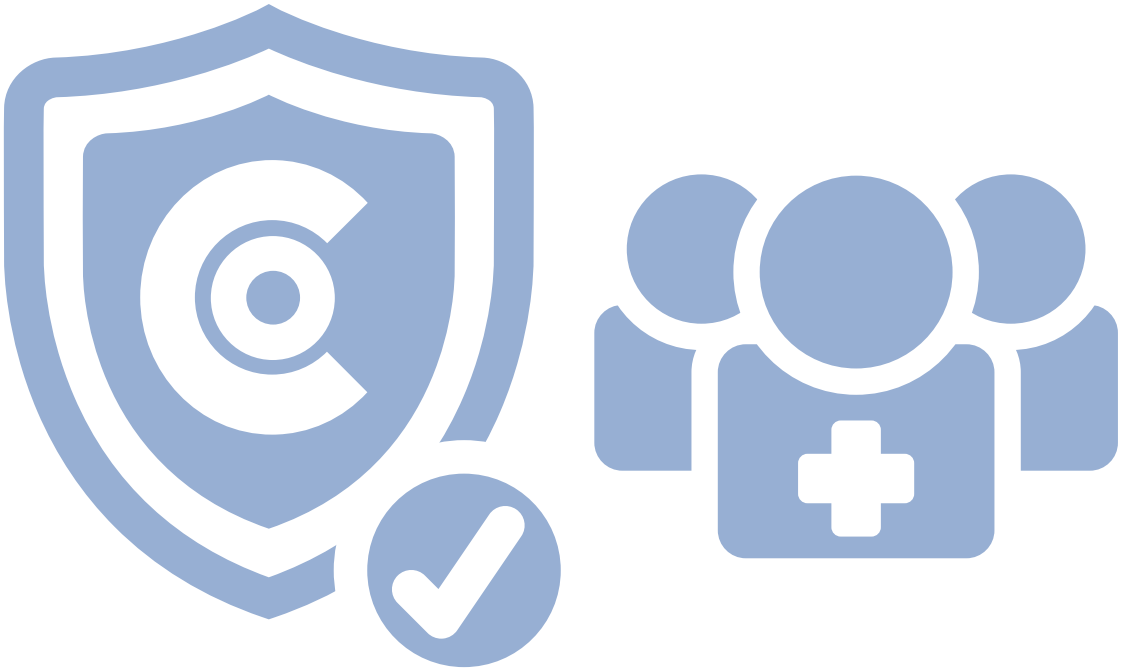
Operating Manual

custo med Systems

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 1: Safety, Maintenance and Warranty



Operating characteristics:
Safety instructions
for technicians, specialised
medical staff and patients

MSH 0001 – DK 1692
Version 007 – 02/03/2021

CE 0123

custo·med
EXCELLENCE IN DIAGNOSTICS

The manufacturer reserves the right to change the information in this Operating Manual without prior notice. The current version can be downloaded from our website: www.customed.de.

CAUTION:
This Operating Manual is part of a modular system, consisting of four parts. All four parts must be downloaded from the Internet or from a CD to ensure the Operating Manual is complete.

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Part 1: Safety, Maintenance and Warranty

Table of contents

1.1 General notes

Strict compliance with the safety instructions protects against personal injury and property damage during device operation. This Operating Manual is designed to accompany the product and must be kept ready to hand close to the device. As either the operator or user of this device you should have read and understood the Operating Manual, in particular the safety instructions.

Should serious incidents occur in connection with a custo med product, they must be reported by the user and/or patient to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Laws and regulations applicable to the product

custo med devices are designed in accordance with the Medical Device Directive 93/42/EEC and Medical Devices Regulation (MDR 2017/745), class IIa and meet the requirements of protection class I or II, depending on the power supply unit used or they are devices with an internal power supply, type BF or CF according to IEC 60601-1.

Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (IEC 62368) or the Standard for Electrical Medical Devices (IEC 60601-1).

The electrical installations in the rooms in which the system is used must meet the requirements of the applicable safety standards.

