rein medical

Manual
Rein Medical CLINIO® 432DCUH

Item/model number : C432DCUH , C432DCUHT C432DCUH-xxx, C432DCUHT-xxx

Regulation model ID [REG]: VM32CUH.0

CE

Document item number: MC432DCUH -EN , Revision: 2024-6-12

Contents

About this document

This section explains the purpose and content of this document.

In order to improve readability, the use of gender forms is omitted. Any references to a person or persons apply equally to all genders.

Your new device

The CLINIO® is a medical video monitor for medical use in hygienically sensitive areas. The high-resolution LCD monitor offers enough space to display RIS, HIS and PACS data, and it is also suitable for typical office work requiring a monitor. The device offers the option of connecting digital and analogue PC signals or conventional video signals.

Thanks to the VESA mounting equipment, you can install the CLINIO® in customised mounting solutions, such as wall constructions, ceiling mounts or on mobile workstations.

Target group

This document is designed for:

- individuals operating the device,
- the technicians responsible for assembly and maintenance,
- the administrators who configure the device and connected systems,
- the operating staff who work with the device every day,
- the cleaning staff responsible for cleaning and disinfecting the device.

Storing the accompanying documents

The accompanying documents are an important part of the product. Please take note of the following tips:

- Always keep them near the device.
- If the operator should change, make sure that this person receives these documents together with the product.
- Order replacement documentation (due to loss, etc) from Rein Medical.

In this way you can minimise risks due to ignorance and careless action.

Important symbols and pictograms

The following table lists the symbols and pictograms used in the user manual and as labels on the device.

Table 1: Safety-related symbols

	General safety hazard; carefully read accompanying documentation before use.		Please note additional information
	Safety hazard due to electric voltage		Please note the additional information in the user manual

Table 2: Symbols for formal device properties

SN Serial number	REG Regulation model ID: Designation of the regulatory basis for this product
MD Medical device	UDI Internationally unique device identification number (UDI number)
Production date	REF Reference number/item number
Manufacturer information	

Table 3: Symbols related to electrical properties

AC power source	Additional potential equalization connection
Electromagnetic interference may occur in the vicinity of this device.	
Power supply and current/power consumption specifications	

Table 4: Market-specific symbols

CH REP Authorized Swiss representative	

Table 5: Symbols on the packaging

60° C -10° C Permissible temperature range for storage.	Fragile!
1013 hPa 266 hPa Permissible air pressure range for storage.	Keep dry!
85% 10% Permissible air humidity range for storage.	This side up!
Do not stack other boxes on top of this box!	Use scissors!
Do not tilt or flip the box!	Packaging made from recycled material.

Table 6: Symbols on the control panel

An explanation of the symbols for the controls can be found in Operating the device on page 29.

DANGER: This keyword describes a potentially life-threatening situation that carries a high risk of immediate severe, irreversible injury or death if instructions are ignored.

WARNING: This keyword describes a potentially life-threatening situation that can lead immediately to injury or death if instructions are ignored.

CAUTION: This keyword describes a situation that can lead to injuries if instructions are ignored.

NOTICE: This keyword identifies tips that prevent device damage or data loss.

NOTE: This key word identifies other useful tips and recommendations.

Contents of this document

This user manual provides technicians and users with all information required for the installation, safe operation, and maintenance of the CLINIO® device.

The document is organised in chronological order from installation to maintenance and servicing. Use the table of contents to look for specific information.

We create our products – as well as this manual – in accordance with the highest standards.
Help us maintain this level of high quality by sharing your experiences and suggestions by e-mail: info@reinmedical.com. In this way, you help us to fine-tune future products even more precisely to your individual needs.

Using the device safely

This chapter contains information on how to use the CLINIO® device safely.

Read the chapter carefully before commencing any work with the device.

Purpose

This video monitor is an accessory for general and specific connection to medical information and imaging systems such as RIS, HIS, PACS, PDMS, or OR image management and is intended for use in displaying data from such systems.

Proper use

The CLINIO® product was developed for use in medical environments. Please note the following provisions before you use the device for the first time.

The device may only be used in a medical environment if compliance with the specified connection settings and parameters is ensured.

Modifications to the device are not allowed without specific authorisation by Rein Medical. Any damage resulting from such modifications is not the responsibility of the manufacturer.

Enclosure and environment

The CLINIO® systems are designed specifically for the stringent cleaning requirements of hygienically sensitive areas in the surgical environment.

The device must not be used in potentially explosive environments.

The device should only be operated and stored in rooms protected from the weather.

Installation

The device must only be installed and commissioned by qualified technicians.

The CLINIO® provides a VESA mounting option (VESA 100). This interface allows you to implement your customised mounting solution. You can also purchase different mounting systems directly from Rein Medical.

The holder must be adapted to the CLINIO® and ensure a load capacity that corresponds to a weight 2.5 times that of the product (see specifications).

The power cable or the optional external power supply unit is the power switch. The device must be installed in such a way that it can be disconnected from the power supply at any time.

Operation

The device may only be operated by medical staff that have been trained on device requirements. Users must carefully read the user manual and be familiar with how the device functions.

The optional touch control system allows optimum direct and ergonomic control of the PC application connected to the CLINIO®.

All device settings can be configured using the touch control buttons (COMMAND BAR) integrated in the glass screen. The COMMAND BAR allows the device surface to be easily cleaned and disinfected.

You can configure and operate the OSD menu of the CLINIO® via a control system connected to the GPIO interface.

The power plug (the optional external power supply unit) is the on-off-switch. To disconnect the device from the power supply, remove the mains plug from the socket.

Display

The modern, high-resolution LCD display produces high-quality images without geometric distortion.

The monitor is not suitable for primary diagnostics. Use the device exclusively for viewing images that have already been evaluated.

The monitor has a DICOM preset that is pre-programmed at the factory. This preset controls the progression of brightness gradations over a characteristic curve, thereby guaranteeing a greyscale display that meets the DICOM standard. The DICOM display is calibrated at the factory.

The monitor features presets for true-colour display calibrated at the factory in accordance with the BT709 and BT1886 colour space standards.

Over the course of the device's operating life, unavoidable changes in the backlight can distort the standardised image. In order to guarantee the display complies with DICOM over longer periods of time, regular recalibrations are required.

Combining devices

The device is intended to be connected to medical systems. For this purpose, the device has standardised video and data interfaces. The medical system and connected devices must comply with the requirements of IEC 60601-1 and provide two protective measures for operator protection (2 x MOOP).

This device must not be used to control life-sustaining and life-support systems.

This device must not be used in connection with alarm systems.

This device must not be used as a primary monitor in medical imaging systems.

The CLINIO® has been tested according to the safety requirements for medical electrical devices (IEC 60601-1) for use in the patient environment and other rooms used for medical purposes, and features an additional, central connection for electrical potential equalisation.

Recognising other dangers

Our products are developed and produced in accordance with the highest safety requirements. Even the best possible technology and professional implementation, however, cannot exclude the risk of danger. Therefore, please read the safety provisions in this section carefully before you set up the device and begin using it.

Danger due to electric voltage

Contact with electrical voltage! Risk of life-threatening injury if working on an opened device. Damage to device possible.	The enclosure should only be opened by authorised Rein Medical technicians. First unplug the device from the power supply, and then open the housing.
An inappropriate power cable can lead to malfunctions and short circuiting.	Only use the power cable delivered with the device or an equivalent earthed cable that conforms to DIN 49547 and IEC 320 standards (max. length: 3 m, for example: H05VV-F, 3 x 1.0 mm²). Furthermore, please be aware of the national safety regulations for electrical devices in your country. Contact your medical device consultant before exchanging a power cable.

Device failure due to broken cable

During assembly pay attention to the specifications of IEC 60364-7-710.

The power cable may only be connected by a trained professional using the appropriate and functional tools and testing equipment. Make sure the cable is placed cleanly such that it does not bend or get stuck or crushed.

Short circuit due to moisture in the enclosure. Moisture can penetrate the interior of the device due to weather influences or if cleaned incorrectly.

- Do not clean the device with high-pressure or steam jets.
- Do not submerse the device in liquids.
- Only use the device in a weatherproof inside area in accordance with the environmental conditions defined in Table 12: Environmental conditions during operation on page 14.

Danger of damaging device

Danger of injury and reading errors if display is damaged! A damaged display can cause serious injuries and malfunctions in operation.

- Immediately replace a damaged or broken display. Contact your Rein Medical consultant.
- Avoid contact with any liquids emanating from the display. Minor skin and eye irritation may result. Immediately rinse any affected body parts with water.

Danger of leakage

IP protection is voided by opening the enclosure!

After opening the device, the seal must be checked and the required tightness verified once again.

Danger caused by incorrect operation

Image errors caused by still images displayed for long periods of time! Still images shown over several hours can cause a permanent polarisation of the crystals (memory effect).

- Do not display still images for several hours. Use a screen saver.
- If a memory effect becomes noticeable, turn the CLINIO® off for several days. As an alternative, creating image noise or quickly moving images can reduce the memory effect.

Memory effects are not defects and are not covered by the warranty.

Display and reading errors resulting from improper handling. Improperly operating the CLINIO® causes damage to the surface of the display.

- Put away all hard or sharp objects (jewellery, tools, etc.) before using the device
- Operate the CLINIO® with your hands only.

Electromagnetic compatibility

The device complies with the electromagnetic compatibility (EMC) requirements for medical devices according to EN/IEC 60601-1-2.

EMC Class B in accordance with EN IEC 55032 Class B (with built-in IOI signal decoder option, the product meets the requirements of class A), IEC/CISPR 32.

This product offers the necessary protection from electromagnetic interference and installations in residential areas.

