Operating Manual

custo diagnostic Systems / Devices

1 Safety | 2 Hardware | 3 Software | 4 Hygiene

Part 1: Safety | Maintenance | Warranty

Operating characteristics:

for custo systems / devices
with custo diagnostic

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custo·med
EXCELLENCE IN DIAGNOSTICS

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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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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 this Operating Manual, in particular the safety instructions.

Laws and regulations applicable to the product

- The custo systems are designed in accordance with the Medical Device Directive 93/42/EEC, Class IIa, and meet the requirements of safety class I or II (depending on the power supply unit used; the recorder and/or the ECG transmitter are devices with an internal power supply), Type BF according to DIN EN 60601-1, (cardio 100/110/130/200: Type BF (defibrillation-protected)).

- Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (DIN EN 60950) or the Standard for Electrical Medical Devices (DIN EN 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

The custo med systems must only be used in a technically perfect condition. Regularly carry out a visual inspection of the devices and the corresponding components. Use only 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 devices. For assembly it is recommended to use portable multiple socket outlets approved by custo med, e.g. medical protector.

1.2.1 General safety instructions

For the installation and the operation of the devices/systems, the EMC notes (electromagnetic compatibility) included in this Operating Manual must be observed.

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

Strong electromagnetic sources in the immediate vicinity of the custo med device/system may result in recording errors. The custo med system must not be stored or used in the vicinity of X-ray equipment, diathermy units and 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 they comply with the applicable emissions requirements according to CISPR.

Do not modify the devices/systems. Only use the supplied power supply units for charging. Contact your authorised custo med dealer for repairs.

The devices/systems must be protected against heat, moisture, dust and dirt. Contact with liquid can impair the functioning of the devices/systems. It is not permitted to wear the devices/systems in a swimming pool, in the sauna or in the bathtub/shower or similar wet environments. Do not submerge the devices/systems in liquid. They must be protected from mechanical impact, such as damage due to dropping or transit damage. Avoid heavy mechanical loads.

Some devices/systems contain a rechargeable lithium polymer battery. Any mechanical stress which is beyond the intended use must be avoided. Do not use force to open the devices/systems.

Some devices/systems contain a rechargeable lithium ion battery. Remove the rechargeable battery when the device is not in use. Only use the supplied charger to charge the rechargeable battery. Do not expose the rechargeable battery to extreme temperatures, fire and moisture. Do not immerse the rechargeable battery 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.

Special features of ABPM systems

The custo screen 300/400/pediatric recorder is not protected against the ingress of dust and spray water. custo screen 300/400/pediatric must be protected against moisture, dust, dirt and mechanical impact such as damage due to dropping or transit damage.

Using the custo screen 300/400/pediatric in an environment where external vibrations are to be expected, e.g. in an ambulance, helicopter or other means of transport, may result in erroneous measurements.

Special features of Holter systems

custo watch and custo guard 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 bathtub. Do not submerge the devices in liquid.

custo kybe is not protected against the ingress of dust and spray water. custo kybe must be protected against heat, moisture, dust and dirt. Contact with liquid can impair the functioning of the device. It is not permitted to wear the device in a swimming pool or in the bathtub. Do not submerge the custo kybe in liquid. custo kybe must be protected from mechanical impact, such as damage due to dropping or transit damage. Avoid heavy mechanical loads.

Special features of Resting/Stress ECG

The custo cardio 100/110/130/300 devices are protected against defibrillation only in connection with the manufacturer's patient cable. For custo cardio 300 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. The custo cardio 100/110/130/300 ECG device has a recovery time of less than ten seconds, in the case of custo cardio 200 it is less than five seconds.

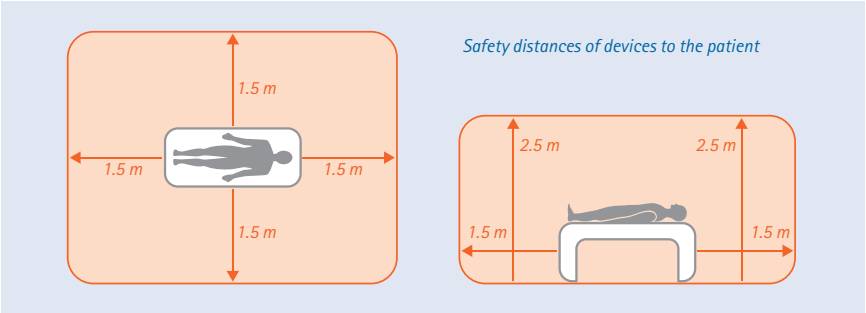
Special features of pulmonary function systems

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.

