Operating instructions

Mona Terminal

CE

clinomic

https://www.clinomic.ai/ifu/
Hardware version: 2.0
English

Read the instructions prior to performing any task!

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About this instruction manual

This instruction manual enables safe and efficient handling of the *Mona* terminal. This instruction manual is a component of the terminal and must be kept in the immediate vicinity of the terminal where it is accessible to personnel at all times.

Personnel must have carefully read and understood the instruction manual before beginning any work with the product. Compliance with the safety information and instructions provided in this instruction manual is an essential prerequisite for safe use of the product. In addition, the local occupational health and safety regulations and the general safety regulations for the area in which the terminal is used must be observed.

Illustrations in this instruction manual are intended for basic understanding and may deviate from the actual design.

The terminal only functions with the corresponding *MonaOS* software. Operation of the terminal is based on the software functions. The relevant instructions can be found in the software manual *'Other applicable documents' on page 3*.

Customers of Clinomic Medical GmbH (hereafter also referred to as Clinomic) will be informed if and when future revisions of this instruction manual are made available.

Copyright

Other applicable documents

The documents listed below apply in addition to this instruction manual.

Document	Note
MonaOS software manual	Note the software version level of *MonaOS*
Manual for remote users of *MonaOS* – telemedicine web interface	Note the software version level of *MonaOS*
Spring arm24 SKYDOQ instruction manual	The spring arm24 Standard version (STD) is used with an appropriate adapter.
Data sheet for Intel 9260.NGWG	Wireless Wi-Fi Bluetooth adapter
Data sheet for TWN4 MULTI-TECH 3 LF	RFID chip reader
Data sheet for Quectel RM500Q-GL	5G module
Data sheet for Infineon BGT 60 TR 13 C	Radar module

Product feedback

In the interests of monitoring our products, we are interested in information and experience relating to use of the terminal and this instruction manual. We would therefore be very grateful for relevant feedback. If you are unsure about any of the information given in this instruction manual, please feel free to contact us.

If you experience any serious incidents involving the product, please contact Clinomic Medical GmbH without delay, as well as the responsible authorities in the EU Member State, where relevant.

Table of contents

1 Structure and function

1.1 Functional description

Area of application

Mona is a data processing, assistance and telemedicine system for use in the field of intensive care and comparable medical environments.

Mona consists of the terminal and the *MonaOS* software operated on the terminal.

Mona provides various functions – depending on which *MonaOS* software version is used – to aid medical documentation in the area of application.

The *Mona* terminal allows efficient language-based interaction between medical specialists in an intensive care unit or comparable environments. It does this by combining suitable hardware components in a single device in order to support medical specialists during treatment.

The *Mona* terminal is a device that provides the hardware and operating system infrastructure for *MonaOS*. The *Mona* terminal is designed to be used in combination with *MonaOS*.

Point of use and interaction

The terminal can be attached in suitable care environments by means of a wall or ceiling bracket or other suitable mount, for example.

The terminal is operated using a touch screen.

Depending on which version of MonaOS is used, other interactive features may be available.

Interfaces and system connection

The system is connected to the hospital's digital infrastructure (hospital information and auxiliary systems) using a wireless LAN or LAN connection.

In addition, the terminal has the following wireless connections that are used for the enhanced functions and for the access authorisation process:

Technology	Use	Additional information
RFID	User authentication with RFID tags	*'ELATEC TWN4 Multi-Tech 3 M LF T430-F4C0 (RFID chip reader)' on page 35*
5G	Data transmission for video calls	*'Quectel RM500Q (5G module)' on page 35*

Technology	Use	Additional information
Bluetooth	Communication with other devices	‘Intel Wireless-AC 9260 (Wireless WiFi Bluetooth adapter)’ on page 35
Radar	Communication and authentication	‘Infineon BGT 60 TR 13 C (radar)’ on page 36

1.2 Functional elements and connections

Front

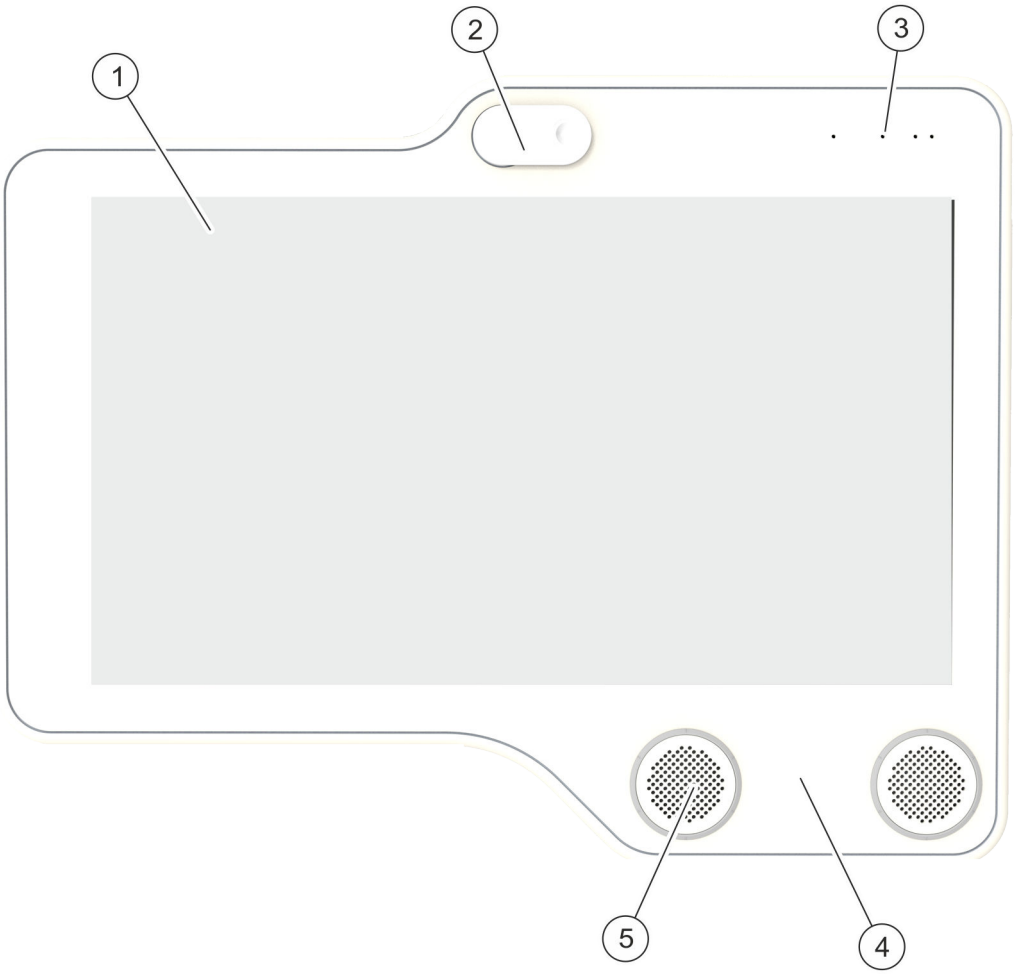


Fig. 1: Front view

1 Touch screen
2 Camera
3 Front microphone
4 RFID recognition
5 Loudspeaker

Touch screen

The software is operated by tapping the touch screen with your finger.