The electronic components create, use and emit high-frequency energy. If the device is installed and used incorrectly, it may result in interference around the area of the device. For technical reasons it is possible that certain installations may experience interference. We recommend taking the following measures if radio or television interference occurs (noticeable when switching the device on and off) when using the device:

- adjust or move receiving antennas,
- increase the distance between the receiver and the device,
- connect the receiver to a circuit different from that to which this device is connected (CLINIO®),
- contact your dealer or service partner for support.

Changes and modifications to the device, which are not specifically indicated by Rein Medical, will lead to the termination of the authority to operate the device.

NOTE: Electromagnetic interference. Unsuitable cables jeopardise the operational reliability of the device.

Electromagnetic environment

The device (CLINIO®) is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Table 7: Electromagnetic emission

Emission	Application	Electromagnetic environment – guidelines
RF emissions under EN IEC 55032 Class B (with built-in IOI signal decoder option, the product meets the requirements of class A), IEC/ CISPR 32	all	This device (CLINIO®) uses RF energy for its internal functions only. Its RF emissions are therefore very low and interference with nearby electronic devices is unlikely.
RF emissions under EN IEC 55032 Class B (with built-in IOI signal decoder option, the product meets the requirements of class A), IEC/ CISPR 32	Class B	This device (CLINIO®) is for use in all establishments, including domestic establishments and those that are directly connected to a public supply network that also supplies buildings used for residential purposes.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000 -3-3	d, max	

For transmitters with a power rating not specified in the above table, the distance can be determined using the equation found in the relevant column, where P is the power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Table 8: Guidelines and manufacturer's declaration 211; electromagnetic immunity

Immunity test	Test specification	Compliance level	electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact, ±15 kV air	±8 kV contact, ±15 kV air	Floors should be wood, concrete, tile or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient (Burst) for power supply cable (AC) IEC 61000-4-4	±2 kV, 100 kHz	±2 kV, 100 kHz	Supply voltage quality should correspond to that of a typical commercial or hospital environment.

Immunity test	Test specification	Compliance level	electromagnetic environment
Electrical fast transient (Burst) for signaling cables IEC 61000-4-4	±1 kV, 100 kHz	±1 kV, 100 kHz	
Voltage surge (Surge) for power supply cable (AC) IEC 61000-4-5	±1 kV (symmetrical), ±2 kV (asymmetrical)	±1 kV (symmetrical), ±2 kV (asymmetrical)	Supply voltage quality should correspond to that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations (Dips and Interupts) on the power supply cables (AC) IEC 61000-4-11	230 V / 50 Hz and 100 V / 50 Hz	230 V / 50 Hz and 100 V / 50 Hz	Supply voltage quality should correspond to that of a typical commercial or hospital environment. If the user of the CLINIO® system requires the system to function continuously even in the event of interruptions in the power supply, it is recommended that the equipment be powered by an uninterruptible power supply or a battery.
Magnetic field at supply frequency on enclosure and lines IEC 61000-4-8	30 A/m, 50 / 60 Hz	30 A/m, 50 / 60 Hz	The line-frequency magnetic fields should correspond to the characteristics of a typical site in a commercial or clinical setting.

Immunity test	Test specification	Compliance level	electromagnetic environment
Conducted RF at the power supply cable (AC) and signaling cables IEC 61000-4-6	0.15... 80 MHz 6 V, 80% AM (1 kHz)	0.15... 80 MHz 6 V, 80% AM (1 kHz)	Portable and mobile RF communications equipment should not be used closer to the device and its cables than the recommended separation distances calculated by the equation applied to the frequency of the transmitter. Recommended distance: $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where ‘P’ is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer and ‘d’ is the recommended distance in meters (m). Field strength from fixed RF transmitters is under the compliance level ‘b’ at all frequencies according to an investigation at site ‘a’. Interference may occur in the proximity of equipment marked with the following symbol 
Radiated RF IEC 61000-4-3 on enclosure and connected cables	80 to 1000 MHz 10 V/m, 80% AM 1.0 to 2.7 GHz 10 V/m, 80% AM 0.38 to 5.8 GHz, PM 18 Hz, PM 217 Hz, FM 1 kHz	80 to 1000 MHz 10 V/m, 80% AM 1.0 to 2.7 GHz 10 V/m, 80% AM 0.38 to 5.8 GHz, PM 18 Hz, PM 217 Hz, FM 1 kHz	

NOTE 1: At 80 MHz and 800 MHz, the higher value applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and people.

a) The field strength from fixed transmitters, such as base stations for radio and land mobile radios, amateur radio, AM and FM radio and TV broadcasters cannot in theory be accurately predicted. To assess the electromagnetic environment of fixed RF transmitters, an electromagnetic investigation of the site is recommended. If the field strength measured at the device’s location exceeds the compliance level specified above, the device (CLINIO®) must be observed to verify normal operation at each site of operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the device.

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

Table 9: Guidelines and manufacturer's declaration – electromagnetic immunity

Power rating of transmitter (W)	Distance in meters based on frequency of transmitter	Distance in meters based on frequency of transmitter	Distance in meters based on frequency of transmitter
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	12	2.3
10	3.8	3.8	7.3
100	12	12	23

The CLINIO® device is intended for use in an electromagnetic environment in which radiated RF interference can be monitored. The customer or user of the device can help prevent electromagnetic interference by maintaining compliance with the minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, in accordance with the maximum output power of the communications equipment.

For transmitters with a power rating not specified in the above table, the distance can be determined using the equation found in the relevant column, where P is the power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: To calculate the recommended working clearance of transmitters in the frequency range from 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the likelihood of interference caused by a mobile/portable communication device brought into the patient area unintentionally.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and people.

Technical data

Table 10: General device data

Product description	CLINIO® 432DCUH
Model name (brand name)	CLINIO® 432DCUH
Item/model number	C432DCUH , C432DCUHT C432DCUH-xxx, C432DCUHT-xxx
Regulation model ID [REG]	VM32CUH.0
Basic UDI-DI	406163100000VM32CUH0WV
Type	Video monitor
Type description	Medical monitor for use in patient environments used for medical purposes, such as an operating room
Weight	approx. 13.2 kg without base, with internal power supply (depending on configuration)
Mounting	VESA 100
IP protection type	Optionally prepared for installation with IP 54 or IP 65 protection Front and enclosure sides IP 65 (rear side depends on wall seal)
Controls	COMMAND BAR touch control,
Touch display	Optional capacitive multi-touch display (PCT)
Enclosure color	RAL9010 / pure white (special colors at customer request, see delivery documents)
Mean time between failures (MTBF)	30,000 hours

Table 11: Power consumption

Power supply	AC 100 V-240 V, 50/60 Hz (±10%)
External power supply unit (optional)	External 24 V DC power supply unit (XLR), optional CO50007, SINPRO HPU150A-108, DC24V, 3-pin XLR
Maximum	approx. 140 VA

Table 12: Environmental conditions during operation

Temperature	0° C to 40° C
Humidity	30 % RH to 90 % RH (non-condensing)
Barometric pressure	701 hPa to 1,013 hPa

Table 13: Environmental conditions for storage/transport

Temperature	-10° C to +60° C
Humidity	30 % RH to 90 % RH (non-condensing)
Barometric pressure	266 hPa to 1,013 hPa

Table 14: Display properties

Display size	81 cm (32")
Panel technology	Active Matrix LCD-TFT
Visible area (H x W)	708.48 x 398.52 mm
Pixel pitch (H x W)	0.1845 x 0.1845 mm
Viewing angle (V x H)	178°/178°
Maximum panel brightness	700 cd/m²
Automatic Lumination Stabilisation	ALS (Automatic Luminance Stabilisation) with backlight sensor, factory-calibrated to 350 cd/m² or 300 cd/m² for DICOM preset
Contrast ratio	1350: 1
Response time	10 ms grey-to-grey
Colour range	16.7 million
Colour depth	8 bit
Greyscales	256
Display norm	UHD (2160p)
Resolution (horizontal x vertical)	3840 x 2160
Aspect ratio	16:9
Backlight	LED
Backlight life	30,000 hours
Pixel defect class	Class II (ISO 9241-307)

Table 15: Video controller properties

Signal inputs	VGA, DisplayPort (1.2), DVI-D, HDMI 2.0, optional 3G-SDI input
Signal outputs	-
Video formats of the signal outputs	-
Loop-through outputs (optional)	3G-SDI (optional) (CO90001)
OSD control (remote configuration)	GPIO (9-pin D-Sub), RS232 (9-pin D-Sub)
Functions	Automatic Lumination Stabilization (ALS), picture-in-picture (PIP, POP), factory-calibrated for DICOM, factory-calibrated for BT1886, factory-calibrated for BT709, factory-calibrated for BT2020 (emulated)

Table 16: Video timings

No.	**Pixel format**	**Pixel frequenc**	**Frequency**		**Standard**	**Signal input**					
		CLK (MHz)	**H (Hz)**	**V (Hz)**	**Type**	**DVI-D 1**	**DP 1.2**	**VGA**	**HDMI 2.0**	**DVI 2**	**DVI 2/ SDI**
1	640 x 480	25.175	31.5k	60	VESA	o	o	o	o	o	-
	640 x 480	36	43.3k	80	VESA	o	o	o	o	o	-
2	800 x 600	40	37.9k	60	VESA	o	o	o	o	o	-