For users outside the Federal Republic of Germany, the respective national accident prevention measures, regulations and requirements apply.

1.2 Safety installations and safe working

1.2.1 Putting into operation, setup

custo med systems must only be used in a technically perfect condition. Regularly carry out a visual inspection of the devices and their associated components. Only use accessories approved by custo med. The use of accessories other than those specified may result in increased emissions or decreased immunity.

A PC with peripherals is required to operate the custo med devices. For assembly it is recommended to use portable multiple socket outlets approved by custo med, e.g. medical protector. The following must be noted:

- Portable socket outlets must not be laid on the ground.

- Portable multiple socket outlets which are supplied with the system are to be used only for supplying devices which are part of the system. Additional portable multiple socket outlets, lines and other equipment, which are not part of the system, must not be connected to the system.

- When using a multiple socket outlet, the maximum permitted load is 3200 VA. Slots which are not used in the delivered system (portable multiple socket outlets) must be provided with covers.

1.2.2 Ambient conditions, handling of the devices

Emissions

The custo med devices/systems are not suitable for use in rooms or areas with a risk of explosion.

For installation and operation of the devices/systems, the EMC (electromagnetic compatibility) instructions in the Operating Manual must be observed, *see the hardware description*.
Strong electromagnetic sources in the immediate vicinity of the custo med device/system may result in recording errors. The custo med device/system must not be stored or used in the vicinity of X-ray equipment, diathermy units or magnetic resonance devices (MRT). Other electrical devices such as mobile phones or radio transceivers may impair the quality of the recording.

Other devices may interfere with the custo med devices/systems, even if the other devices comply with the applicable emissions requirements according to CISPR.

Mechanical impact

No modifications may be made to the custo med devices/systems. Contact your authorised custo med distributor for repairs.

custo med devices for outpatient use (recorder, transmitter) must be protected from heat, moisture, dust and dirt. The devices may not function properly if they come into contact with liquid. It is not permitted to wear the devices in a swimming pool, in the sauna, bathtub, shower or similar wet rooms. Do not submerge the custo med devices.
The custo med devices must be protected from mechanical impact, such as falls or transport damage. Avoid heavy mechanical loads.

Rechargeable batteries

Some custo med devices contain an integrated lithium polymer battery (permanently installed in the housing). Any mechanical stress which is beyond the intended use must be avoided. Do not use force to open the devices.
Some custo med devices contain a lithium-ion battery or other batteries that can be removed. Remove the rechargeable battery when the device is not in use. Do not expose the rechargeable battery to extreme temperatures, fire and moisture. Do not immerse in liquids. Observe the operating and storage conditions. Do not subject the rechargeable battery to strong shocks or drop it. The rechargeable battery must not be disassembled, modified or short circuited. Only use the supplied charger to charge the rechargeable batteries.

Do not remove battery compartment covers or other covers during use.

USB cable

Some custo med devices have a USB cable. This cable must not be kinked. Do not step on the USB cable, only roll up the cable loosely and allow it to hang freely during operation. Always hold the USB cable by the plug in order to disconnect it from the PC.

Memory cards

Some custo med devices contain memory cards. custo med recommends that you leave the supplied memory cards (if present) in the respective recorders to ensure that they cannot get lost and to prevent dirt from entering the opening.

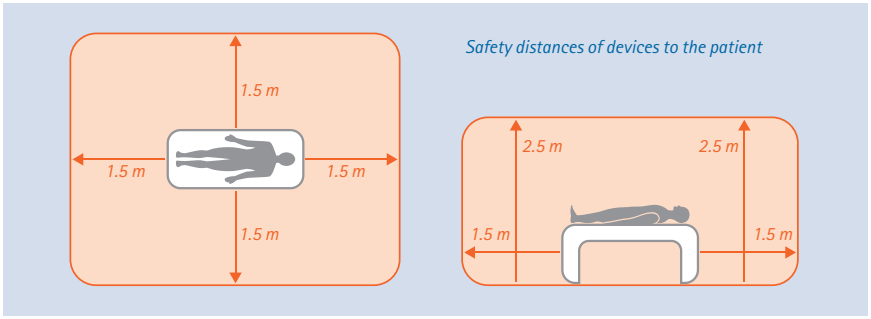
Do not insert or remove memory cards unless the device is switched off. The supplied memory cards are only intended for the respective device. Do not use the card to store any other data.