Camera

The camera facilitates image transmission for the telemedicine application. The camera can be covered with a slider.

Front microphone

The microphone is used to record audio signals and can be used to enter voice commands and for telemedicine applications.

RFID recognition

RFID recognition consists of an RFID reader embedded in the device. Hold an RFID token into the indicated area to have it read.

Loudspeaker

Loudspeakers allow the user to hear information from *Mona*, system messages, and information in telemedicine applications.

Lighting

The terminal features ambient lighting. The lighting can light up when you interact with the terminal, in order to provide feedback to the user.

Observe the MonaOS software manual.

Back

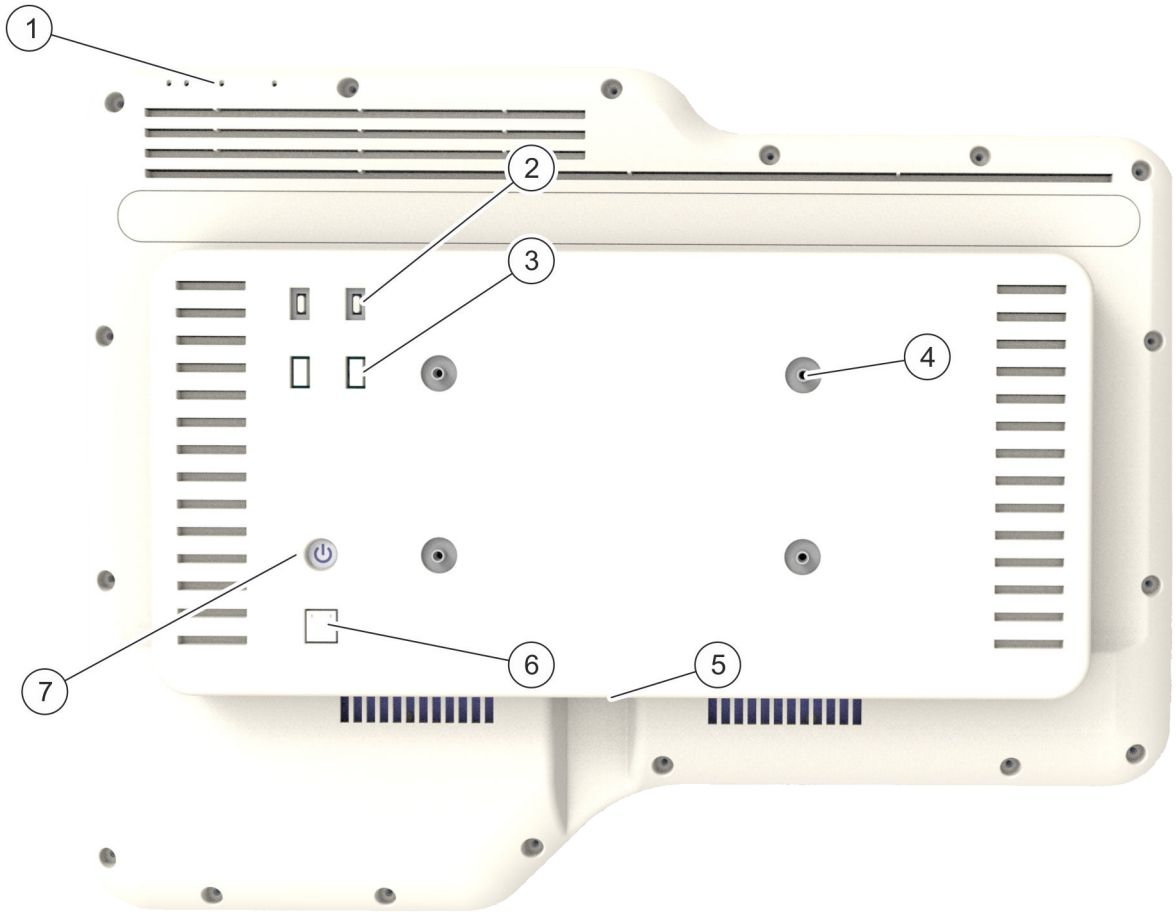


Fig. 2: Rear view

1 Rear microphone
2 USB-C port
3 USB-A port
4 Fastening screw thread for VESA adapter (4x)
5 Functional unit: Low-heat device connection and main isolating switch (rocker, secondary)
6 Ethernet connection
7 On/off switch (push button, primary)

Rear microphone

The rear microphone is an addition to the microphones on the front. The microphone can be used to issue voice commands and generate an audio signal for video conferences.

USB ports

The USB ports on the back are used to connect USB flash drives when servicing is required. Only service personnel may use the USB ports.

Fastening screw thread for VESA adapter

The fastening screw threads for VESA adapter can be used to attach a VESA adapter plate due to standardised thread intervals. This makes attachment to compatible fastening systems possible.

Functional unit: Power supply connection and main isolating switch

The power supply connection supplies the device with mains voltage. The main isolating switch is a rocker, which is used to switch on the supply voltage or disconnect the device from the mains power supply.

Ethernet connection

The Ethernet connection can be used to establish a network connection if the building's network connection is equipped with a 4 kV isolation barrier.

On/off switch

The on/off switch (Fig. 2/7) can be used to switch the terminal on and off, and it functions like the on/off switch on a PC.

Pushing it briefly boots or shuts down the terminal in controlled fashion. Pushing it for a long time switches the terminal off immediately instead of performing a controlled shut-down.

1.3 Scope of delivery

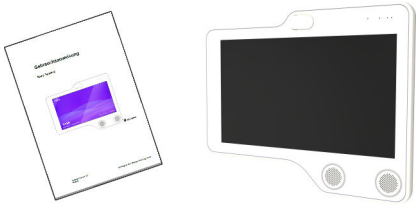


Fig. 3: Scope of delivery

The scope of delivery contains the following:

- *Mona* terminal
- Instruction manual

2 Safety

2.1 Symbols in this instruction manual

Safety information

Safety information is indicated in this instruction manual by symbols. The safety information is introduced by signal words that indicate the magnitude of the hazard.

In order to avoid accidents, injuries and property damage and to ensure the greatest possible patient safety, always follow the safety instructions and proceed with caution.

DANGER!
This combination of symbol and signal word indicates an imminently hazardous situation that will result in death or severe injuries if it is not avoided.

WARNING!
This combination of symbol and signal word indicates a potentially hazardous situation that may result in death or severe injuries if it is not avoided.

CAUTION!
This combination of symbol and signal word indicates a potentially hazardous situation that may result in minor or slight injuries if it is not avoided.

NOTICE!
This combination of symbol and signal word indicates a potentially hazardous situation that may result in property damage and/or environmental damage if it is not avoided.

Tips and recommendations

This symbol highlights useful tips and recommendations, as well as information that helps ensure efficient and trouble-free use of the device.