No.	Pixel format	Pixel frequenc	Frequency		Standard	Signal input					
		CLK (MHz)	H (Hz)	V (Hz)	Type	DVI-D 1	DP 1.2	VGA	HDMI 2.0	DVI 2	DVI 2/ SDI
	800 x 600	49.5	46.9k	75	VESA	o	o	o	o	o	-
3	1024 x 768	65	48.4k	60	VESA	o	o	o	o	o	-
	1024 x 768	78.75	60k	75	VESA	o	o	o	o	o	-
4	1280 x 1024	108	64k	60	VESA	o	o	o	o	o	-
	1280 x 1024	135	80k	75	VESA	o	o	o	o	o	-
5	1600 x 1200	162	75k	60	VESA	o	o	o	o	o	-
6	1920 x 1080	148.5	67.5k	60	VESA	o	o	o	o	o	-
7	1920 x 1200 (RB)	154	74k	60	VESA	o	o	o	o	-	-
8	3840 x 2160	297	67.5k	30	*1, *2	o	o	-	o	o	-
9	3840 x 2160	594	135k	60	*1, *3	-	o	-	o	-	-
10	3840 x 2160	297	67.5	50	CEA-861	--	o	-	o	-	-
11	720 (1440) x 576i	-	-	50	CEA-861	-	-	-	-	-	o
12	1280 x 720p	-	-	59.94/ 60	CEA-861	o	o	o	o	-	o
13	1280 x 720p	-	-	50	CEA-861	o	o	o	o	-	o
14	1920 x 1080i	-	-	59.94/ 60	CEA-861	o	o	o	o	-	o
15	1920 x 1080i	-	-	50	CEA-861	o	o	o	o	-	o
16	1920 x 1080p	-	-	25	CEA-861	o	o	o	o	-	o
17	1920 x 1080p	-	-	23.98/ 24	CEA-861	o	o	o	o	-	o
18	1920 x 1080p	-	-	30	CEA-861	o	o	o	o	-	o
19	1920 x 1080p	-	-	59.94/ 60	CEA-861	o	o	o	o	-	o
20	1920 x 1080p	-	-	50	CEA-861	o	o	o	o	-	o

***1)** Numbers 8 to 9 depend on graphics card functionality. The specified values were tested and guaranteed using the NVIDIA QUADRO® K2200 graphics card model.

***2)** A single DVI input supports 3840 x 2160 at 30 Hz. Operates with HDMI 1.4 PC outputs via a DVI input.

***3)** A single DisplayPort input supports 3840 x 2160 at 60 Hz.

Table 17: standards and directives

Protection class in accordance with IEC 61140	Class I
EU Conformity	Medical device in accordance with CE (MDR (EU) 2017/745), RoHS-compliant according to CE (2011/65/EU)

UMDNS	Video-Monitor (16-603)
GMDN	Monitor, VDU, colour (36612)
EMDN	Various devices not included in other classes - other (V9099)
Hygienic properties	The device is certified by Prof. R. Mutters, Institute for Medical Microbiology and Hygiene, Philipps-Universität Marburg, Germany. Rein Medical recommends the following or similar disinfectants based on alcohol or quaternary ammonium compounds from the list of disinfectants published by the VAH (Association for Applied Hygiene)/DGKH (German Society for Hospital Hygiene) such as **Terralin liquid®** fast-acting disinfectant (contact time of 30 seconds) or **Terralin protect®** surface disinfectant (contact time of ten minutes).
Product safety	EN 60601-1:2006 + Cor. :2010 + A1:2013, IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012
Electromagnetic compatibility	EN 60601-1-2:2015, IEC 60601-1-2:2014
Immunity	EN IEC 61000-4-2, EN IEC 61000-4-3, EN IEC 61000-4-4, EN IEC 61000-4-5, EN IEC 61000-4-6, EN IEC 61000-4-11
Emission	EN IEC 55032 Class B (with built-in IOI signal decoder option, the product meets the requirements of class A), IEC/CISPR 32, EN IEC 61000-3-2, EN IEC 61000-3-3
Usability	EN IEC 60601-1-6
Risk management	EN ISO 14971
WEEE category	Category 2 (display measuring > 100 cm²)

Table 18: Medical product specifications

Responsible person	+49 (0) 216 1 69 84 0 sibemp@reinmedical.com
Medical device risk class (EU MDR)	Class I according to (EU) 2017/745 Annex VIII Rule 13
Conformity assessment procedure (EU MDR)	Annex II, Annex III, Article 19
Actor ID/single registration number (SRN) (EU-MDR)	DE-MF-000018721
Specific rules according to MedBetreibV (Annex 1/2)	none
In vitro diagnostics	n/a
Applied part in accordance with EN IEC 60601-1	no
Treatment unit/system in accordance with the EU Ordinance on Medical Devices	The device is not a treatment unit/not a system
Device/system collects patient data in accordance with Federal Data Protection Law	no

Use in explosion-proof areas in accordance with the ATEX directive 2014/34/EU	no
STK/MTK in accordance with §6 of the Medical Devices Operator Ordinance (MPBetreibV)	no specific manufacturer specifications
Radiation protection requirements	n/a
Manufacturer induction obligation	None required. See manual. The operator is obliged to provide training to operating staff.

Unpackaging the CLINIO®

Please note the storage conditions in the section Table 13: Environmental conditions for storage/ transport on page 14 if you would like to store the device in its original packaging.

1. Store the cardboard box upright on a stable surface.

   The box must stand up straight and not wobble.
2. Open the top of the box (see the marking on the box).
3. Lift the device, along with its cushioning parts and protective foil, out of the box and place it on a secure surface.

   Only transport the CLINIO® after you have completely removed the packaging.

Keep all of the packaging components for purposes of later transportation and storage.

Installation

In this chapter, you will learn how to set up your device to meet your needs, and how connect it to other devices.

Warnings

Please take note of the following tips.

CAUTION:

Slippery protective cover poses risk of accident!

Devices wrapped in a protective cover could slip during transportation.

Serious injury could result.

– Remove the protective cover before transporting.

- Move the device while it is in its box.

CAUTION:

Risk of accidents caused by fastening elements!

Mounting the CLINIO® requires special fastening elements If the fastening elements are not approved by the building authorities or if they are incorrectly mounted, the CLINIO® may detach from the wall.

Serious injury could result.

- Select approved fastening elements for the backing.

- Use fastening elements that are approved by the building authorities.

NOTICE:

Device malfunction as a result of overheating!

Inadequate air circulation can cause the device to malfunction.

- Pay attention to the cooling function of the enclosure during assembly.

- Operate the CLINIO® without additional coverings on the display (Plexiglas sheet, protective foil and similar).

- Make sure there is adequate air circulation around the device.

- Also note the environmental conditions specified in Table 12: Environmental conditions during operation on page 14.

Assembly

The mounting system on the rear side of the enclosure is compatible with VESA mounting systems (VESA 100). This enables you to mount the device on any wall mount, ceiling mounts or on special mobile PC workstations.

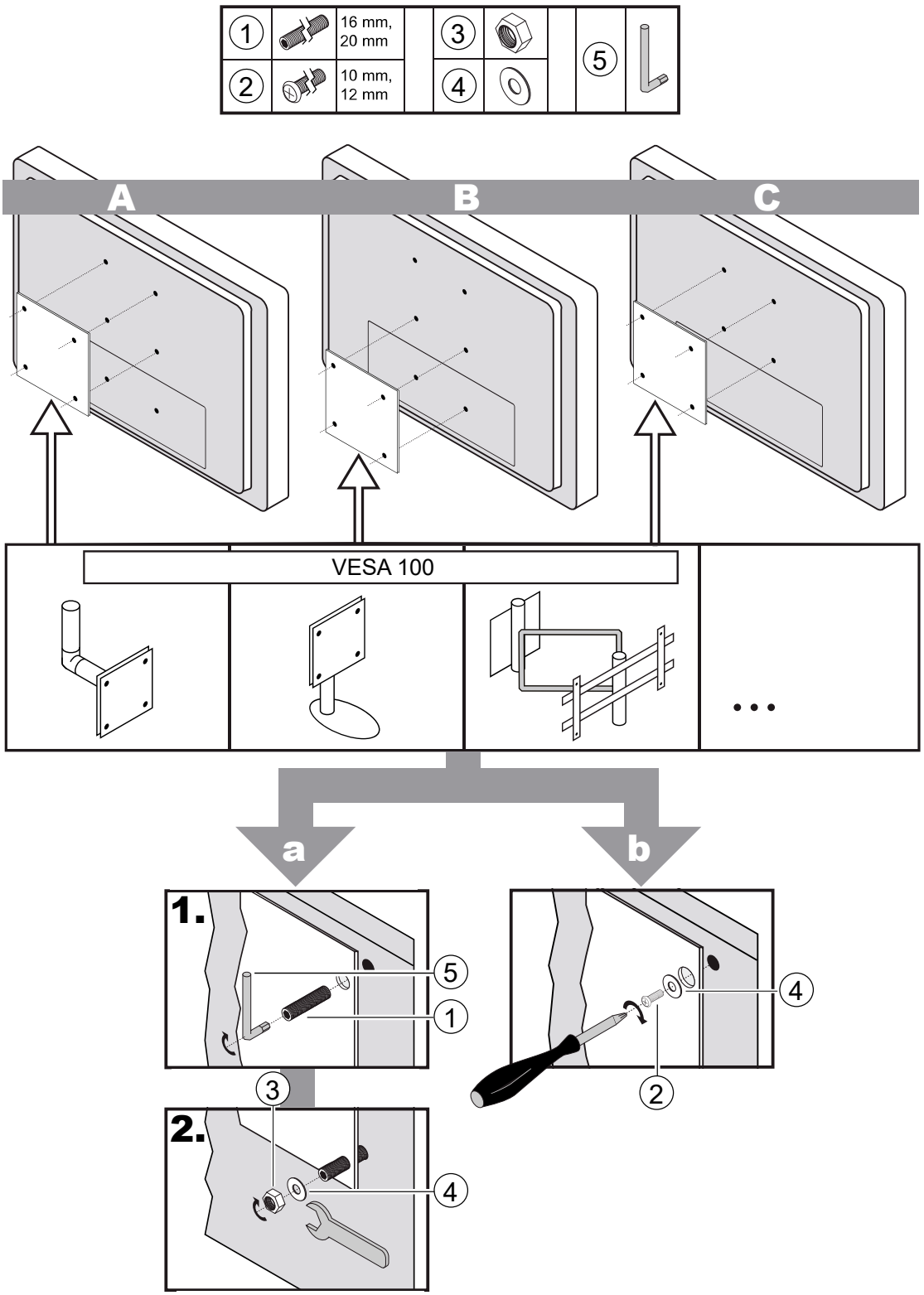
The delivery contents include screws for direct mounting and additional threaded bolts in different lengths to accommodate different mounting solutions.