Only use the original memory card. Additional memory cards are available as accessories. Use the supplied memory card case to send in defective memory cards.

If using multiple recorders and/or memory cards, be careful not to confuse them.

1.2.3 Patient safety

Applies to:
all custo med systems



Without medical protective devices, e.g. medical protector, the PC and all the non-medical devices connected to the system (e.g. the monitor and printer) must be set up and used at a distance of at least 1.5 m to the patient unit (see the orange area in the figure) as leakage currents can occur.

Non-medical devices and the patient must not be touched at the same time during the examination or routine maintenance measures (risk of electric shock). Make sure that the electrode contacts do not come into contact with other conductive parts.

All results achieved by automatic analysis and the resulting unconfirmed reports produced by the system must be considered as suggestions only. For diagnosis and therapy purposes it is essential that the results are checked and assessed by a qualified physician.

1.2.4 Examination-specific safety instructions

ABPM

Applies to:
custo screen 300
custo screen 310
custo screen 400
custo screen pediatric

custo screen 300/310/400/pediatric is not protected against the ingress of dust and splash water, meaning it must be protected accordingly.

Continuous cuff pressure, e.g. exerted by a kinked cuff tube, can cause patient injuries. If the cuff pressure is continuous, the patient should open the cuff's hook and loop fastener and contact his/her medical practice.

In patients with severe blood coagulation disorders, the cuff can cause hematomas. The decision for or against automatic blood pressure measurements should be carefully considered in such patients.

Make sure that the cuff tube does not become crushed or that the cross-section of the cuff tube is not reduced.

The cuff must not be applied to wounds, open or newly operated areas. If the patient suffers from conditions such as arterial occlusive disease or severe blood coagulation disorders, the physician has to decide whether the device should be used or not.
A too loosely applied cuff leads to incorrect measurement results. A cuff that is too tight can lead to vein blockage. It may also cause contusions of the skin and bruising. If the patient is not feeling well, the patient should consult his/her medical practice.
Make sure that the patient does not suffer any long-term adverse effects as a result of the short-term interruption of the blood circulation as required by the measurement method. Such measurements should not be conducted too often.

When conducting blood pressure measurements, the function of additional medical devices which are used in the vicinity of the blood pressure cuff on the patient may be affected.

The following factors can have an effect on the results of a blood pressure measurement: the patient's posture (whether the patient is lying down, standing or sitting), movement, the patient's physical condition, heart rate-related or ventricular events, as well as extreme temperatures and air humidity. Observe the operating conditions and the patient instructions.

The device is not protected against the potential effects of radiofrequency (RF) surgical equipment.

The system is not suitable for unsupervised use with unconscious patients.

Never use damaged batteries or rechargeable batteries. If custo screen 300/310/400/ pediatric is not to be used for a prolonged period of time, remove the batteries. If liquid has been spilled on the device, remove the batteries or the rechargeable batteries immediately and send the device for inspection to your authorised custo med distributor or custo med.

custo screen 300
custo screen 310
custo screen 400
custo screen pediatric

Resting and stress test ECG

Applies to:
custo cardio 100
custo cardio 110
custo cardio 130
custo cardio 200
custo cardio 300
custo cardio 400 BT
custo cardio 400 accu

The custo med ECG devices are not protected against the ingress of dust and splash water, meaning they must be protected accordingly.

The custo med ECG devices are protected against defibrillation only in connection with the manufacturer's patient cable. For custo med ECG devices only patient cables with a defibrillation protection resistance of 10 or 100 KΩ must be used.