Signs in this document

The following signs are used in this instruction manual to highlight instructions, results, lists, cross-references and other elements:

Sign	Explanation
	Step-by-step instructions
⇨	Results of actions

Sign	Explanation
↳	References to sections of this instruction manual
■	Lists with no specified order

2.2 Intended purpose

The *Mona* terminal enables efficient language-based interaction between medical specialists within an intensive care unit or comparable medical environments by making appropriate hardware and software components available on a single device, in order to support medical specialists in providing treatment.

The *Mona* terminal is a device that provides the hardware and operating system infrastructure for the *MonaOS* software. The *Mona* terminal is designed to be used in combination with the *MonaOS* software.

The *Mona* terminal supports the *MonaOS* software in the following areas:

- Medical documentation by means of voice recognition, hardware components, and modules
- Displaying information that is created and controlled by *MonaOS* on special monitors and screens
- Providing a user interface runtime environment for operating the *MonaOS* software
- Providing the computing infrastructure for the *MonaOS* software

The precise scope of functions is defined by the version of the *MonaOS* software that is used.

The intended purpose includes compliance with all the information in this instruction manual.

Any use beyond or other than the intended purpose is considered misuse.

WARNING!

Danger in the event of misuse!

Misuse of the terminal can result in hazardous situations. The following is therefore essential:

– Never use the terminal for mobile emergency care (e.g. ambulance).
– Never allow unauthorised persons to access the terminal.
– Never open the terminal’s housing.
– Do not stack the terminal with other devices.
– Never lay the power supply cables for other devices across the terminal or wind them around the terminal’s mounting elements.

Indications

The *Mona* terminal is used in combination with *MonaOS* for all patients who are being treated in the intensive care unit or in other similar environments.

Contraindications

There are no known contraindications or exceptions to the use of the terminal in combination with the *MonaOS* software.

Reciprocal effects

There are no known reciprocal effects in the use of the terminal in combination with the *MonaOS* software.

Further intended purpose

A further intended purpose is regular cleaning of the terminal by means of wipe disinfection once per shift.

Personnel characteristics

The terminal is designed for exclusive operation by medical specialists or service personnel. This instruction manual distinguishes groups of specialists as shown in the section below: ↳ *Chapter 2.5 ‘Specialist qualifications’ on page 18*

It differentiates between the following groups of persons who are authorised to handle the terminal as specialist personnel:

Medical specialists (principal operators)	Doctors and nursing staff in intensive care units or other similar environments
Service staff (secondary operators)	Specialists responsible for installation, updates and configuration
	Specialists responsible for disinfecting medical devices

Patient characteristics

The patients are critically ill patients who are being treated in an acute care unit or intensive care unit (e.g. accident and emergency unit, intensive care unit, operating theatre, anaesthetic recovery room, intensive care).

Use of the terminal in combination with the *MonaOS* software is not restricted to specific illnesses, comorbidities or demographic characteristics.

2.3 Residual risks

Electric current

DANGER!

Risk of fatal electric shock!

Contact with live parts poses an immediate danger of fatal electric shock. Damage to the device or the power supply cable can be life-threatening.

- Make sure that the building's mains connection has a 4 kV isolation barrier (network isolator).
- Only connect the device to a mains supply with a protective earth conductor.
- To isolate the device from the mains supply, unplug the power supply cable.
- Keep moisture away from the device and the power supply cable. Moisture can result in a short circuit.
- If the device is damaged, switch it off immediately, put it out of use and arrange for repairs.
- If the power supply cable is damaged, switch off the device immediately and replace the power supply cable.
- Have defective devices repaired by Clinomic customer service only.

Risk of infection

WARNING!

Risk of infection in the event of insufficient hygiene and disinfection!

There is a risk of infection in the event of contact with parts of the device that have not been cleaned and disinfected.

- Clean and disinfect the device at least once per shift ↬ *Chapter 5.3 'Cleaning and disinfecting the terminal' on page 27*. If local circumstances require more frequent cleaning and disinfection, clean and disinfect the device more often accordingly.
- The device may only be cleaned with the described cleaning materials as described in ↬ *Chapter 5.3 'Cleaning and disinfecting the terminal' on page 27*.
- Note the information on the type of disinfection and the disinfectants to use.

Electromagnetic compatibility

WARNING!

Danger due to failure to comply with the electromagnetic compatibility requirements!

Medical electrical equipment is subject to specific electromagnetic compatibility (EMC) requirements. Failure to comply with the safety requirements can result in malfunctioning of the device and it poses a risk of adverse effects on other equipment, which can in turn result in damage, malfunctions or even total failure, with corresponding dangers to patients receiving treatment.

Make sure that the device is installed and operated in accordance with the following specifications:

- Only use connecting cables recommended by the manufacturer *Chapter 8.5 'Accessories' on page 37*.
- Do not use any accessories other than those described and sold by the manufacturer. Spare parts that have not been produced or approved by the manufacturer may increase electromagnetic interference emissions or impair the device's electromagnetic immunity.
- Wearable HF communication devices (including peripheral devices such as antenna cables and external antennas) should not come closer than 30 cm (12 inches) to any component of the *Mona* terminal, including the cables and lines as specified in this instruction manual *Chapter 8.10.3 'Recommended safety distances' on page 43*. Otherwise the performance of the device can be affected.
- The use of this device with neighbouring devices or stacked with other devices should be prevented, as it could result in incorrect operation. If such an application is required, this device and the other devices should be monitored to ensure that the devices behave normally.
- Doctors, medical specialists and patients receiving treatment must not come into physical contact with one another while the device is being operated.

Unsuitable spare parts and accessories

WARNING!

Risk of injury due to the use of unsuitable spare parts or incorrect accessories!

Using unsuitable or faulty spare parts or accessories can result in dangers to personnel, as well as damage, malfunctions or complete failure.

– Only use genuine spare parts and accessories from Clinomic or approved by Clinomic ↳ *Chapter 8.5 'Accessories' on page 37*.
– Do not make any technical modifications.
– If in doubt, always contact Clinomic customer service.

Falling

CAUTION!

Risk of injury from falling device!

If the device is not properly mounted, it may fall down and cause injuries.

– Only mount the device with the appropriate adapter plate on a spring arm / fastening system designed for the purpose ↳ *Chapter 8.5 'Accessories' on page 37*.
– Make sure that the device is fastened properly during the course of installation.

2.4 Property damage

USB port

NOTICE!

Overloading of the USB ports if unsuitable peripheral equipment is connected!

If equipment with a high current consumption is attached to a USB port, it may cause overloading and damage to the USB port.

– Do not operate any USB devices on the USB port. The USB ports are intended solely for service tasks performed by Clinomic customer service.

Electrostatic discharge

NOTICE!

Damage to the microphones if handled incorrectly!

Improper handling may result in electrostatic discharge, which can damage the built-in microphones.

– Do not touch the microphone openings on the terminal.

Electrostatic discharge cannot impair any of the fundamental device functions.

Liquids

NOTICE!