First, insert the threaded bolts into the VESA attachment points. Next, you can hang the device in the mount and fasten it with the self-fastening domed nuts.

NOTICE: Risk of fall during disassembly!

When removing the self-locking nut from the VESA mount, the threaded bolts may be unscrewed from the housing. The device may then lose its grip unexpectedly and fall down. Prevent the device from falling before disassembly. Make sure that you loosen the nuts and not the threaded bolts.

We recommend that you apply bolt adhesive to the threaded bolts in the housing, so that the bolts do not begin to turn.



For safe and easy installation, first attach the device to the upper VESA mounting position (A). Then reposition the cables behind the hygiene cover. Afterwards, you can remount the device on the other VESA mounting position (B), as required.

Mounting specifications :

Screws	4
Screw type	M4 x 10 mm , M4 x 12 mm
Screw size	4 mm
Screw-in depth for mount (wall)	100 mm (with suitable dowels)
Screw-in depth (housing)	7 mm
Torque	Max. 1 Nm
Threaded bolts	M4 x 16 mm, M4 x 20 mm
Hole spacing	100 x 100 mm

Preparing for installation

Please take note of the following tip when installing the CLINIO®:

The CLINIO® requires special fastening elements for mounting on a wall or bracket . Select the fastening elements based on the following criteria:

- existing approval of the fastening elements from the building authorities
- Weight of the CLINIO®

The selection of fastening elements and the subsequent installation must be supervised by the relevant building authorities or a person authorised by Rein Medical.

The mounting system and supporting elements need to be able to support a weight 2.5 times that of the product.

Dimensional drawing

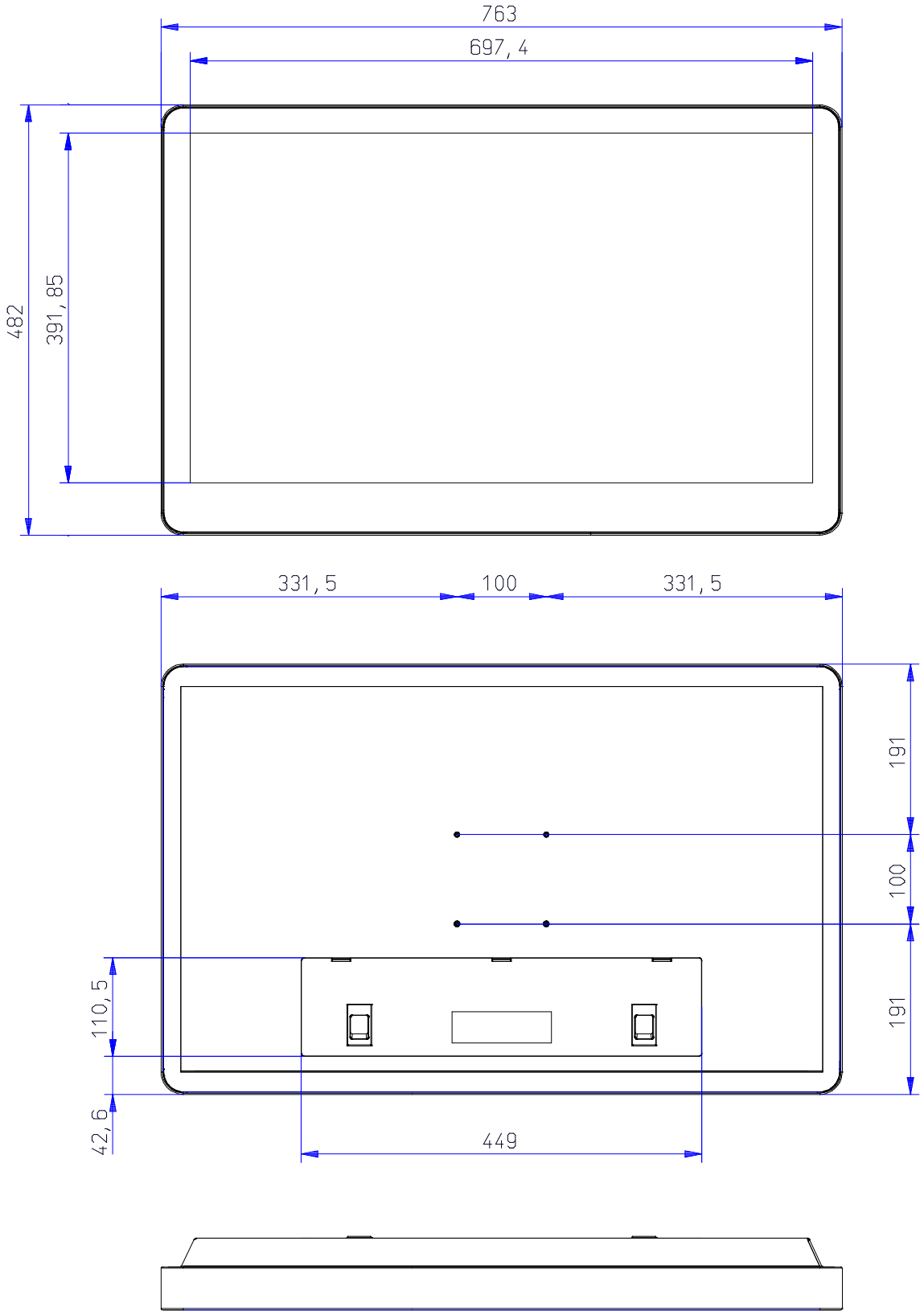


Figure 1: Drawing not true to scale.

Ergonomic workstation

In Germany, a workstation with a monitor must be configured in accordance with labour protection laws as well as the ordinance on work involving monitors. National guidelines may vary in other countries. Comply with the applicable regulations and legislation in the country where the device is installed.

When installing the CLINIO® take note of the following points in particular:

- Orient the top edge of the display to the eye level of the user, preferably slightly lower.
- Situate the mouse and keyboard such that the user's lower arms create a right angle with the upper arms.
- Situate the mouse and keyboard such that they are on the same level as the user's lower arms.
- Position the display so that it does not exhibit reflections and glare.
- Align the screen so that it is centred directly towards the viewer.

Complete requirements for display workstations can be found in national ordinances and laws.

Combination with other devices

NOTICE:

This device must not be used to control life-sustaining and life-support systems.

Please note that all devices combined with this product and its signaling cabling in a medical environment must meet the national versions of the following IEC standards and provide at least two protective measures for operator protection (2 x MOOP)

- EN/IEC 60601-1 Medical electrical equipment – Part 1: 'General requirements for basic safety and essential performance' for medical electrical equipment and systems
- EN/IEC 60601-1-2 Medical electrical equipment – Part 1-2: 'General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests for medical electrical equipment

Furthermore, additional regulations may apply for device combinations in particular areas.

Details about your specific system configuration can be found in the accompanying documentation. If you have any questions, please contact your contact at Rein Medical directly.

Safety of IT networks

The CLINIO® is designed to connect to networks for sharing data with other devices.

This type of data sharing can lead to previously unidentified risks for patients, operators and third parties. The basic risk areas are:

- Damages to the infrastructure due to viruses and other malware
- Failure of central network components
- Unauthorised data access (data protection)
- Unauthorised data manipulation (data integration)

The operator needs to conduct an appropriate procedure for the identification, analysis, evaluation and control of all risks.

The following changes can have an effect on the risks for the network and require new analyses:

- Changes to the network/data network configuration
- Connecting of additional elements to the network/data network
- Removing elements from the network/data network
- Update of devices that are connected to the network/data network
- Upgrade of devices that are connected to the network/data network

The standard IEC 80001-1 describes a process for safely operating IT networks with medical devices.

Rein Medical recommends the following measures for protecting your IT infrastructure:

- E-mail spam filter
- An Internet firewall
- Anti-virus software
- Installation of all security patches for the operating system and the applications being run.
- Shutting down of available interfaces, such as USB interfaces, for sharing data.

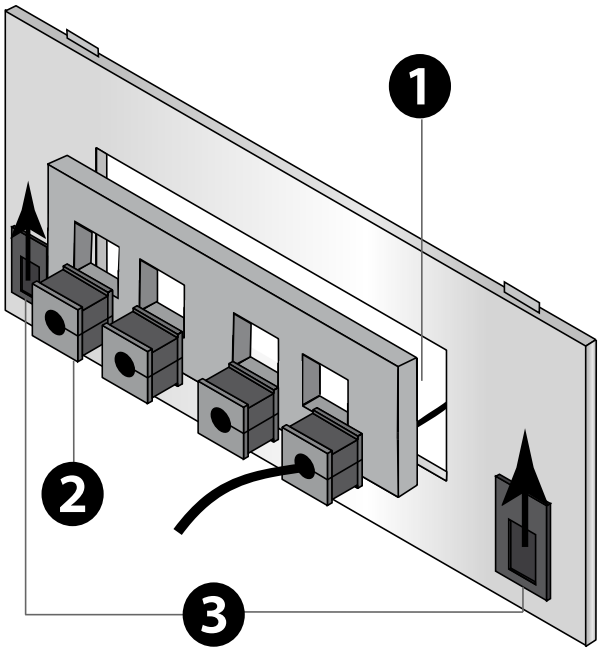
Detailed recommendations can be found on the website of the German Office for Information Security (BSI):

https://www.bsi.bund.de/EN

You can find the technical requirements of the CLINIO® for the IT network in the technical specifications under Table 14: Display properties on page 15 .