In the event of defibrillation, take note of the manufacturers' instructions regarding the safe and proper use of the defibrillator. Defibrillation has an interfering effect on the ECG recording. custo cardio ECG devices have a recovery time of less than five seconds.

For ECG recordings with custo cardio 200/400 in connection with the telescopic boom, the plug coupling (power supply cable at the lower end of the boom) and the patient must NOT be touched simultaneously.

Make sure that the electrode contacts do not come into contact with other conductive parts.

If electrodes become detached from the patient during an ECG recording or the electrode contact is too weak, a red signal line will be displayed on the corresponding ECG channel in custo diagnostic. Below the ECG recording a hint will appear (in red letters) indicating which electrodes are concerned. Reattach them. The appearance of red signal lines in custo diagnostic does not indicate that the patient has an asystole.

custo diagnostic provides pacemaker detection. Here, the pacemaker pulse from the ECG signal (in two channels at least) is detected and then projected into the ECG recording as an (artificial) spike, precisely timed. However, the pulse width of the pacemaker is not calculated with the pacemaker detection in custo diagnostic (custo cardio 1xx/200). These devices are not suitable for binding pacemaker checks. In case of doubt, use the device approved by the pacemaker manufacturer (see the patient's pacemaker record).

If custo cardio 200/400 is used (electrode application system), operating at higher suction levels may cause irritation or haematoma on sensitive skin due to the negative pressure. Please ensure that the suction levels are set correctly. If the patient suffers from conditions such as arterial occlusive disease or severe blood coagulation disorders, the physician has to decide whether the device should be used or not.

Holter and examination types with holter functionality

(Holter-ABDM, cardiac rehabilitation, telemetric holter)

custo watch and custo guard/custo guard holter are protected against the ingress of dust and splash water (IP65).

It is not permitted to wear the devices in a swimming pool or in the bath. Do not submerge the devices in liquid.

custo flash 5xx, custo kybe and custo screen 400 are not protected against the ingress of dust and splash water, meaning they must be protected accordingly.

custo med holter systems are not suitable for intracardiac use or for electrocardiographic monitoring of patients in accordance with IEC 60601-2-27, e.g. use in intensive care.

Make sure that the electrode contacts do not come into contact with other conductive parts.

custo belt, neck strap, cable adapter and custo guard ECG cable not to be left unattended with infants or young children, risk of strangulation.
Small parts must be kept away from children due to risk of suffocation.

custo wing disposable adhesive electrodes must not be used on infants or small children. Use suitable neonatal or paediatric electrodes.

Disposable adhesive electrodes must be changed daily to avoid skin irritation.

In the case of known allergies, e.g. against substances in the adhesive electrodes or custo belt, the further procedure must be agreed with a doctor before the commencement of recording. If patients experience discomfort during a recording, they must contact their physician.

The custo med holter systems are perfectly safe for patients with a pacemaker. In Holter systems without pacemaker detection, disturbances in the ECG signal may be incorrectly interpreted as a pacemaker.

custo guard/custo guard holter may only be used in combination with the custo belt electrode belt or adhesive electrodes. Electrode belts from other manufacturers may change the band width and amplitude of the ECG signal which could result in a misdiagnosis.

Applies to:
custo flash 500
custo flash 501
custo flash 501/light
custo flash 510
custo flash 510V
custo guard
custo guard holter
custo kybe
custo screen 400
custo watch
custo EDAN SE-2012

Notes on custo diagnostic holter software options

Applies to:
custo flash 500
custo flash 501
custo flash 501/light
custo flash 510
custo flash 510V
custo guard
custo guard holter
custo kybe
custo screen 400
custo watch
custo EDAN SE-2012

The custo diagnostic function "ANS diagnostics" (balance of the autonomic nervous system) serves as a supporting measure. A correct evaluation of the holter recording must always be preceded.

If the patient has cardiac arrhythmia (especially atrial fibrillation), HRV analysis (RR variability) is not suitable for diagnostic purposes.

The HRV parameters shown in custo diagnostic are to be considered in the individual overall context (general condition and life situation of the patient). The evaluation of the results by a qualified physician is essential.