Damage to the terminal if liquids penetrate it!

Liquids can enter the terminal through slots and openings in the housing and cause damage.

– Do not store any liquids in the immediate vicinity of the terminal that could spill into the terminal if knocked over.
– When disinfecting the terminal, use only surface disinfection, not spray disinfection.
– When disinfecting the terminal, make sure that liquid disinfectant does not leak into the terminal through slots and openings.

2.5 Specialist qualifications

WARNING!

Danger if personnel are insufficiently qualified!

If unqualified personnel carry out work or make adjustments on the terminal, there is a risk of injury and property damage.

– All work and adjustment on and to the terminal must be carried out by qualified specialists only.
– Keep unqualified personnel away from the terminal.

Qualifications

This instruction manual specifies the following personnel qualifications for different areas of activity:

Medical specialists
Medical specialists are doctors and nursing staff in intensive care units or similar environments. Thanks to their professional education, medical specialists are able to carry out the duties entrusted to them.

Service personnel
Service personnel are trained by Clinomic and are responsible for IT administration (installation, configuration, updates) (hospital IT department). Thanks to their professional education and specific training, service personnel are able to carry out the duties entrusted to them.

The group of service personnel also includes specialists who are responsible for disinfecting medical devices.

Only persons who can be expected to perform their tasks reliably are permitted as personnel. Persons whose reactions are impaired, e.g. due to drugs, alcohol or medication, are not permitted.

When selecting personnel, observe the locally applicable age-specific and professional regulations.

2.6 Necessary equipment and resources

The following equipment is needed for certain activities on the device:

Hexagon socket wrench SW4
Hexagon socket wrench with wrench size 4

Torque wrench, torque range approx. 1 – 10 Nm
Torque wrench with adjustable tightening torque between approx. 1 and 10 Nm

The following resources are needed for certain activities on the device:

Disposable disinfectant wipes
Disposable disinfectant wipes for wiping surfaces that require medical disinfection.

Fastening screws: 4 pieces; M5x20; A2-70 DIN 912 (included in scope of delivery of spring arm / fastening system)
Fastening material for installation of the terminal on the spring arm / fastening system

Surface disinfectant
Approved disinfectant for medically disinfecting surfaces.

Washers: 4 pieces; washer ISO 7089-5-200 HV-A2 (included in scope of delivery of spring arm / fastening system)
Fastening material for installation of the terminal on the spring arm / fastening system

If special equipment or resources are necessary for specific activities, these are specified at the start of the respective chapter.

2.7 Environmental protection

ENVIRONMENT!

Danger to the environment due to improper handling of environmentally hazardous substances!

If environmentally hazardous substances are handled incorrectly, in particular if they are disposed of incorrectly, there is a risk of severe damage to the environment.

– Always comply with the information specified below on handling and disposing of environmentally hazardous substances.
– If environmentally hazardous substances are accidentally released into the environment, take suitable measures immediately. If in doubt, inform the local authority of the damage and enquire about suitable measures.

Electronic components

Electronic components may contain environmentally hazardous or recyclable substances or modules. Collect electronic components separately and have them recycled or disposed of by authorised disposal specialists only.

Packaging materials

Packaging materials are valuable raw materials and can in many cases be reused or usefully treated and recycled. If you plan to transport the terminal or place it in storage, it is useful to retain the original packaging.

- Recycle or dispose of unneeded packaging materials in an environmentally sound manner.
- Observe the locally applicable disposal regulations. If in doubt, arrange for a specialist company to dispose of the materials.

3 Transport and storage

3.1 Transporting the terminal

Transport packaging and reuse

The terminal is packed in a cardboard box on delivery. The packaging is intended to protect the terminal against transport damage, corrosion and other damage until it is installed.

Only remove the packaging shortly before installation and, if applicable, retain it for later use in case the terminal needs to be put back into storage or transported.

Transport

If the terminal needs to be transported again, package the terminal well in its original packaging if possible and subject it to as little vibration as possible during transport. Do not throw!

Note the storage conditions *'Correct storage' on page 21*.

3.2 Storage conditions

Correct storage

To prevent the terminal from being damaged in storage, certain requirements must be met.

Before putting it into storage, make sure that the following conditions are met:

Store in dry conditions

Protect the medical device against moisture and store in dry conditions.

Keep away from sunlight

Protect the medical device from direct sunlight.

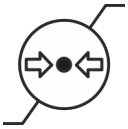
Stay within the temperature range

Store the medical device between -20 and 60 °C.

Stay within the humidity range

Store the medical device at a relative humidity of 15 to 95%.

Stay within the air pressure range



Store the medical device at an air pressure of 570 to 1060 hPa (427 to 795 mmHg).

Store in low-vibration conditions

Do not expose the medical device to vibrations during storage if possible.

Avoid contact with aggressive media

Do not store the medical device where it can be affected by aggressive media (e.g. gases).

4 Installation and connection

4.1 Preparing and configuring the terminal

Personnel:
- Service personnel

Requirements:

- The Clinomic devices and server are located in the hospital or at the installation site.
- Clinomic employees have access to the hospital's IT infrastructure (via VPN or on site).

A separate terminal is needed for each patient bed and it must be configured accordingly.

To prepare and configure the terminal, proceed as follows:

1. Configure the terminal's network connections in accordance with the hospital's specifications.
2. Have the *Mona* Bridge/Core system component installed by Clinomic employees.
   ⇨ The *Mona* Bridge/Core system component is ready for use.
3. Have the terminal configured and verified by Clinomic employees.
   ⇨ The terminal is ready for use.

4.2 Installing the terminal

Personnel:
- Service personnel

Tool:
- Hexagon socket wrench SW4
- Torque wrench, torque range approx. 1 – 10 Nm

Material:
- Fastening screws: 4 pieces; M5x20; A2-70 DIN 912 (included in scope of delivery of spring arm / fastening system)
- Washers: 4 pieces; washer ISO 7089-5-200 HV-A2 (included in scope of delivery of spring arm / fastening system)

Requirements:

- The spring arm or fastening system is installed in line with all the manufacturer's specifications.
- All the connecting cables have been routed.

The terminal can be mounted on a spring arm or a fastening system with the help of a VESA adapter.