USB cable

Some devices/systems have a USB cable. It must not be kinked. Do not step onto the USB cable and only roll up the cable loosely and allow it to hang freely during operation. Always use the connector on the USB cable to disconnect it from the PC

1.2.2 Patient safety



When coupled with other devices, make sure that there is no danger due to the summation of leakage currents. 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).

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

Special features of ABPM systems

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. If the cuff is too tight, this can lead to vein blockages, contusions and bruising. If the patient is not feeling well, the patient should consult his/her medical practice.

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 is suffering from diseases such as arterial occlusive disease or serious blood coagulation disorders, the physician has to decide whether the device should be used or not.

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. 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.

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. The device is not protected against the potential effects of high frequency (HF) surgical equipment.

Never use damaged batteries or rechargeable batteries. If custo screen 300/400/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 accumulators immediately and send the device for inspection to your authorised custo med dealer or custo med.

Special features of Holter systems

With custo guard no pacemaker detection is possible. Any disturbances in the ECG signal may incorrectly be interpreted as a pacemaker.

In the case of known allergies, e.g. against substances in the adhesive electrodes or custo belt, the further procedure must be agreed with the physician before the commencement of recording.

If patients experience discomfort during a recording, they must contact their physician.

The results obtained from a Holter evaluation, in particular the pathological events, must be verified by a qualified physician.

The custo guard ECG transmitter may only be used in combination with the custo belt electrode belt or ECG cable guard 3. Electrode belts from other manufacturers may change the band width and amplitude of the ECG signal which could result in a misdiagnosis.

Special features of Resting/Stress ECG

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 (in some devices). 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. The device is 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 with an electrode application system, operating at higher suction levels may cause irritation or hematoma 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 doctor must decide whether to use the device.

Special features of pulmonary function systems (custo spiro mobile)

Use only bacterial and viral filters approved by custo med, e.g. 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.

1.2.3 System and data security

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 dealer.

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 surgery 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

When 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.

When 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.

Data management in custo diagnostic: allocate new 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. An incorrect allocation can lead to a 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 Allocate new evaluation function deactivated; however it can be reactivated via user rights if necessary. Only the Supervisor can configure the user rights. If the Allocate new 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 Allocate new evaluation function.

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.

Recorder and memory cards

If using several recorders and/or memory cards, make sure not to mix them up.

custo med recommends leaving the supplied memory cards (if available) in the respective recorders to ensure that they cannot get lost and that no dirt can enter through the opening.

The memory cards may only be inserted or removed when 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.

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

1.3 Maintenance (regular safety checks)

According to the Medical Devices Operator Ordinance (MPBetreibV), the operator is responsible for maintenance. custo med does not prescribe any technical safety checks (TSC) should be carried out. However, inspections of all electrical systems and equipment must be carried out every two years according to DGUV Regulation 3 (accident prevention regulation, formerly BGV A3).

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

1.4 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 and/or system have been performed by an authorised custo med dealer or custo med and the Operating Manual has been observed during device operation.

1.5 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.

1.6 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.

1.7 Putting out of operation, storage, transport, disposal

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 dealer.

Transport

Clean and disinfect the devices and their components before transport.

Use the original packaging for transport. These are sensitive electronic devices. 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.

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, see chapter Cleaning and disinfection.

The original packaging is recyclable (cardboard/waste paper).

Symbols for storage, transport and disposal

Fragile, handle with care	
Keep dry	
Protect from sunlight	
Temperature limit	
Separate collection of electric and electronic devices	
Separate collection of electric and electronic devices (placed on the market after 23/03/2005)	

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 dealer. A list of authorised custo med dealers can be found on the Internet at www.customed.de, under Contact, Dealers.

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 dealer or contact your authorised custo med dealer and forward your queries.

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