Cabling

Open/close hygiene cover

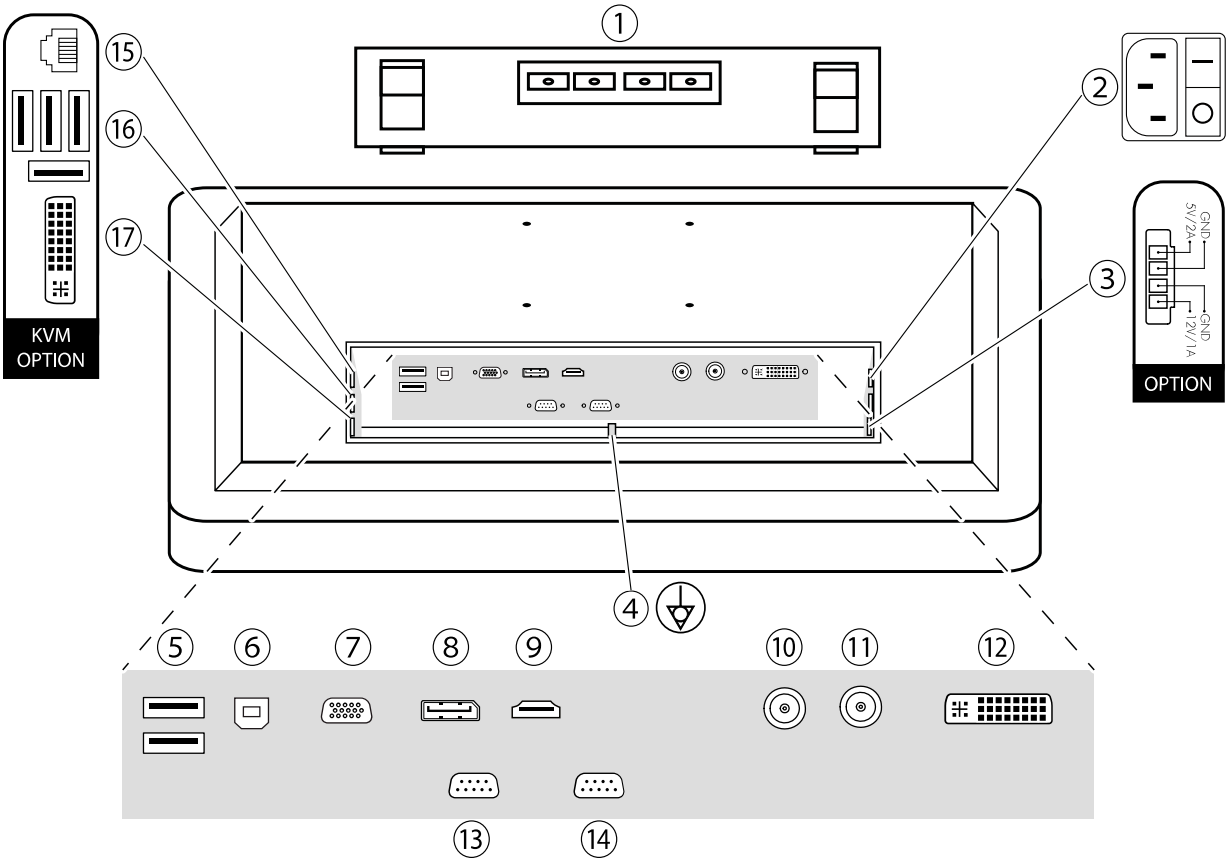


Behind the hygiene cover ❶ you will find all of the device connection ports.

To install or remove cables, open the hygiene cover by opening the fasteners ❸ open/close the hygiene cover by opening the fasteners.

NOTICE: The hygiene cover can be pressed out again in the event of misuse. Make sure the internal wiring does not hinder the closing mechanism. After closing the hygiene cover, check that the closing mechanism is correctly locked in place and that the flap cannot fall out.

Overview of connections



No.	Connection (signal direction) (connection type)
1	Hygiene cover
2	Power supply AC 100 V-240 V, 50/60 Hz (±10%) (C13/C14 (IEC 60320)), power switch
3	DC output 5 V max. 2 A, 12 V max. 1 A
4	Connection bolt for additional potential equalisation
5	Downstream USB hub: USB 2.0 (USB 1.0 / 2.0 Type-A)
6	Upstream USB hub and Service interface (USB 1.0 / 2.0 Type-B)
7	VGA input (15-pin D-Sub)
8	DisplayPort 1.2 input Gen2
9	HDMI 2 input
10	3G-SDI loop-through output (BNC) (optional)
11	3G-SDI input (BNC) (optional)

|
(alternatively, a further DVI-D output is also available as an option)
|

No.	Connection (signal direction) (connection type)
⑫	DVI-D output
⑬	Device remote control (GPIO) (9-pin D-Sub)
⑭	Remote control and calibration interface (RS232) (9-pin D-Sub)
⑮	KVM link (RJ45/8P8C) (optional) (KVM extender)
⑯	4 x USB 2.0 (USB 1.0 / 2.0 Type-A) (optional) (KVM extender)
⑰	DVI-D output (optional) (KVM extender)

Pin assignment for connections

NOTE:

The pin assignments for all device interfaces meet the official standards for each connection type. The following provides more information on the proprietary pin assignments, if necessary. Connections must conform to the requirements for the connection types. Check to ensure that other devices are connected via interfaces of the same type.

For information on connectivity and pin assignments for optional, proprietary connections, refer to the system data sheet.

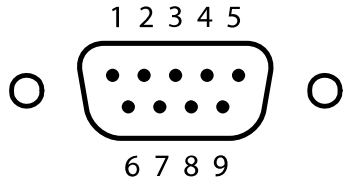


Figure 2: GPIO

Pin number	Pin assignment
1	UP
2	DOWN
3	Menu
4	Power ON/OFF
5	Power LED
6	GND
7	-
8	Source
9	-

Unused signal outputs are automatically terminated to prevent signal reflections. An additional terminator is not necessary.

Connecting additional potential equalisation

In a patient environment (1.5 m), additional potential equalisation (PE) can be used to reduce leakage currents in the connected medical system in accordance with the requirements of IEC 60601-1.

Observe the stipulations for setting up potential equalisation in the DIN VDE 0100 standards, parts 410, 540 and 710.

CLINIO® features a connection bolt for additional potential equalisation (PE) connecting sockets in accordance with DIN 42 801.

How to connect the additional potential equalisation:

1. Set the equipotential connection socket on the connecting bolts.
2. Connect the opposite end of the equipotential bonding conductor to the room's additional potential equalisation connection.
3. Install and shield the equipotential bonding conductor.

The additional potential equalisation has now been connected.

Connecting the device to the power supply

NOTICE: To ensure electrically safe operation and prevent malfunctions, only use the power cord delivered with the device or an equivalent cable with the following specifications:

- Connection type: IEC 60320-1 C13
- Max. length: 3 m
- Cable type: H05VV-F
- Cable cross-section: 3 x 1.0 mm²

NOTICE: The device may be damaged if you use an unsuitable external power supply unit! To avoid damaging the device, only use the supplied external power supply unit, type: External 24 V DC power supply unit (XLR), optional CO50007, SINPRO HPU150A-108, DC24V, 3-pin XLR. Rein Medical is not liable for malfunctions or damage caused by the use of a power supply unit other than the one provided.

1. Depending on the type of power supply:

For internal power supply:	Plug the power cable into the device's power cable receptacle.
For external power supply (optional):	Connect the external power supply unit (Type External 24 V DC power supply unit (XLR), optional CO50007, SINPRO HPU150A-108, DC24V, 3-pin XLR) to the device's 12 V DC input.
	Connect the power cable to the power unit block.
	Fasten the power unit block with cable ties so that it cannot fall down. **NOTICE:** Danger of overheating! The power unit block emits heat through the housing. Do not cover the unit and ensure sufficient ventilation to prevent overheating.