To install the terminal, proceed as follows:

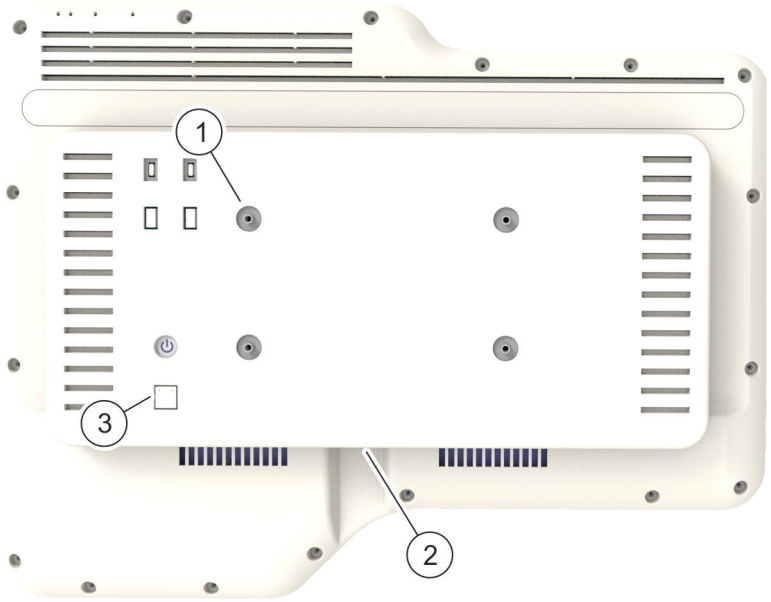


Fig. 4: Fastening the VESA adapter to the terminal

1 Fastening screw thread for VESA adapter
2 Power connection
3 Ethernet connection

1. Screw the terminal to the VESA adapter using the four screws (M5x20) and the four fastening screw threads (Fig. 4/1) on the back of the terminal. Use one washer for each screw.

2. Tighten screws crosswise with the torque wrench.

Tightening torque
2.5 – 4 Nm

3. Install the VESA adapter together with the screwed-on terminal onto the spring arm or the fastening system.

Observe the instruction manual for the spring arm or the fastening system.

4. **CAUTION!**
Risk of injury from falling terminal!

Make sure it is held securely. The terminal must be firmly connected to the spring arm or the fastening system.

5. **DANGER!**
Risk of fatal injury if the network connection is installed incorrectly!
In the case of copper-based network cables, if the cable screen or the conductor cores are damaged, there is a risk of unexpected electrical connection with other live parts of the mains network. This can result in stray currents that could have fatal consequences for users and patients.
– Before connecting the device, make sure that the building's mains connection has a 4 kV isolation barrier (network isolator).

Plug the Ethernet cable (network cable) into the Ethernet connection (Fig. 4/3) on the back of the terminal.

6. Plug the power supply cable into the power connection on the underside of the terminal (Fig. 4/2).

7. Switch on the terminal (↬ *Chapter 5.1 'Switching the terminal on and off' on page 26*).

⇨ The terminal is ready for use if it switches on and a network connection is present.

5 Operation

5.1 Switching the terminal on and off

Personnel:
- Medical specialists
- Service personnel

The terminal has an on/off switch on the underside of the housing.

To switch the terminal on and off, proceed as follows:

Switching on

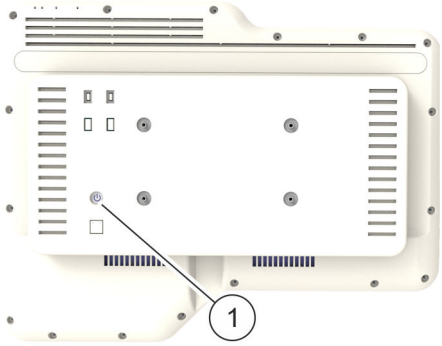


Fig. 5: On/off switch on the terminal

1. Press the on/off switch (Fig. 5/1) to switch the terminal on.
   ⇨ The terminal starts the software. The procedure may take a while.

Switching off

2. **NOTICE!**
   Data loss if device is switched off too soon!

   Make sure that the entries you have made have been saved in the software.
3. Press the on/off switch (Fig. 5/1) to switch the terminal off.
   ⇨ The terminal is switched off.

5.2 Operating the terminal

Personnel:
- Medical specialists
- Service personnel

Requirement:

- You have washed and disinfected your hands before operating the terminal.

You can operate the terminal using the touch screen. You operate the touch screen by touching it with your fingers.

Depending on which version of MonaOS is used, other interactive features may be available.

Observe the MonaOS software manual.

To operate the terminal from the touch screen, proceed as follows:

Selecting screen elements

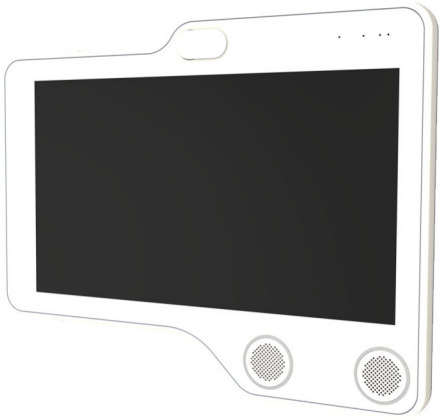


Fig. 6: Terminal with touch screen

1. To select the buttons, menus, symbols and input fields displayed on the touch screen and to operate the on-screen keyboard, tap the corresponding area on the touch screen.

Moving the screen display

2. To move the displayed area of the screen, tap and hold a scroll bar and slide it in the desired direction with your finger (horizontally or vertically, depending on the scroll bar).

> *Scroll bars are displayed when the screen elements do not all fit on the displayed area of the screen.*
>
> *Observe the MonaOS software manual.*

5.3 Cleaning and disinfecting the terminal

Personnel:	■ Service personnel
Protective equipment:	■ Disposable gloves
Material:	■ Disposable disinfectant wipes ■ Surface disinfectant

> **NOTICE!**
>
> **Damage to the terminal if disinfectant penetrates it!**
>
> Liquid disinfectant can enter the terminal through slots and openings in the housing and cause damage.
>
> – When disinfecting the terminal, use only surface disinfection, not spray disinfection.
> – When disinfecting the terminal, make sure that liquid disinfectant does not leak into the terminal through slots and openings.

The terminal has to be cleaned and disinfected at least once a day and in accordance with the locally applicable requirements.

1. Soak an unused disinfectant wipe in surface disinfectant.
2. Disinfect the entire surface of the terminal with the disinfectant wipe. Take particular care when wiping the touch screen.

Where applicable, observe the locally valid requirements for the disinfection method.

3. Dispose of the used disinfectant wipe.

⇨ The terminal is cleaned and disinfected.

6 Maintenance

If used as intended, the terminal is largely maintenance-free.

The terminal service has to be cleaned at regular intervals and disinfected in accordance with local specifications.

Interval	Maintenance work	Personnel
Daily or, depending on local specifications, multiple times per day	Disinfect the terminal ↳ *Chapter 5.3 'Cleaning and disinfecting the terminal' on page 27*	Medical specialists Service personnel
Monthly	Check the power supply cable for damage and replace if necessary	Service personnel

7 Malfunctions

7.1 List of possible malfunctions

For software-related error messages, also consult the software manual.

