Operating Manual

Mobile Cardiac Telemetry

Telemetric ECG monitoring with custo kybe and custo diagnostic

Operating characteristics:

custo diagnostic V04 and higher for Windows®

GEB 0195 – DK 1634
10/01/2017

CE 0123
Operating Manual

Mobile Cardiac Telemetry

Telemetric ECG monitoring with custo kybe and custo diagnostic

© 2017 custo med GmbH

This Operating Manual may not be copied in its entirety or in part, duplicated in any form or by any means or translated into another language without the prior written consent of custo med GmbH.

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, under SUPPORT, Operating manuals.

Manufacturer’s contact details:
custo med GmbH
Maria-Merian-Str. 6
85521 Ottobrunn, Germany
Germany

Phone: +49 (0) 89 710 98 - 00
Fax: +49 (0) 89 710 98 - 10
Email: info@customed.de
Internet: www.customed.de
Table of contents

01 Introduction
01.1 Symbols on the devices.......................................................... 6
01.2 Intended use ......................................................................... 6
01.3 Symbols used in this Operating Manual .................................. 7

02 Safety instructions
02.1 General notes ....................................................................... 8
02.2 Safety installations and safe working .................................... 8
02.3 Information on EMC (Electromagnetic Compatibility) ............ 14
02.4 Maintenance (regular safety checks) ..................................... 14
  02.4.1 custo kybe service life .................................................... 14
  02.4.2 Maintenance tips for the custo kybe device ....................... 15
02.5 Disclaimer ........................................................................... 15
02.6 Warranty ............................................................................. 15

Description of device, basic instructions for initial operation
03.1 Part names, components for ECG monitoring ....................... 16
03.2 Overview of commissioning of the custo kybe device .......... 18
03.3 custo kybe ports and buttons .............................................. 19
03.4 custo kybe SIM card and micro SD card .............................. 20
03.5 Charging the custo kybe ....................................................... 21
03.6 Charging the custo guard ..................................................... 22
03.7 Switching custo kybe on and off ......................................... 23
03.8 custo kybe screens at commissioning ................................. 24
03.9 custo kybe main menu, operating elements ....................... 25
03.10 Overview of all custo kybe screens .................................... 26
  03.10.1 Show ECG ................................................................ 27
  03.10.2 Mark ECG ................................................................. 27
  03.10.3 Send ECG ................................................................. 28
  03.10.4 Call physician ........................................................... 28
  03.10.5 Messages ................................................................. 29
  03.10.6 Status information ..................................................... 29
  03.10.7 Functions in the settings menu ................................... 30
03.11 custo diagnostic – basic program structure ....................... 31
03.12 Functionality of the custo MCT system ............................ 32
03.13 Commissioning of the custo MCT system .......................... 33
03.14 Settings on the "Master PC" of the custo MCT system .......... 34
03.15 Print Settings (user-specific) ............................................. 35

04 Hygiene
04.1 Cleaning and disinfection .................................................... 36
04.2 Approved cleaning agents and disinfectants ....................... 37
04.3 Disposing of the adhesive electrodes (single-use items) ........ 37

05 Starting custo kybe recording
05.1 Overview of the steps .......................................................... 38
05.2 Patient information, operating the device ......................... 39
05

05.3 Preparing the custo kybe.................................................................40
  05.3.1 Connect device to the PC..........................................................40
  05.3.2 Program start........................................................................40
  05.3.3 Setting analysis parameters, configure the device for patients…41
  05.3.4 Specifying custo kybe functionality........................................42
  05.3.5 Enter the telephone number of the SIM card........................44
  05.3.6 Start, transmit data................................................................44
  05.3.7 Equipment for the recording..................................................45
  05.3.8 Device management.................................................................46

05.4 Receiving custo guard ECG
  05.4.1 Connecting custo guard with the custo kybe..........................48
  05.4.2 Checking ECG on the custo kybe............................................49
  05.4.3 Fitting the custo guard with the custo belt electrode belt........50
  05.4.4 custo belt 3 length adjustment..............................................51
  05.4.5 Fitting custo guard w. cable adapters & adhesive electrodes.....52

