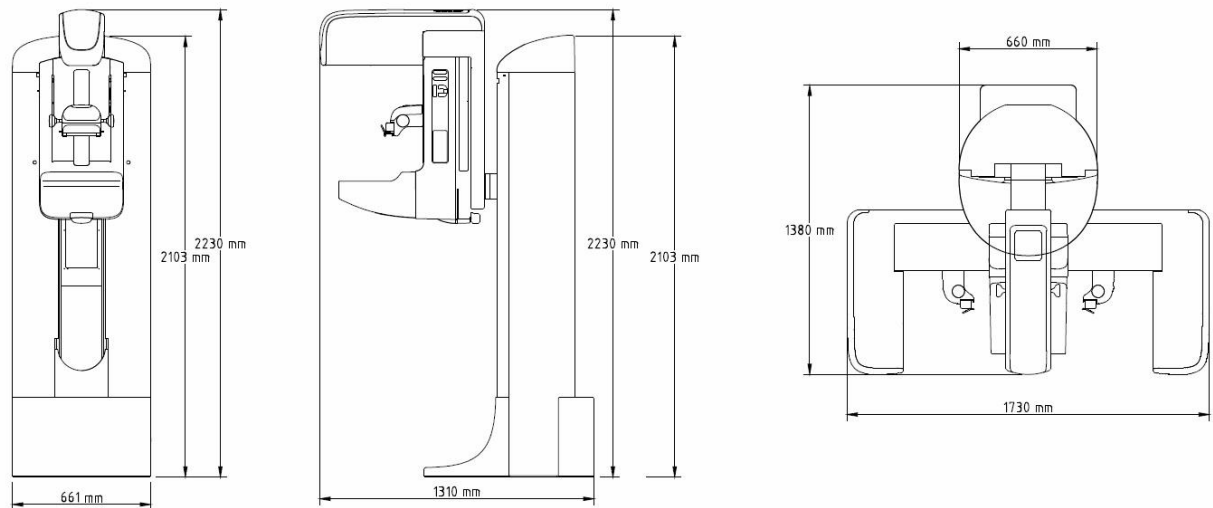
Reproduction and / or publication of this information in any form requires written permission of Tromp Medical. When the room preparation was not performed in accordance with the conditions set out in this document, Tromp Medical reserves the right to postpone the installation. Tromp Medical cannot be held liable for any delays, costs or damages that may arise from inaccurate or incomplete room preparation.

2 System description

The system contains two units; a 'gantry' with x-ray tube and detector and the control panel referred as 'console'.

2.1 Gantry

2.1.1 Dimensions/ weight



Weight of the gantry: 400 kg

2.1.2 Electric requirements gantry

Phase:	1
Main voltage:	230Vac
Peak line current:	11,5 kW, gedurende 5 sec.
Fuse:	32A slow / C characteristic

See chapter 3 for the electric specifications.

2.1.3 Climate conditions gantry

Humidity:	10 - 80 % (non-condensing)
Temperature range:	15 °C to 30 °C

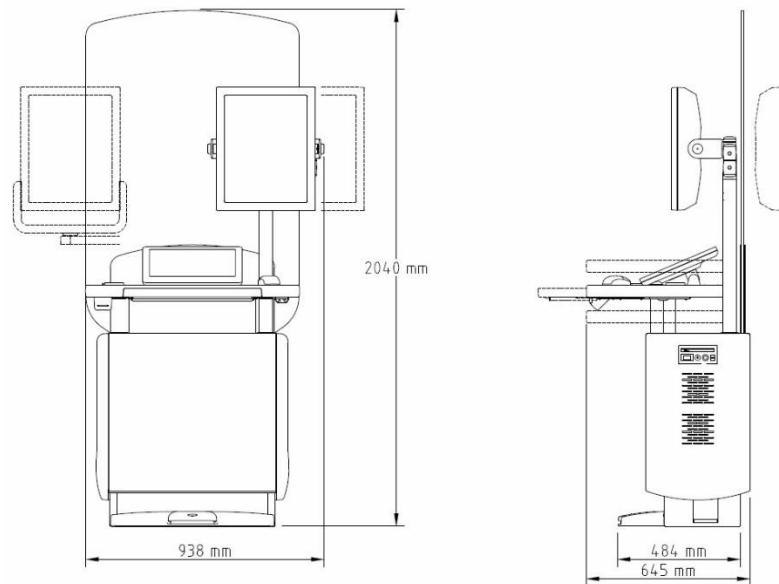
See chapter 5 for the complete climate conditions.

2.1.4 Length standard system cables

AWS to gantry: 7,5 meter

2.2 Console

2.2.1 Dimensions/ weight



Weight of the console: 209 kg

2.2.2 Electric requirements console

Phase:	1
Main voltage:	230Vac
Max power consumption:	800 Watt
Fuse:	16A – C - characteristic

See chapter 3 for the electric specifications.