Fault description	Cause	Remedy	Personnel
The terminal does not switch on.	Power supply cable not plugged in or defective.	Check the power supply cable and replace if necessary.	Service personnel
The terminal does not start correctly.	Network cable not plugged in or defective.	Check the network cable and replace if necessary.	Service personnel
	General network error.	Check the building's network connection and network connectivity.	Service personnel
The terminal is not detecting any RFID tags.	System fault.	Reset the terminal ↳ *Chapter 7.2 'Rectifying system faults' on page 31*.	Medical specialists Service personnel
	RFID tag defective.	Check the RFID tag on another terminal and replace if necessary.	Medical specialists Service personnel
	Terminal is defective.	Have the terminal checked by Clinomic customer service.	Service personnel
The terminal is unable to establish a video connection.	System fault.	Reset the terminal ↳ *Chapter 7.2 'Rectifying system faults' on page 31*.	Medical specialists Service personnel
	Mobile network or internet connection not available.	Check mobile network availability and internet connection.	Service personnel
	Terminal is defective.	Have the terminal checked by Clinomic customer service.	Service personnel
The microphone or the terminal's audio playback is not working.	System fault.	Reset the terminal ↳ *Chapter 7.2 'Rectifying system faults' on page 31*. If the problem persists, briefly disconnect the mains plug from the mains and then reinsert it.	Medical specialists Service personnel
	Terminal is defective.	Have the terminal checked by Clinomic customer service.	Service personnel

Fault description	Cause	Remedy	Personnel
The terminal is unable to connect to other devices.	Device incompatible or defective.	Check the device's function and the compatibility of the communication interface ↳ *Chapter 8.4 'Module specifications' on page 35*.	Service personnel
	Device authentication failed.	Repeat the login procedure.	Service personnel
	System fault.	Reset the terminal ↳ *Chapter 7.2 'Rectifying system faults' on page 31*.	Medical specialists Service personnel
	Terminal is defective.	Have the terminal checked by Clinomic customer service.	Service personnel
The terminal does not react to operator inputs.	System fault.	Reset the terminal ↳ *Chapter 7.2 'Rectifying system faults' on page 31*.	Medical specialists Service personnel
	Terminal is defective.	Have the terminal checked by Clinomic customer service.	Service personnel

7.2 Rectifying system faults

Personnel:
- Medical specialists
- Service personnel

If a system fault is displayed on the terminal or the terminal no longer reacts to operator input, it may be necessary to restart the terminal.

To restart the terminal, proceed as follows:

1.

NOTICE!
Data loss due to unnecessary restarting of the terminal!

Make sure that the fault is not caused by incorrect operation of the software (e.g. dialogue not confirmed, user is not authorised for the function in question).

Consult the MonaOS software manual for information on incorrect operation.

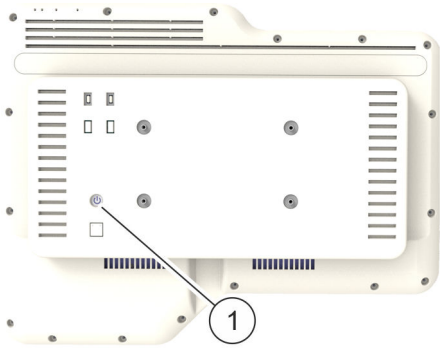


Fig. 7: On/off switch on the terminal

2. If there is genuinely a system error, switch the terminal off and on again using the on/off switch on the back of the terminal (Fig. 7/1).

⇨ The terminal is restarted. The procedure may take a while.

If the fault persists, inform IT administration and, if necessary, contact Clinomic customer service.

8 Technical specifications

8.1 Information on the type plate

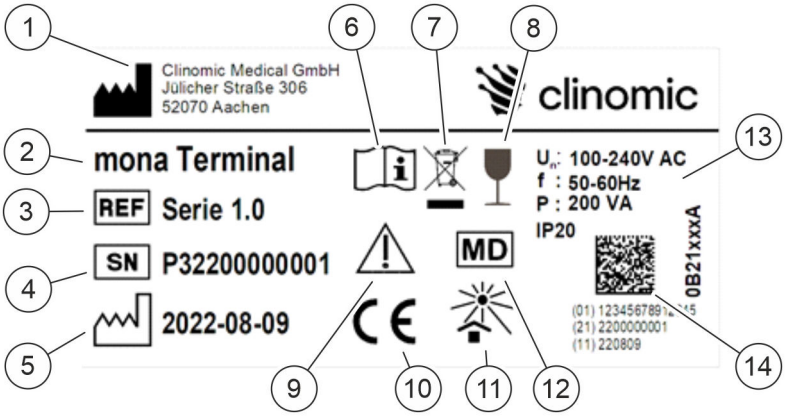


Fig. 8: Type plate example

The type plate is located on the back of the terminal and it contains the following information.

1	Manufacturer of the medical device, with address
2	Name of the medical device
3	Manufacturer’s catalogue number
4	Serial number of the medical device
5	Date of production for the medical device
6	Read the instruction manual before use
7	Do not dispose of electrical equipment in domestic waste
8	Device is fragile; handle with care
9	Observe the safety information in the instruction manual when handling the device
10	CE conformity
11	Protect from direct sunlight
12	Medical Device marking
13	Connected loads and degree of protection (see *Chapter 8.7 ‘Performance data’ on page 37*) ■ U_N: operating voltage ■ f: mains frequency ■ P: Performance ■ IP: Degree of protection
14	QR code UDI

8.2 Additional symbols

Observe instruction manual

This marking indicates that the notes and information in the instruction manual are important for persons handling the *Mona* terminal and must be observed.

8.3 Device classification

Classification	Category
Conformity	Directive 2014/53/EU (Radio Equipment Directive – RED)
	IEC 60601-1-2:2014/ AMD1:2020
Device class (CISPR 11) acc. to IEC 60601-1-2:2014/ AMD1:2020	Class B (Group 1)
Device class (CISPR 14-1) acc. to IEC 60601-1-2:2014/ AMD1:2020	Not applicable
Device class (CISPR 32) acc. to IEC 60601-1-2:2014/ AMD1:2020	Class B (Group 1)
Key characteristics acc. to IEC 60601-1-2:2014/AMD1:2020	None, as failure does not cause unacceptable risks for the patient, user or third parties.
Device for use exclusively in specially screened environments acc. to IEC 60601-1-2:2014/AMD1:2020	Not applicable
Fixed large device acc. to IEC 60601-1-2:2014/AMD1:2020	Not applicable
Device compatibility with HF surgical equipment acc. to IEC 60601-1-2:2014/AMD1:2020	Not applicable

8.4 Module specifications

For more information on the module specifications, contact Clinomic directly.