05.5 Creating and storing individual recording profiles..........................53

06

ECG monitoring, reading the recording
  06.1 Procedures for ECG monitoring................................................54
  06.2 Structure and navigation in the custo MCT software....................55
  06.3 Transmission of the ECG data to the custo MCT software.............56
  06.4 Open and evaluate ECG data
    06.4.1 Access via patient list..........................................................56
    06.4.2 Access via targeted selection of a patient..............................58
    06.4.3 Overview screen of a patient...............................................59
  06.5 Control options, communication with the patient
    06.5.1 Online monitoring.................................................................60
    06.5.2 Send a message to the patient..............................................61
    06.5.3 Request ECG from the patient...............................................62
    06.5.4 Make remote settings on the custo kybe..............................53
    06.5.5 Create printout.................................................................64
    06.5.6 Export ECG by email or fax.................................................66
  06.6 Reading ECG recording
    06.6.1 Read and store ECG in the custo MCT software....................67
    06.6.2 Open recording data as Holter evaluation in custo tera...........68
  06.7 End ECG recording on custo kybe..............................................69

07

Product information
  07.1 custo kybe – possible malfunctions and countermeasures............70
  07.2 Technical data and system requirements.....................................72
  07.3 Support....................................................................................75
  07.4 Manufacturer’s Declaration regarding EMC (electromagnetic
                  compatibility) according to IEC 60601-1-2:2007......................76
  07.5 EC Declaration of Conformity..................................................79
  07.6 Decommissioning, storage and transport.....................................80
  07.7 Disposal....................................................................................80
  07.8 Keyboard navigation and shortcuts in custo diagnostic..................81
## 01 Introduction

### 01.1 Symbols on the devices (custo kybe, custo guard, custo charger)

<table>
<thead>
<tr>
<th>Manufacturer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CE 0123</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection class classification of medical electrical equipment according to IEC 60601-1 (Type BF)</td>
</tr>
</tbody>
</table>

| Non-ionising electromagnetic radiation, |
| Device includes an RF transmitter |

| Observe the Operating Manual |

| Separate collection of electrical and electronic equipment, |
| do not dispose with domestic waste. The disposal of the rechargeable lithium polymer battery (custo kybe) can be carried out by the manufacturer. |

### 01.2 Intended use

custo kybe is a battery-powered, medical recording, analysis and information device, which can be used in both the clinical and ambulatory environment, and is designed for continuous operation.

The device is intended for use by trained specialist staff or physicians in clinics and medical practices. Patients are only allowed to use the recording device after receiving instruction by trained specialist staff. Patients who are not capable of understanding and following the instructions given are not allowed to use the device. This applies in particular to senile patients or patients suffering from dementia.

Users wear the device on their body in a carrying case, or in a trouser or jacket pocket. The device receives medically relevant vital signs from the user (e.g. continual ECG signals with the aid of custo guard and custo belt) with additional, manufacturer-approved sensors. This data is stored on the device, analysed and, if necessary, transmitted by telemetry to the custo kybe center (evaluation software in the medical practice).
The device is not suitable for use with infants and 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.

01.3 Symbols used in this Operating Manual

This Operating Manual uses the following symbols to indicate important information, comments and tips:

**ACTIONS THAT ARE PROHIBITED**
or not allowed under any circumstances!

**WARNING**
used to indicate situations which, if not avoided, may result in personal injury or property damage

**NOTE**
provides important information which must be observed

**TIP**
contains practical information to assist you with your work

Words highlighted in colour indicate buttons or click paths for each described program section, such as Examination, Mobile Cardiac Telemetry. Words highlighted in colour.
02 Safety instructions

02.1 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

- This system is designed according to the Council Directive on Medical Devices 93/42/EEC, Class II a, and complies with protection class I or II (depending on the power supply unit used), custo kybe and custo guard are devices with internal power supply, type BF (only applies to custo guard) 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 60950) 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.

02.2 Safety installations and safe working

custo kybe must only be used in a technically perfect condition. Regularly carry out a visual inspection of the device and its 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.

Installation of the system

- 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.

**Ambient conditions for custo kybe and custo guard**

For the installation and operation of the device the EMC instructions (electromagnetic compatibility) in this manual must be observed, see *Chapter 07.4 Manufacturer’s Declaration regarding EMC*...

custo kybe system is not suitable for operation in rooms and areas with a risk of explosion.