2.2.3 Climate conditions console

Humidity:	10 - 80 % (non-condensing)
Temperature range:	15 - 30 °C

See chapter 5 for the complete climate conditions.

3 Electric specifications

3.1 Electric classifications

The electric specifications depend on the classification of the installation room. Depending on the use of the system, the room can be classified as K1 or K2. The Hologic 3Dimensions Mobile will comply with the K1 and K2 classification.

The electrical connections (work switches) must meet the requirements set out below. If connections do not meet the requirements, please contact TM's project manager in advance.

3.2 Network connection

The system needs two separated network connections:

- | | | |
|----|--------------------|---------------------------------------------------------------------------------------------------------------------------------|
| A. | Fase: | 1 + N |
| | Line resistance: | Max. 200mOhm |
| | Peak line current: | 32 A slow / C characteristic
(65A maximum for < 2 seconds) |
| | Circuit breaker: | 30mA |
| | Connection: | In the room on the isolating switch with connection 3 *
6mm ² The isolating switch will not be in the scope of TM |
| B. | Fase: | 1 + N |
| | Line resistance: | 16A / B characteristic |
| | Circuit breaker: | 30mA |
| | Connection: | In the room as separated group by double power socket or
by an isolating switch. |

The system is standard provided with multiple emergency switches, it will not be necessary to install an extra emergency switch in the electric system. If there is nevertheless need for an extra emergency switch, please inform us before the installation. In this situation we can decided to exclude connection B for this emergency switch.

3.3 Grounding

The ground connection must be dimensioned so that possible short-circuit safely will be discharged to the earth. The ground connection of 6mm² will be connected with phase and neutral through a three-wire cable into the isolating switch, if there is no separate earth settlement offered.

3.4 Network connections

The console needs a connection to the hospital network. At least one week before the installation TM needs to have the IP-address and AE titles to prepare the system. The hospital is free to choose the IP-address and the AE titles. The network needs to be tested and approved before the installation of the system.

- TCP/IP 100 Mbit/sec for 2D mammographic.
- TCP/IP 1000 Mbit/sec for 3D mammographic (Tomosynthesis) and high workload.

3.5 VPN

There will be an option of remote controlled service by a VPN connection on the system. If this is desirable this need to be specified to the project manager of TM, he will make sure all need information will be provided.

3.6 Cables and Cable trays

All cable duct, cable trays and other cable facilities on the floors, walls or underneath the ceiling has been situated in the site layout drawing are not part of the scope of TM. To avoid a delays, all cable facilities need to be installed before installation of the system.

3.7 X-ray light indicator

Regarding the x-ray safety, light indicator is normally installed above the doors that directly access to the exam room. This does not hold for doors that are normally locked.

The system standard provides a potential-free contact. This contact will be suitable for 24V-4A. These lights are not part of the scope of TM and need to be installed before installation of the system. Cables for the light indicator need to be provided to the bottom of the gantry including 3 meter extra. The lights need to be tested and approved before the installation of the system.

See chapter 6.2 for more configurations.

4 Constructional facilities

Before the start of the installation, the room and trailer need to be cleaned and dust free. Depending on local regulations, cable recesses need to be provided with fire resistant sealing. If this will be necessary, please inform or project manager before the installation.

4.1 Floor

Before installation the floor need to be completely finished, cleaned and able to bear the weight of the system. The system need to be mounted with four steel anchors to the floor of the mobile trailer. We recommend a steel baseplate pinned to the chassis of the mobile trailer.

Please note that TM will not be responsible for the mounting into the trailer.

4.2 Walls

Items that can be installed at the walls:

- Compression paddle holders
- Isolating switch

Normally the paddle holders will be mounted by chipboard screws or cavity wall plugs. If under any circumstance these cannot be use, please inform TM's project manager before the installation.

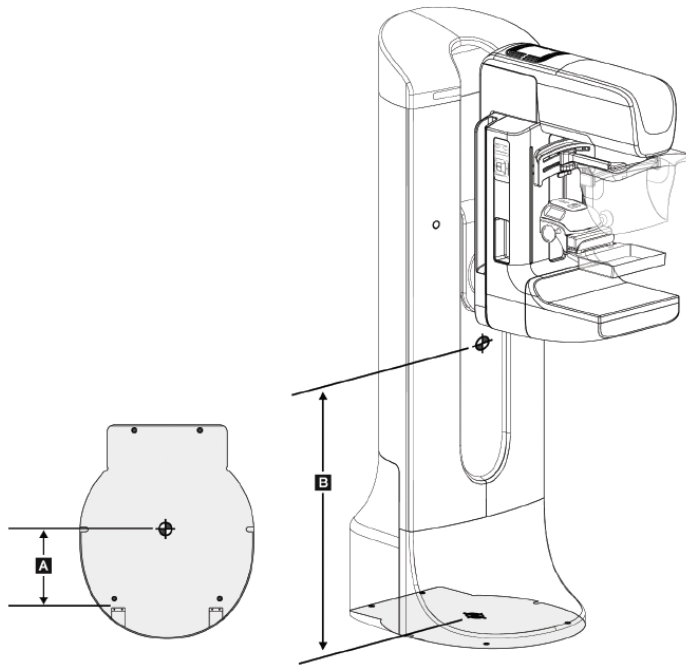
4.3 Construction

The mobile trailer construction should be solid that the vibrations are less than or equal to 0.35G (2-200Hz), measured on the floor mounting points of the system. Shocks need to not greater than 1G (measured as amplitude), measured on the floor mounting points of the system. An "air ride" suspension on the mobile trailer is recommended.