Intel Wireless-AC 9260 (Wireless WiFi Bluetooth adapter)

Specification	Value
Supported frequencies	2.4 G (2.4 GHz – 2.4835 GHz), 5G (5 GHz – 5.825 GHz)
Transmission power	20 dBm (2400 – 2485 MHz) IEEE 802.11 b/g/n & BT 10 dBm (2400 – 2485 MHz) BLE 23 dBm (5150 – 5725 MHz) IEEE 802.11 a/n/ac 13.98 dBm (5725 – 5875 MHz) IEEE 802.11 a/n/ac
Rate of transmission	1.73 Gbps
WLAN standard	IEEE 802.11a/b/g/n/ac
Bluetooth standard	Bluetooth 5.1

ELATEC TWN4 MultiTech 3 M LF T430-F4C0 (RFID chip reader)

Specification	Value
RFID technologies	125 kHz
Transmission power	55.79 dBµA/m at 10 m
Supported standards	ICT, IDTECK, Isonas, Keri, Miro, Nedap, PAC, Pyramid, Q5, T5557, T5567, T5577, TIRIS/HDX, TITAN (EM4050), UNIQUE, ZODIAC, Cotag, G-Prox2

Quectel RM500Q (5G module)

Frequency	Frequency range
5G-NR	n1/n2/n3/n5/n7/n8/n12/n20/n25/n28/n38/n40/ n41/n48/ n66/n71/n77/n78/n79
LTE-FDD	B1/B2/B3/B4/B5/B7/B8/B9/B12/B13/B14/B17/ B18/B19/B20/B25/B26/B28/B29/B30/B32/B66 /B71
LTE-TDD	B34/B38/39/B40/B41/B42/B43/B48

Frequency	Frequency range
LAA	B46 (only supports 2 x 2 MIMO)
WCDMA	B1/B2/B3/B4/B5/B6/B8/B19

Frequency	Transmission power
5G-NR	23 dBm ± 2 dB
LTE-FDD	23 dBm ± 2 dB
LTE-TDD	23 dBm ± 2 dB, 26 dBm ± 2 dB for B38/B40/B41/B42
LAA	-
WCDMA	24 dBm +1/-3 dB

Data transmission	Speed
5G SA Sub-6	DL 2.1 Gbps; UL 450 Mbps
5G NSA Sub-6	DL 2.5 Gbps; UL 600 Mbps
LTE	DL 1.0 Gbps; UL 200 Mbps
WCDMA	DL 42 Mbps; UL 5.76 Mbps

Infineon BGT 60 TR 13 C (radar)

Specification	Value
Power consumption	200 mA
FoV	90 °
Frequency range	58 GHz min., 63.5 GHz max.
Transmission power	8.03 dBm
Gain	5 dBi
Max. detection	15 m (from the front)
Number of Rx antennas	3
Number of Bx antennas	1
Qualification/ standard	JEDEC 20/22
Supply voltage	1.8 V
Temperature range	-20 °C to +70 °C

8.5 Accessories

Designation	Version
Distributor block in wall mounting	WAGO 261-103
Distributor block in monitor bracket MC-1	WAGO 261-103
Power supply cable (on wall)	Shock-proof plug (CEE 7/7) > C13 low-heat device connection acc. to IEC-60320-C13 Cable type: H05VV-F3G 0.75 mm² Cable length: 3 m
Power supply cable (on *Mona*)	C13 low-heat device connection acc. to IEC-60320-C13, angled Cable length: 0.5 m
Network cable	Patch cable acc. to TIA-568A Plug: 2 x RJ45
SKYDOQ spring arm or fastening system	Standard version
Adapter plate	VESA

8.6 Dimensions and weight

Data	Value	Unit
Dimensions, approx. (L x W x H)	628 x 490 x 105	mm
Weight, approx.	17	kg

8.7 Performance data

Data	Value	Unit
operating voltage	100 – 240	VAC
mains frequency	50 – 60	Hz
Performance	200	VA
Protection class	1	
Degree of protection	IP20	

8.8 External connection

Connection	Type
USB	2x type A, 2x type C
Ethernet	RJ45
Low-heat device connection	IEC-60320-C13

The USB ports are intended solely for use with USB flash drives.

The building's mains connection must have a 4 kV isolation barrier (network isolator).

8.9 Requirements for the ambient conditions

Specification	Value	Unit
Ambient temperature during operation	+10 – +40	°C
Air pressure during operation	795 – 1060	hPa
Relative humidity during operation RH	15 – 80	%

Only use the Mona terminal in environments that meet the following environmental criteria:

Environmental criterion	Requirement
Surrounding area	Intensive care unit or similar environment
Lighting	Well illuminated
Ambient noise	Quiet, apart from acoustic signals from other devices
Climate	Only air-conditioned rooms/ wards
Working environment and social field of interaction	Low visitor traffic and little communication
Devices in the operating environment that are used together with the terminal	Devices that communicate with the terminal to exchange data

Environmental criterion	Requirement
Furnishings	Typical for an intensive care unit or similar environment
Disruptive factors	Exclusively acoustic alarm signals from other devices

8.10 EMC and requirements from the electrical standards

8.10.1 Electromagnetic compatibility (EMC) requirements

Notes

NOTICE!
This device is not a life-saving or life-supporting device. There are no key characteristics relating to IEC 60601-1-2:2014/AMD1:2020, as failure does not cause unacceptable risks for the patient, user or third parties.

NOTICE!
The device may be operated only in the ambient conditions of intensive care units or similar environments.

NOTICE!
The device must not be operated near high-frequency surgical devices or in MRT device rooms that are shielded against radio frequencies. Otherwise, malfunctions and device damage could result.

8.10.2 Electromagnetic immunity

Information and manufacturer's declaration – emitted electromagnetic interference

This device is intended for use in the electromagnetic environment described below. The customer or user of this device must ensure that the device is used in the environment described.

Testing the emitted interference	Conformity	Electromagnetic environment – guidelines
HF emissions	CISPR 11, class B, group 1	This device uses HF energy exclusively for its internal functions. Its HF emissions are therefore very low and it is unlikely that adjacent electronic equipment will experience interference. The device can be used in health care environments (e.g. hospitals, medical practices) that have a separate power supply.
Harmonics IEC 61000-3-2	Not applicable	
Voltage fluctuation (flicker) IEC 61000-3-3	Not applicable	

The key characteristics of the device were not impaired by electromagnetic interference under test conditions.

Housing

Testing the immunity	IEC 60601-1-2:2014/ AMD1:2020 test level	Con-formity	Electromagnetic environment – guidelines
Static electrical discharge IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	Yes	The supporting surface should be made of wood, concrete or ceramic tiles. If the supporting surface is made of synthetic material, the relative humidity should be at least 30%.
Radiated HF disturbance variables acc. to IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz	Yes	The field strengths of stationary HF transmitters, according to the electromagnetic site investigation **a**, should be less than the conformity value in the individual frequency ranges **b**. Interference can occur in the vicinity of devices that are marked with the following symbol:.
Near fields of wireless communication devices acc. to IEC 61000-4-3	9 – 28 V/m 385 – 5785 MHz	Yes	
Magnetic field at the mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m X and Y direction	Yes	Magnetic fields at the mains frequency should exhibit levels that are typical for applications in a commercial or hospital environment.
Magnetic field immunity IEC 61000-4-39	30 kHz, 8A/m 134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m	Yes	The magnetic fields in the vicinity of the device should exhibit levels that are typical for applications in a commercial or hospital environment.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection on surfaces, objects and persons.

a: The field strengths of stationary transmitters, e.g. base stations for wireless telephones (mobile/cordless) and land mobile radio installations, as well as transmitting equipment for amateur radio, MW and VHF radio transmission and TV transmission cannot be precisely forecast on a theoretical basis. In order to appraise the electromagnetic environment due to stationary HF transmitters, an electromagnetic site investigation should be considered. If the measured field strength at the site where the product is to be used exceeds the relevant HF conformity value specified above, the unit should be monitored to check normal operation. If abnormal performance is identified, further measures may be necessary, e.g. realigning or moving the product.