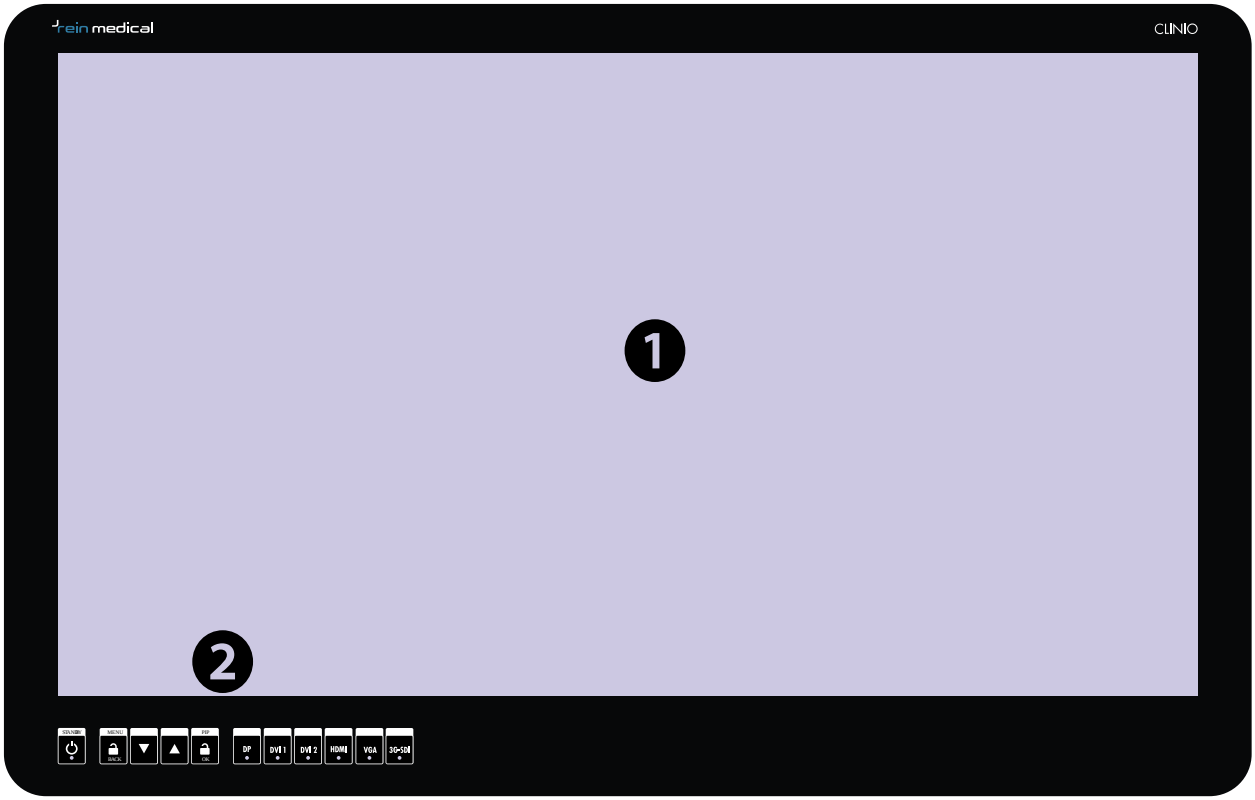
2. Plug in the power cable to an earthed power socket near the device.
   Make sure that the cable is not stretched, bent or crushed.

Now you can switch on and start up the device.

Operating the device

Overview of the device

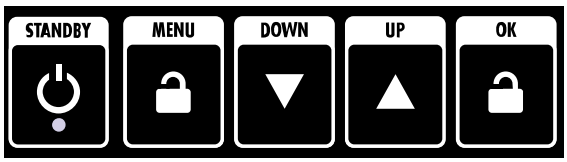
The CLINIO® is equipped with the following controls.



No.	Control
1	LCD display
2	COMMAND BAR touch panel

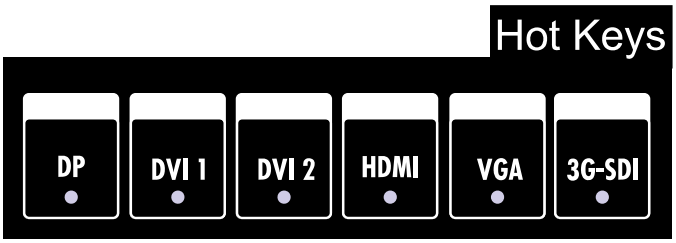
Controls on the COMMAND BAR

The COMMAND BAR is your interface to the CLINIO®. Use the COMMAND BAR to manage image settings and signal routing.



	Standby	Power on/off for the monitor with built-in status LED.
	Status LED: off	The device is switched off
	Status LED: orange	Standby mode (device waiting for input signal)

	Status LED: green	The device is switched on
	Menu	Call up the OSD menu
	Keylock	Switch on/off the key lock for the COMMAND BAR. Status LED lights up when lock function is switched on. The key lock has no effect on the touchscreen function of the unit.
	Menu down	OSD menu Navigation down
	Menu up	OSD menu Navigation up
	OK	OSD menu Navigation Confirm selection/setting
	Keylock	Switch on/off the key lock for the COMMAND BAR. Status LED lights up when lock function is switched on. The key lock has no effect on the touchscreen function of the unit.



	Hot keys for fast activation of input signal sources and user presets with built-in status LEDs.
 PC input	PC signal input (DisplayPort, DVI). Status LED lights up when PC signal input is displayed
 Video signal input DVI 1	Video signal input (DVI 1). Status LED lights up when PC signal input is displayed.
 Video signal input DVI 2	Video signal input (DVI 2). Status LED lights up when PC signal input is displayed.
 Video signal input HDMI	Video signal input (HDMI). Status LED lights up when PC signal input is displayed.
 Video signal input VGA	Video signal input (VGA). Status LED lights up when PC signal input is displayed.
 Video signal input 3G-SDI	Video signal input (3G-SDI). Status LED lights up when PC signal input is displayed.

Starting up the device

As soon as you connect the device to a power source it is ready to use and begins searching for existing input signals. Once a signal is recognised, the device turns on automatically. If the **Standby** touch button is not lit, the device is switched off.

1. If no image is displayed and the status LED of the **Standby** touch button is not lit, press the **Standby** touch button.

   The status LED displays the operating status:

green	switched on, video signal is available
orange	Standby mode, no video signal available
off	The device is switched off or not connected to the power supply

2. Press the **Standby** touch button to end signal transmission of the CLINIO®.
   The status LED lights up orange when the CLINIO® is in standby mode. Pressing the **Standby** touch button again starts the device with the last selected configuration.

Unlocking the control panel

The factory setting for the control panel of the CLINIO® is 'blocked'. This prevents unintended inputs, for example while cleaning the device. In order to control the device via the control panel, you must first unlock the keys.

Press the keys and hold them for two seconds.
As soon as relevant information is displayed on the screen, the control panel is unlocked.

All of the touch buttons in the control panel are preset to be operational for 20 seconds. After this time elapses, the key lock is automatically activated. As long as you have called up the OSD menu and are working in it, the control panel will remain unlocked.

Press the keys and hold them again for two seconds to reactivate the key lock.

The OSD menu

The OSD menu allows adjustments to the display. You can launch the menu, regardless of the displayed image signal, to make individual settings. The functional scope of the OSD menu depends on the attached image signal type.

You have the following options, among others:

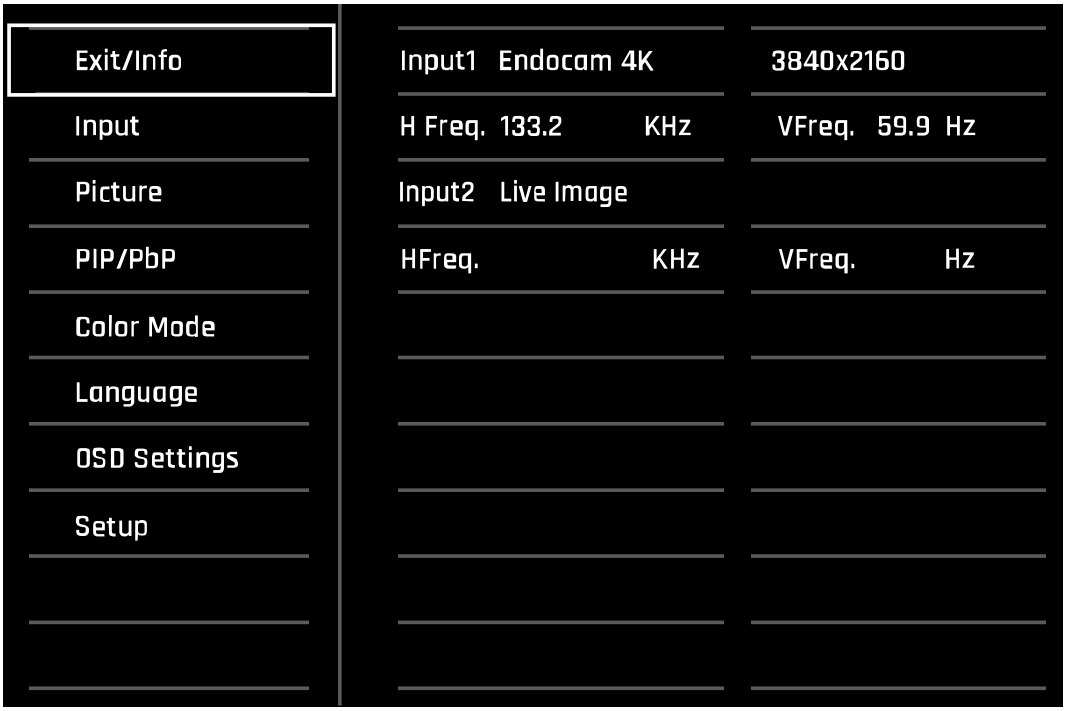
- Switch between different input signals.
- Display multiple signal sources simultaneously on the monitor (picture-in-picture).

Overview of the OSD menu

The following overview provides you with a quick and helpful introduction to the CLINIO® settings in the OSD menu. You will find detailed function descriptions in the following section Useful settings on page 35.

NOTICE: Depending on the firmware version, there may be changes to the OSD structure and the individual menu items. Some of the settings listed here are unavailable for certain products.

The OSD menu is divided into the following sections:



End/Info (Exit/info)	System information
Input (Input)	Selection of image signal to be displayed
Picture (Picture)	No settings options
Picture-in-picture (PiP/PbP)	Display several picture signals simultaneously on a single monitor, determine position, and set screen size.
Color mode (Color Mode)	No settings optionsManual color configuration and ADC calibration
Language (Language)	Selects the OSD menu language
OSD menu settings (OSD Setting)	Configure transparency, timeout, and menu position settings
Setup (Setup)	Firmware update, EDID touch input selection, factory settings

End/Info section (Exit/info)

Click **End** to exit the OSD menu display. In addition, you receive important system information here, such as operating time and the characteristics of the image signal currently being displayed.