For an improved informative value, it is advisable to repeat the examination so that a development of the condition can be seen.

Cardiac rehabilitation

Applies to:
Rehab systems

All devices comprising the custo med rehab system (exercise devices, external blood pressure gauges, etc.) must be medical devices.

The ECG signal of a patient displayed and recorded in custo diagnostic may not be used for clinical evidence or diagnosis. The ECG signal is heavily filtered to facilitate the most stable and continuous heart rate display during rehabilitation training. The ECG signal as well as the heart rate are used exclusively for training control during rehabilitation training.

Telemetric Holter (custo kybe centre)

Applies to:
custo kybe
with custo guard

custo kybe is not designed for use with infants or small children.

The use of the device in connection with life-sustaining devices is prohibited. The device is not suitable for intensive care or as an alarm system for life-sustaining bodily functions.

Spirometry

Applies to:
custo spiro mobile

If custo spiro mobile is transported at temperatures below freezing point, the device must only be put into operation when it has reached ambient room temperature. Observe the operating conditions

To ensure precise measuring results, the environmental data in custo diagnostic must be adapted to local conditions (air humidity, temperature, etc.). Otherwise this may falsify the measurement data obtained.

Only use bacterial and viral filters approved by custo med, such as custo spiro protect. Unsuitable filters may falsify the measurement data obtained.custo spiro protect is a single-use article. Make sure that it is disposed of after each examination in a safe and environmentally responsible manner.

Technical accessories

Applies to:
custo router

custo router – virtual device interface

Never expose the device to water or moisture and do not place it on a conductive surface while it is in operation.

Never expose the device to external heat sources; custo router is designed for use at normal room temperature.

Avoid any mechanical impact as it could cause damage to the circuit board and the connections.

1.2.5 System and data security

IMPORTANT: Patient data must be handled in accordance with the legal requirements of the respective country (this includes the General Data Protection Regulation (GDPR)). custo diagnostic offers functions to help you meet these requirements (e.g. user administration, password assignment).

Manufacturer's note for users/customers for the integration of programmable electronic medical systems (PEMS) into existing IT networks

The custo med products and systems are programmable electronic medical systems (PEMS). The integration of custo med products into an IT network that includes other devices can lead to risks for patients, operators or third parties that were not previously known. The responsible organisation should identify, analyse, evaluate and control these risks. Subsequent changes to the IT network can lead to new risks, and therefore require additional analysis.
Changes to the IT network include the following: Changes to the IT network configuration, connecting additional items to the IT network, removing items from the IT network, updates/upgrades of devices that are connected to the IT network.

custo diagnostic

The device must only be used with the supplied custo med software (custo diagnostic).

As the operator you are responsible for ensuring regular data backups (patient databases, evaluations etc.) and system backups. We recommend that you backup the data at the latest before new installations, updates and far-reaching system configurations.
custo diagnostic new installations, updates and system configurations may only be performed by your authorised custo med distributor.

Only change data generated in custo diagnostic within custo diagnostic itself and not in your surgery IT system or your hospital information system (HIS). custo med does not accept any responsibility for any changes to data in your IT system or your HIS which were made after the export from custo diagnostic.

To ensure the safe operation of custo diagnostic, deactivate the screensaver and energy management options on your PC. Set up your operating system in such a way to prevent the PC from being switched off either accidentally or automatically during the examination (standby mode/idle mode).

custo connect

If you use custo connect to integrate additional medical devices in the custo med system, for automatic PDF printouts from the connected medical device, check whether the PDF file belongs to the current patient. Do not trigger any PDF printouts in other programs during the PDF printout in the connected medical device.
If you use custo connect to integrate additional medical devices in the custo med system, on starting the connected medical device check whether the patient name was taken over correctly.

Allocation of case and job numbers

If case or job numbers are manually entered into the system or they are changed in the system, there is a risk of confusing patients and subsequent misdiagnosis if an incorrect entry is made by a user. Always make sure that case or job numbers are entered correctly!
Scanning or manually entering patient, case or job numbers does not relieve the user of the obligation to check the patient to be physically treated.