Strong electromagnetic sources in the immediate vicinity of the custo kybe and custo guard may result in recording errors. custo kybe and custo guard 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 custo guard, even if they comply with the applicable emissions requirements according to CISPR.

custo kybe is not protected against the ingress of dust or spraying water. custo kybe must be protected from heat, moisture, dust and dirt. Contact with liquids may impair proper functioning of the device. Wearing the device in the swimming pool or in the bathtub is prohibited. custo kybe must not be submerged.

custo kybe must be protected from mechanical influences such as falling or transport damage. Excessive mechanical stress should be avoided.

custo guard is protected against the ingress of dust and spray water (IP65). Wearing the device in the swimming pool or in the bathtub is prohibited. custo guard must not be submerged.

custo kybe and custo guard contain rechargeable lithium polymer batteries. Any mechanical stress which is beyond the intended use must be avoided. Do not use force to open the device.

The custo guard ECG transmitter may only be used in combination with the custo belt electrode belt or adhesive electrodes. Electrode belts from other manufacturers may alter the bandwidth and amplitude of the ECG signal which may result in a misdiagnosis.
Safety instructions

Do not modify the device. Only use the supplied charger for custo kybe for charging. Contact your authorised custo med dealer for repairs.

Patient safety

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.

Bei bekannten Allergien, z.B. gegen Substanzen in Klebeelektroden oder custo belt, ist die weitere Vorgehensweise vor der Aufzeichnung mit dem Arzt zu klären.

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

All results of the 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.

Do not leave small children unattended with the device. Risk of strangulation with the supplied cables and belts, risk of suffocation from small parts that could be swallowed.
Notes on pacemaker detection

With custo guard pacemaker detection is not possible.

Any interference in the ECG signal may be interpreted as a pacemaker by mistake.

custo kybe memory card, SIM card

The micro SD card contains the custo kybe operating system and serves as the storage medium for the ECG data. custo kybe only functions if the micro SD card is inserted.

Removal of the card is not required in normal operation and should only be performed by your authorised custo med dealer.

The micro SD and SIM cards may only be inserted or removed when custo kybe is switched off.

The prepaid SIM cards distributed by custo med are supplied with 60 call minutes and 200 MB data volume (for the transmission of ECG data).

The SIM card contained in the custo kybe may not be inserted in any other devices. The SIM card may be used only for custo kybe.

Hygiene

For cleaning and disinfection observe the legal requirements and the current state of technology.

Use only cleaning agents and disinfectants approved by custo med for cleaning and disinfection. Clean and disinfect your device in accordance with the specifications given in Chapter 04 Hygiene.
02 Safety instructions

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 backing up data before new installations, updates and far-reaching system configurations, at the latest.

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 EPR system (Electronic Patient Record) or your hospital information system (HIS).

custo med does not accept any responsibility for any changes to data in your EPR 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 a way that prevents 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 start any PDF printouts in other programs during a PDF printout from 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: 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. 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 Assign evaluation function deactivated; however it can be reactivated via user rights if necessary. Only the Supervisor can configure the 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.

Assignment of case and job numbers

If the case or job numbers are manually entered or modified by the user in the system and if an incorrect entry is made, there is a risk of incorrectly identifying the patient and of a subsequent misdiagnosis. Always ensure that the case or job numbers are entered correctly!
02 Safety instructions

02.3 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 may be used.

02.4 Maintenance (regular safety checks)

The operator is responsible for maintenance. The operator must ensure that the device is checked for proper condition at the latest every two years. The functionality and the state of accessories must be checked at regular intervals. If damaged and/or heavily soiled, the entire system must no longer be used.

Any interventions in the existing system, changes to system components, enhancements as well as internal cleaning and repairs may only be performed by your authorised custo med dealer or custo med.

Technical safety check
After each system or device repair, modification or conversion, a technical safety check must be performed by your authorised custo med dealer.

02.4.1 custo kybe service life

The service life duration of custo kybe is reached after 24 months or 350 charging cycles, whichever occurs first. The service life duration is a result of the capacity loss of the rechargeable battery.

After 24 months or 350 charging cycles, the condition of the device should be checked and the rechargeable battery replaced. If the maintenance interval of 24 months or 350 charging cycles is respected, the service life duration of the device is extended by another 350 charging cycles. Please contact your authorised custo med dealer.