Input section (Input)

In the **Input** menu, you can select the main signal input to be displayed.

Touch Enable (Touch Enable) (optional)
Enable/disable transmission of the touch control signal for specific signal inputs to specify that display touches are only transmitted when an image matching the touch function is displayed.

Picture section (Picture)

You can adjust the image setting to the relevant image signal and your needs under **Image settings**. Please note that the options in this menu change according to the input signal. You will find basic color modes for color, gray scale, and DICOM display in the following **Color mode** section.

Picture Format (PictureFormat)
The image formats full, original, and 1:1 are available.

Brightness (Brightness)
Sets the brightness level for the display

Contrast (Contrast)
Sets the light/dark contrast for the display

Black level (Black Level)
Sets the transparency level for the display

Image sharpness (Sharpness)
Sets the sharpness of an interpolated image. Has no effect on non-interpolated signals.

ALS (ALS)
Activates/deactivates Automatic Lumination Stabilization (ALS)

Picture-in-picture section (PiP/PbP)

In the **Multipicture** menu, you can allow the display of multiple image signals at the same time on the display. This section is only displayed if an active signal input has been selected in **Source** > **PiP** .

PiP/PbP mode (PiP/PbPMode)
Activate or deactivate the type of multi-picture display (Off, PiP, 2PbP)

Signal input 2 (Input2)
Select the second signal input (VGA, HDMI, DVI, SDI, DisplayPort)

Size (Size)
Set the size of the image (small, middle, large)

PiP Position (PiP Position)
Set picture positions (Top-Right, Top-Left, Bottom-Right, Bottom-Left)

Swap (Swap)
Swap the position of images from main signal input and PIP signal input

OSD menu settings panel (Menu)

Configure the OSD menu and the COMMAND BAR control buttons under **OSD menu settings**.

Menu position (Position)	
Horizontal	Shifts the OSD menu position horizontally
Vertical	Shifts the OSD menu position vertically

Transparency (Transparency)
Set the transparency value for the OSD menu: Off, 1, 2, 3, or 4

Display timer (OSD Time Out)
Define how long the OSD menu will remain displayed if it is not being used (5s, 10s, 15s, 20s, 30s, or 60s)

Setup section (Setup)

You can find general display settings in the **Setup** section.

Activate auto set-up (Auto)
Activate/deactivate the auto-setup function for VGA/RGB input. Automatically triggered when set to ‘on’ and a VGA/RGB signal is initially connected.

L. Position
Sets the horizontal position of the image (50 = center)

V. Position
Set the vertical position of the image (50 = center)

Phase
Compensates for errors by shifting frequency

Time (clock)
Set the time

Keylock
Always Off (hotkeys are always enabled) Always On (hotkeys are always disabled), Except Hotkeys (only hotkeys can be used), Keylock Timer= 20s/40s/60s (keys remain disabled for 20s/40s/60s)

DisplayPort
Select version: 1.1 or 1.2

Reset (Reset)
Return all settings to factory settings (yes/no)

Useful settings

This chapter describes the various settings options for the CLINIO®. The information and instructions are categorised according to typical everyday tasks.

Functions for protecting the device

The CLINIO® offers settings options that, if used in an ideal manner, extend your device's expected lifespan.

Adjusting the monitor brightness

Brightness is a setting for background illumination and is independent of the image signal.

In surroundings with bright illumination or direct sunlight, increase the display brightness for optimal image perception. Keep the display brightness as low as possible to reduce wear and tear on the display.

In the OSD menu, select **Image settings** > **Brightness** to set the display brightness.

Optimising image properties

You can connect image sources of different types and qualities using the monitor's various digital and analogue image signal inputs. In order to get the best display result for any signal, the OSD menu offers specific optimisation options

Dynamic image with contrast, black level and brightness settings

A realistic display depends above all on the perceived difference between deep black and bright white image areas. If the difference is particularly great, the image appears brighter, naturally dynamic and possibly even exaggerated. If the difference is rather minimal, the image appears dull.

The effect of the dark-bright contrast depends on the **Image settings** menu in the OSD menu, which contains the settings for **Brightness**, **Contrast** and **Black level**.

The contrast, however, is also measurably affected by ambient lighting conditions. Even with the same device settings, the subjectively perceived contrast is higher in bright ambient lighting (daylight) than in a dark room. Contrast perception decreases with extremely bright ambient lighting (direct sunlight).

Adjust the **Contrast**, **Brightness** and **Black value** settings so that, in typical ambient lighting conditions, a deep, non-luminous black and the purest possible white tones are displayed.

For analogue image signals, you can make the system automatically determine the optimum image settings for image size, position, brightness and contrast. You can do this under **Image** > **Auto setup** . If this option is not available, this means that the system has already determined the optimal settings.

The right colours for individual requirements

The optimum display of colours depends on the work that will be performed on the display. Depending on the work context, the display must deliver true to original printing colours, look natural, support optimal readability and, last but not least, relieve the stress on the user's eyes. You can adjust the display for your needs with the various colour settings.

The device has colour configurations that are in line with standardised colour spaces. If your video source transmits standardised colour spaces, you should set the monitor to the same colour space. In the OSD menu, select the colour space standard that matches the video source in the OSD menu under **Color Mode**.

Under **Color Mode** > **Normal**, you can choose from three preset colour profiles that are designed for typical work contexts:

- *Cold*: Bluish white, particularly well suited for extended periods of use that require good legibility. Use this colour profile for typical office workstations.
- *Warm*: Reddish white, typically used for photography and retouching.
- *Neutral*: The neutral colour profile produces a white similar to daylight and is therefore well suited for graphic and print design.

When setting these values, attempt to get the most natural colouring possible. We recommend that you set up the display by using test images.

You can also leave the colour configuration to the colour space presets. If a colour space preset is activated, all colour settings are fixed and cannot be adjusted manually.

Quality assurance for medical science

The CLINIO® offers various settings that cater to the special display requirements of the medical field.

Activate DICOM preset

Even though the CLINIO® is not a diagnostic device, you can nevertheless display greyscale images for viewing and thereby rely on an image that meets the DICOM standard.

In the OSD menu, go to **Colour mode** and select the DICOM option to load the DICOM preset.

The DICOM present provides fixed settings for contrast, brightness, gamma correction and other colour settings. Therefore, you cannot change these parameters when the DICOM preset is activated.

NOTICE: Even though it offers the DICOM preset, the device is not suited for performing primary medical diagnostics.

Stabilising the display illumination (ALS)

The display's background illumination can change over time. In order to guarantee consistent brightness, the CLINIO® is equipped with a background illumination management system (Automatic Luminance Stabilisation). The system continuously controls the display's brightness and prevents loss of illumination. This ensures consistent brightness of the display, even after long periods of use.

In the OSD menu, select **Image settings** > **ALS**, to activate or deactivate Automatic Lumination Stabilisation (ALS).

When brightness stabilisation is activated, you cannot manually influence the display's brightness. In DICOM mode, the automatic brightness stabilisation is always active.

ALS (Automatic Luminance Stabilisation) with backlight sensor, factory-calibrated to 350 cd/m² or 300 cd/m² for DICOM preset

Cleaning

This chapter provides instructions and information for cleaning the device.

Protective equipment for professional cleaning technicians

Use your personal protective equipment (PPE) for any activities and work with the CLINIO®. Personal protective equipment will protect you from injuries and health risks.

Wear personal protective equipment:

- closed-toe shoes
- sturdy, long fabric trousers
- tunic
- latex gloves

Check your personal protective equipment to make sure it is in proper condition. Inform the operator of any defects.

Cleaning the device

Although the surface of the CLINIO® enclosure is designed to be hygienic, dust and potential pathogens can still collect on this surface over time.

It is particularly necessary in hygienically sensitive areas to clean the surface of the CLINIO® enclosure at regular intervals in order to prevent contamination.

The device is certified by Prof. R. Mutters, Institute for Medical Microbiology and Hygiene, Philipps-Universität Marburg, Germany. Rein Medical recommends the following or similar disinfectants based on alcohol or quaternary ammonium compounds from the list of disinfectants published by the VAH (Association for Applied Hygiene)/DGKH (German Society for Hospital Hygiene) such as **Terralin liquid®** fast-acting disinfectant (contact time of 30 seconds) or **Terralin protect®** surface disinfectant (contact time of ten minutes).

If you have any further questions about listed disinfectants, please contact Rein Medical.

NOTE: Pay special attention to the requirements of the Robert-Koch Institute and national hygiene requirements for medical environments.

How to clean and disinfect the CLINIO®:

NOTE:

The hygiene cover must be installed for thorough damp cleaning and disinfection. Only the front side of the device should by cleaned and disinfected with liquids when the hygiene cover is not in place.

1. Check that the device's hygiene cover is in place.
2. Clean the surface of the device with an all-purpose cleaner.
3. Disinfect the surfaces of the device by spraying or wiping with disinfectant.

   Disinfecting with all-purpose cleaners or other unlisted disinfectants increases the risk of contamination by pathogens.
4. Allow the disinfectant time to take effect, depending on the extent of germ or bacterial contamination.

   Apply the disinfectant for at least 5 minutes. In special cases, the disinfectant must be applied for up to an hour (e.g., if there is a danger of hepatitis B contamination).

The device has now been cleaned and disinfected.