Data management in custo diagnostic: Assign evaluation (allocate evaluation)

If an examination was conducted with incorrect patient data, the evaluation can be subsequently allocated to the correct patient. Make sure that the evaluation is definitely allocated to the correct patient. Incorrect allocation can lead to misdiagnosis. Please note that data which has already been exported to an external system (e.g. surgery IT system) cannot be changed.

custo diagnostic is preset with the Assign evaluation function deactivated; however it can be reactivated via user rights if necessary. Only the Supervisor can configure user rights. If the Assign evaluation function is activated, it can be found in the evaluation search or in open evaluations in the Options menu.

We recommend configuring user rights in custo diagnostic so that only authorised persons can execute the Assign evaluation function.

1.3 Information on EMC (Electromagnetic Compatibility)

The use of other accessories, other converters and leads than those indicated, except for the converters and leads sold by custo med as spare parts for inner components, can lead to increased electromagnetic emissions or to a reduced electromagnetic immunity of the system. For connecting the device to other equipment, only specially screened cables supplied by custo med must be used.

1.4 Maintenance (regular safety checks)

The operator is responsible for maintenance.

Observe the legal regulations for checking electrical systems and equipment (e.g. Regulation 3 "Accident Prevention Regulation" of the German Social Accident Insurance (DGUV) in the Federal Republic of Germany).

The functionality and the state of accessories must be checked at regular intervals. If damaged or heavily soiled, the complete system must no longer be used.
After each system or device repair, modification or conversion, your authorised custo med distributor must perform a safety and conformity assessment.

1.5 Putting out of operation, storage, transport, disposal

1.5.1 Putting out of operation and storage

Clean and disinfect the devices and their components before putting them out of operation.
Make sure that the storage location is dust-free, dry and away from direct sunlight.

After a long period of non-operation, the devices may only be used again if a technical safety check has been carried out by your authorised custo med distributor.

1.5.2 Transport

Clean and disinfect the devices and their components before transport. Use the original packaging for transport. These devices are sensitive pieces of electronic equipment. If the original packaging is not available, pack the devices in such a way that they are protected against impact, moisture and dust.
The devices must comply with the operating conditions when they are put into operation again, e.g. operating temperature.

1.5.3 Disposal

The devices and all their components must be disposed of in a proper manner in compliance with applicable regulations (that is, in accordance with the valid laws governing waste electrical and electronic equipment). The devices must not be disposed of as normal domestic waste. Observe the disposal instructions for consumables. The original packaging is recyclable (cardboard/waste paper).

1.5.4 Symbols used for storage, transport and disposal


Fragile, handle with care


Keep dry


Protect from sunlight


Temperature limit


Separate collection of electrical and electronic equipment
(placed on the market after 23 March 2005)

1.6 Disclaimer

The manufacturer will not be held liable for improper operation, non-compliance with safety instructions and negligently skipped instructions.

custo med only assumes responsibility for the safety and reliability of the device if all changes, enhancements, repairs and other work on the device or system have been performed by an authorised custo med distributor or custo med and the Operating Manual has been observed during device operation.

1.7 Warranty

Our product philosophy is committed to providing you with faultless products which meet your expectations. Should you have reason to complain we aim to rectify any defects immediately or provide a replacement delivery.
This does not include damage that can be attributed to usual wear and tear, improper use, unauthorised modification of parts and the use of violent force.
After the warranty period has expired, only use original spare parts and accessories supplied by custo med. Only this will ensure the safe and problem-free operation of your device.

1.8 Support

If you have any questions or problems which are not dealt with here, please do not hesitate to contact your authorised custo med distributor. A list of authorised custo med distributor can be found on the Internet at www.customed.de, under Contact, Distributors.
You can also contact custo med GmbH directly at any time. We will be pleased to provide you with information about your authorised custo med distributor or contact your authorised custo med distributor and forward your queries.

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