b: In the frequency range of 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

AC connection

Testing the immunity	IEC 60601-1-2:2014/ AMD1:2020 test level	Conformity	Electromagnetic environment – guidelines
Quick, electrical transients/signal sequences IEC 61000-4-4	± 2 kV (earth) 100 kHz repetition	Yes	
Voltage impulses/surges IEC 61000-4-5	± 0.5 kV, ± 1 kV (conductor – conductor, differential mode) ± 0.5 kV, ± 1 kV, ± 2 kV (conductor – earth, common mode)	Yes	The quality of the power supply must correspond to that of a typical commercial or hospital environment.
Conducted HF disturbance variables acc. to IEC 61000-4-6	3 V/6 V RMS 150 kHz to 80 MHz 80% AM at 1 kHz	Yes	Portable and mobile radio equipment should not be used at a distance to the product (including its wires) of less than the recommended safety distance resulting from the transmission-frequency-specific equation. Recommended safety distance: ■ d = 1.2 √P ■ d = 1.2 √P, 80 MHz to 800 MHz ■ d = 2.3 √P, 800 MHz to 2.7 GHz
Voltage drops, short interruptions and voltage fluctuations in the power supply lines IEC 61000-4-11 Only devices with plug-in power supplies with DC voltage transformation	0% UT: ½ period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT: 1 period at 0 degrees 70% UT: 25/30 periods at 0 degrees 0% UT: 250/300 periods at 0 degrees	Yes	The quality of the power supply should correspond to that of a typical commercial or hospital environment. If the device needs to remain in continuous operation even in the event of interruptions to the power supply, it should be connected to an uninterruptible power supply.

Note 1: UT is the mains AC voltage before applying the test level.

Note 2: 6 V for ISM band.

Signal lines

Testing the immunity	IEC 60601-1-2:2014/ AMD1:2020 test level	Con-formity	Electromagnetic environment – guidelines
Quick, electrical transients/signal sequences IEC 61000-4-4	± 1 kV at 50 Ω 100 kHz repetition	Yes	
Conducted HF disturbance variables acc. to IEC 61000-4-6	3 V/6 V RMS 150 kHz to 80 MHz 80% AM at 1 kHz	Yes	Portable and mobile radio equipment should not be used at a distance to the product (including its wires) of less than the recommended safety distance resulting from the transmission-frequency-specific equation. Recommended safety distance: ■ d = 1.2 √P ■ d = 1.2 √P, 80 MHz to 800 MHz ■ d = 2.3 √P, 800 MHz to 2.7 GHz

Note: 6 V for ISM band.

8.10.3 Recommended safety distances

Comply with the recommended safety distances between portable and mobile HF telecommunications devices (e.g. mobile phones) and the product, which is not life-sustaining.

The product is intended for operation in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the product can help prevent electromagnetic disturbances by complying with the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the product – depending on the rated output of the communication device, as specified below.

Rated output of transmitter (W)	Safety distance, depending on the transmission frequency		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.7 GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum rated output that is not included in the table above, you can calculate the recommended safety distance d in metres (m) by applying the equation from the corresponding column, where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer's specifications, and d is the recommended separating distance in metres (m).

Notes: At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply to all cases. The propagation of electromagnetic variables is affected by absorption and reflections on buildings, objects and people.

Test specifications for immunity of the housing interface against wireless HF communications devices

Test frequency (MHz)	Band[a] (MHz)	Service[b]	Modulation[b]	Max. output (W)	Distance (m)	Immunity test level (V/m)
385	380 – 390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	3	27
450	430 – 470	GMRS 460 FRS 460	Fm[c] ± 5 kHz Deviation 1 kHz sine	2	3	28
710 745 780	704 – 787	LTE bands 13, 17	Pulse modulation[b] 18 Hz	0.2	3	9
810 870 930	800 – 960	GSM 800 /900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	Pulse modulation[b] 217 Hz	2	3	28
1720 1845 1970	1700 – 1990	GSM 1800 GSM 1900 CDMA 1900, DECT LTE bands 1, 3, 4, 25, UMTS	Pulse modulation[b] 217 Hz	2	3	28

Test frequency (MHz)	Band[a] (MHz)	Service[b]	Modulation[b]	Max. output (W)	Distance (m)	Immunity test level (V/m)
2450	2400 – 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation[b] 217 Hz	2	3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	3	9
5500						
5785						

Note: To achieve the immunity test level, the distance between the transmitting aerial and the ME device or ME system can be reduced to 1 m, if necessary. The test distance of 1 m is permitted in accordance with IEC 61000-4-3.

[a] Some services only include uplink frequencies.

[b] The carrier should be modulated with a square wave signal and a duty factor of 50%.

[c] As an alternative to frequency modulation, a 50% pulse modulation at 18 Hz may be used. As this pulse modulation does not correspond to the current modulation, this would be the worst case.

9 Disposal

Inadequate disinfection

WARNING!

Risk of infection and risk of contaminating the environment!

If the *Mona* terminal is not suitably cleaned and disinfected before disposal, there is a risk of infection and a risk of contaminating the environment.

– Clean and disinfect the *Mona* terminal in line with local regulations before disposing of it.

ENVIRONMENT!

Danger to the environment due to improper disposal!

Improper disposal can result in hazards to the environment.

– Comply with local regulations on disposal.
– Have electronic scrap and electronic components disposed of by authorised specialists.
– If in doubt, seek advice on environmentally sound disposal from your local authorities or specialist disposal companies.

Disposal

Once the terminal has reached the end of its service life, it must be sent for environmentally sound disposal.

Before disposing of the terminal, clean and disinfect the device in line with the local guidelines of the hospital.

Please contact Support at Clinomic for information on disposal of the device (support@clinomic.ai).

Do not dispose of the device in domestic waste.

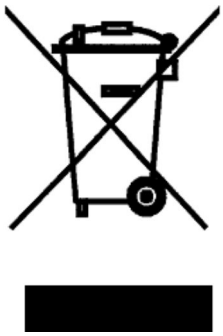


Fig. 9: Not domestic waste

Data deletion

The *Mona* terminal does not store any data locally, so no additional deletion is required.

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Appendix

A Declaration of conformity

Manufacturer	Clinomic Medical GmbH
Address	Clinomic Medical GmbH Jülicher Straße 306 52070 Aachen
Product and version	Mona Terminal 2.0
EU Directives and Regulations	■ Regulation 2017/745 EU of the European Parliament and of the Council (MDR) ■ Directive 2014/53/EU of the European Parliament and of the Council (RED) ■ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

We, the manufacturer, Clinomic Medical GmbH, declare under our sole responsibility that the Mona Terminal Version 2.0 is in conformity with the fundamental requirements and other applicable provisions of the above-mentioned EU Directives and Regulations.

This is an abbreviated version of the declaration of conformity.

For the full version, go to: www.clinomic.ai/ifu