System changes

When making changes to the hardware on the device, please pay attention to the following warning:

NOTICE: Equipment failure possible due to improper changes!

Unauthorised components can result in overheating and the complete failure of the device.

Unauthorised changes to the device void the warranty.

Changes to the device should only be carried out by authorised Rein Medical technicians.

Maintenance

In all phases of maintenance, please observe the national and international standards for inspection, maintenance and repair of medical devices and electrical equipment:

- EN/IEC 60601-1 for the operation of medical electrical equipment
- EN/IEC 62353 for recurrent test and test after repair of medical electrical equipment
- National inspection specifications for medical electrical equipment (Germany: Medical Devices Operator Ordinance (MPBetreibV))
- National control requirements for electrical equipment (Germany: DIN VDE 0701-0702, DIN VDE 0105-100)
- EU Directive 2009/104/EC for occupational safety and national implementations (Germany: Ordinance on Industrial Safety and Health (BetrSichV), TRBS 1201, TRBS 1203, DGUV Regulation 3.

Warnings

Contact with electrical voltage! Risk of life-threatening injury if working on an opened device. Damage to device possible.	The enclosure should only be opened by authorised Rein Medical technicians. First unplug the device from the power supply, and then open the housing.
IP protection is voided by opening the CLINIO®!	After opening the device, the seal must be checked and the required tightness verified once again. Contact Rein Medical if you require support for sealing the device.

Troubleshooting

Before you contact the customer service team, please attempt to fix any problems that may arise using the information in this section. If you require assistance, please call the telephone number listed on the warranty card or in Contact on page 45, or contact the service partner in your area.

When starting up the system, the screen flickers/the resolution changes	During the boot procedure, or when the resolution is modified, the graphics card resets the graphics memory, which can sometimes cause the screen to flicker. This effect varies from card to card and is not a problem.
Schematic representations, image fragments or image shadows are visible on the display	These images appear when still images are displayed for long periods of time (several hours). Switch off the device for several days or consistently display quickly moving images, such as image noise, to counter this effect. Do not display still images for several hours without interruption. Screensavers also help to avoid this effect.
How can I change the display resolution?	The resolution is controlled by the graphics card and the operating system. The monitor renders the signal transmitted by the graphics card at a 1:1 ratio and cannot change the resolution on its own. Most graphics card manufacturers offer drivers and utilities that permit the use of different resolutions for different applications.

Inspection

There is no requirement on the manufacturer's part to carry out safety or metrological inspections in accordance with the Medical Devices Operator Ordinance.

The device should be checked for operational safety at least every two years by an electrically qualified person. Please take note of the stipulations for recurrent tests in EN 62353 (IEC 62353) and in the relevant requirements and standards.

Use the following checklist to check that the device is working safely and effectively:

Visual inspections:

- Discolouration on the enclosure
- Damaged or loose connecting sockets and plug connectors
- Damaged glass components
- Fan function (only for devices with fans that are lead to the outside)
- Damaged, kinked or broken cabling
- Integrity of the electrical connection
- Tightness of seals, service covers, cable feedthroughs (for IP-protected devices)

Functional test:

- Switching on and off in accordance with user manual
- Quality inspection and configuration of image reproduction according to requirements of operational use
- The relevant inspection specifications of the operator (responsible organisation) also apply

Safety testing:

- Test device in accordance with EN 62353 (IEC 62353)
- siehe Conduct a safety test on page 41

If defects in the device become evident during inspection, take the device out of service and contact your Rein Medical consultant immediately.

Special requirements for safety inspections, metrological inspections or necessary repeat tests may arise with individual medical systems. Details of these can be found in the risk management documentation of your medical system.

Maintenance

The device is maintenance-free. For technical systems with high availability requirements, redundancy should be built in for all safety-related system components.

Repair

Repair work and system modifications that involve opening the enclosure may only be performed with the relevant authorisation by Rein Medical. Instructed access to the connection terminal plates and interfaces described in the user manual does not count as opening the enclosure.

Rein Medical provides no warranty for devices opened and modified independently.

Please note the requirements for safety testing after repairs in the requirements and standards listed at the beginning of Maintenance on page 39.

In the case of IP-protected devices, technicians authorised by Rein Medical must inspect the condition of the seal after the CLINIO® has been opened.

Recurrent tests and tests after repair

The device needs to be tested in accordance with the applicable requirements set out in EN 62353 (IEC 62353) every time the device is installed or repaired or the enclosure is opened, as well as at regular intervals (at least once every two years).

Notes regarding the safety test

Read the following information before you carry out a safety test in accordance with EN 62353 (IEC 62353).

For the safety test, a calibrated test device that conforms to the EN 62353 (IEC 62353) standard for safety tests is required.

Make sure that the test device complies with all other applicable national regulations for conducting safety tests on medical products.

Only specialists who have expertise in electronics and medical equipment as well as the respective device may test the device before it is commissioned. The expert must be authorised to carry out safety tests.

Conduct all required function tests on the device and the connected system before carrying out the safety test on the device.

It is not necessary to open the enclosure for the test.

Conduct a safety test

Conduct all required function tests for the specimen and the connected system before undertaking the safety test on the specimen (CLINIO®).

1. Conduct a visual inspection (Inspection on page 40)

   Ensure that no cables have become clamped during installation.
2. Remove the power cable from the socket to disconnect the specimen from the power supply.
3. You can now connect the test equipment.
4. Connect the power supply outlet of the test device to the CLINIO® specimen.

   NOTE: Connect the test device either directly to the mains connection socket of the specimen or to the pre-installed mains cable, which was included in the scope of delivery for the specimen.
5. Connect the additional protective conductor of the test device to the ZPA connection () of the CLINIO®.
6. You now need to put the specimen and the system to be tested into operating mode.
7. Activate the image or signal sources connected to the specimen.
8. Activate any devices and signal sources connected to the specimen.
9. Perform the test in accordance with EN 62353 (IEC 62353).
10. As soon as the test has been completed, the specimen can be disconnected from the power supply and the test equipment can be dismantled.
11. Re-connect the specimen to the power supply.
12. The test results should be logged in the medical device book for the system/device.

The device is now ready to use.

We support you.

We support you and all of your equipment.

Rein Medical offers you personal support through various communication channels. Our medical device consultants offer assistance for new and existing installations and answer all of your questions regarding medical IT.

Reporting problems with the device

We do not expect you to experience any difficulties with the device, but if you do, our customer service team will be on hand to assist you with the minimum of fuss.

When contacting us, please have the following information about ready:

- Model (see name plate),
- serial number (see name plate)
- description of the problem
- way in which the product is being used
- name of the system integrator/dealer of the product
- proof of purchase (invoice/packing slip)

Service number	Contact on page 45
Email contact	Contact on page 45

If our customer service team is unable to help you directly, you will be given an RMA number, which initiates the appropriate repair process. Depending on the applicable warranty agreement and type of device, you can either send your device in or a service technician will visit your location.

NOTE: All serious incidents involving the product must be reported to the manufacturer and to the competent authority of the member state in which the user and/or the patient is located.

Sending the device in for repair

The following steps explain the process for sending a device in for repair:

1. By telephone, request an RMA number and a return form from the Rein Medical customer service team.
2. Fill out the return form.

   You can fill out the form by hand or electronically as a PDF.
3. Clean and disinfect the malfunctioning device.
4. Include the completed return form with the device.

   We can only accept returns with an accompanying return form! For safety reasons, potentially contaminated packages will not be accepted. We reserve the right to clean the shipment for the sender and charge a fee.
5. Send the device together with the RMA number and the return form to the contact address in the original packaging.

   The address you need can be found in Contact on page 45.

As soon as we receive the device, our customer service team will prepare an estimate for you, including details of how long the repair will take.

Decommissioning the device

The following chapter contains important information regarding the decommissioning, storage and disposal of the CLINIO®

Warnings

Contact with electrical voltage! Risk of life-threatening injury if working on an opened device. Damage to device possible.

The enclosure should only be opened by authorised Rein Medical technicians.

First unplug the device from the power supply, and then open the housing.

Technicians protective equipment

Use your personal protective equipment (PPE) for any activities and work with the device. Personal protective equipment will protect you from injuries and health risks.

- safety shoes

When moving the device, also wear:

- protective gloves

Check your personal protective equipment to make sure it is in proper condition. Inform the operator of any defects.

Disposal tips

Discarded electronics do not belong in household waste. The substances and materials they contain must be properly separated so that they can be prepared for the manufacture of new products. Rein Medical offers quick return and environmentally sound disposal of all Rein medical products.

Old devices supplied by Rein Medical GmbH,

- may be returned at no charge for the purposes of salvage or disposal, as long as the old device was introduced after 13 August 2005.
- must be properly salvaged or disposed by the operator, if the old device was introduced before 13 August 2005. This excludes individual agreements regarding specific returns.
- may not be delivered to any public waste disposal authority.
- may only be given or sold to private users such as employees if the salvaging and disposal of the old devices is guaranteed at the end of their useful life, in accordance with the cited regulations.

Recycling and disposal are free of charge for the operator through Rein Medical. Please send the device with the appropriate information postage-free to the following address (see Contact on page 45).

WEEE category: Category 2 (display measuring > 100 cm²)

Report the return of old devices by **calling (+49-21) 6169-840** . We are happy to answer any questions about salvage and disposal at any time.

NOTICE: Dispose of electrical and electronic refuse only in accordance with local legislation and regulations.

Storage

- Store the device in its original packaging. This is the only way to properly protect it from environmental damage.
- Select a storage area that is dry and protected from sunlight. Optimum environmental conditions for storage can be found under Table 13: Environmental conditions for storage/transport on page 14.

Contact

Germany (manufacturer)
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