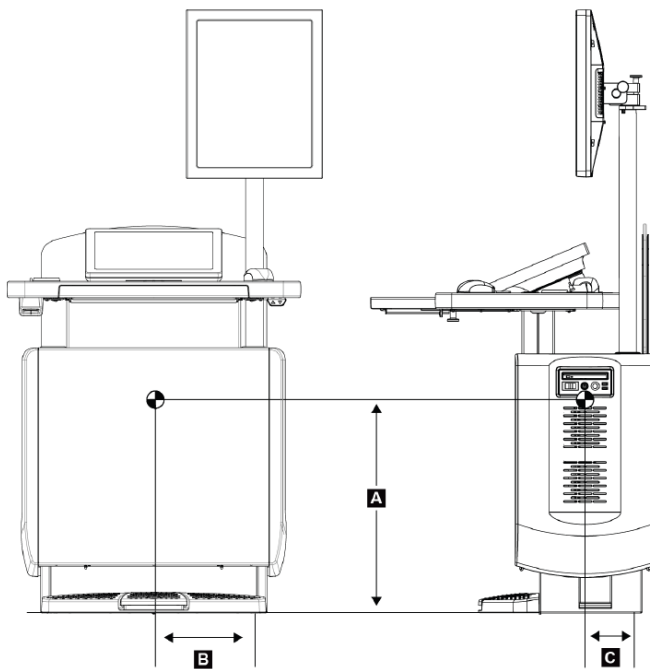
4.4 Location of mobile trailer

Do not locate or park the mobile trailer near sources of high power (such as power transmission lines and outdoor transformers). Make sure that any mobile power generator, uninterruptable power system (UPS), or voltage stabilizer is at least 3 meters form the closest point of the image detector travel.

4.5 Center of gravity reference



- A. 31.8 cm
- B. 95.5 cm



- A. 61.7 cm
- B. 28.95 cm
- C. 14.2 cm

5 Climate conditions

5.1 Power consumption and heat output of the system

	State 1 (X-ray on)	State 2 (Standby)	State 3 (Sleep mode)
Power consumption Console	240	240	60
Power consumption Gantry	3492	400	200
Total	3732W	640W	260W
Heat output (BTU/hr)	6800	2183	887

- State 1 - Acquisition (X-ray on – average exposure settings) 30kV 100mAs
- State 2 - Standby (Power on, ready for acquisition, but without exposure)
- State 3 - Sleep mode (System shut down, but power on detector)

5.2 Humidity and temperature of the room

The temperature and humidity inside the mobile trailer must be maintained at all times. Do not allow environmental conditions to exceed stated specifications when the trailer is not in use.

Humidity: 10% - 80% (without condensing).

Operating temperature: 20 - 30 °C (maximum rate of temperature change < 10°C/uur).

Temperature stand-by (transportation): 10 - 35 °C, max 24 hours (maximum rate of temperature change < 10°C/uur).

6 X-ray protection

6.1 X-ray protection of the environment

During normal use the system will generate a low dose of radiation. TM advises that the client will calculate and control the protective measures by a qualified person or authority. Based on these calculates, x-ray proof materials in the exam room on walls, floors, sealing, doors, windows and other constructional shell to protect patents and employees can be used.

Depending on local regulations a qualified person or authority need to arrange a permit for this system. TM cannot be responsible for any damage or injury that may result out of insufficient protective measures against x-ray radiation.

6.2 X-ray light indicator

The x-ray light indicator need to be installed according to local regulation. The light can be programmed in the three following manners:

1. When the system will be powered;
2. When the system makes an exposure;
3. During preparation and the exposure (standard);

The client need to inform TM before installation about the preference of the settings.

7 Transport route

If the research area where the system need to be installed is not on ground level, it's necessary that there is an elevator or forklift (minimum 500 kg) available which is suitable for transporting the system.

The minimal dimensions of the system vertically for transportation are:

- Height minimal 2,10 meter
- Weight minimal 0,72 meter

If there are any doubts regarding the accessibility of the room or the transportation route, please contact the project manager of TM.

8 Site layout specification.

There are two type of site layout drawings;

1. Site Layout for the users;
2. Site layout for the preparations;

All installation drawings need to be approved by the client before the installation. The scale on the drawings can be variable with the purpose to provide a big as possible image of the situation.

Attachment 1: work switch