Failure to meet the specified maintenance interval leads to a reduction in the service life duration.
02.4.2 Maintenance tips for the custo kybe device

➤ Regular cleaning of the device, see Chapter 04 Cleaning.
➤ Disconnect the device from the power supply once it is fully charged and only recharge as needed.
➤ Compliance with the maintenance interval specified by the manufacturer (350 charging cycles or 24 months, whichever occurs first).
➤ In the case of external damage or malfunction, contact your authorised custo med dealer or custo med.

02.5 Disclaimer

The manufacturer is not responsible for improper operation, failure to comply with the safety instructions and non-observation of specifications due to negligence.

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

02.6 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.

Only use original spare parts and accessories from custo med even after the end of the warranty period. This is the only way to ensure the safe and trouble-free operation of your device.
03 Description of device, basic instructions for initial operation

03.1 Part names, components for ECG monitoring

- (Art.-Nr. 10402) custo kybe UMTS
- (Art.-Nr. 55038) micro SD card and SIM card (in the device, not shown)
- (Art.-Nr. 20055) custo kybe carrying case
- (Art.-Nr. 20011/C) custo kybe carrying belt
- (Art.-Nr. 10110-T) Charging cable for custo kybe
- (Art.-Nr. 10101/R) USB cable for connecting the custo kybe with the PC

Only use the power supply unit specified/defined by the manufacturer!
## Approved accessories for ECG recording

<table>
<thead>
<tr>
<th>Art.-Nr.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10102</td>
<td>custo guard 1, ECG transmitter for 1-channel ECG</td>
</tr>
<tr>
<td>10101/R</td>
<td>custo belt 1 red, electrode belt for 1-channel ECG</td>
</tr>
<tr>
<td>10302</td>
<td>custo guard 3, ECG transmitter for 3-channel ECG</td>
</tr>
<tr>
<td>10301/R</td>
<td>custo belt 3 rot, electrode belt for 3-channel ECG</td>
</tr>
<tr>
<td>10103</td>
<td>custo single charger (charger and programming unit for ECG transmitter)</td>
</tr>
<tr>
<td>23064</td>
<td>Case and for custo guard</td>
</tr>
<tr>
<td>23065</td>
<td>Neck strap for custo guard</td>
</tr>
<tr>
<td>10106</td>
<td>Cable adapter for disposable adhesive electrodes (for custo guard 1: two pieces, for custo guard 3: three pieces)</td>
</tr>
<tr>
<td>10118</td>
<td>custo belt 1/3 extender, extension for electrode belt</td>
</tr>
<tr>
<td>10301/R</td>
<td>Power Pack für custo charger single</td>
</tr>
<tr>
<td>20012/C</td>
<td>Carrying belt long, 155 cm</td>
</tr>
<tr>
<td>20015/C</td>
<td>Carrying belt children, 96 cm</td>
</tr>
</tbody>
</table>

![Approved accessories for ECG recording](image-url)
03.2 Overview of commissioning of the custo kybe device

During commissioning of the custo Mobile Cardiac Telemetry (MCT) system your authorised custo med dealer may have prepared the custo kybe devices for operation. In this case the step by step instructions described below can be omitted. If you are commissioning the devices yourself, proceed as described in the following chapters.

Chapter 03.4
Insert the micro SD card and SIM card in the custo kybe

Chapter 03.5 and 03.6
Fully charge custo kybe and custo guard

Chapter 03.7
Switch on the custo kybe

Chapter 03.8
Enter the PIN code of the SIM card

Chapter 03.8
Select the language for the user interface of the custo kybe

Chapter 03.8 and 05.4.1
Connect custo guard ECG transmitter to the custo kybe
03.3 custo kybe ports and buttons

1. Display
2. Speaker
3. Microphone
4. USB 2.0 interface
5. Micro USB connection for the charger and connection with PC
6. On/off button:
   - Pressing the button briefly switches on the custo kybe,
   - pressing the button for 3 seconds activates the power off menu,
   - pressing the button for 5 seconds or more switches off the kybe in the event of a malfunction.
7. Cover for card slots and the restart button
8. Restart button
9. Card slot for SIM card
10. Card slot for micro SD card
03.4 custo kybe SIM card and micro SD card

The micro SD card is used to store data. The SIM card is required so that the patient can communicate with the custo MCT software via mobile telephony (transmission of ECG data, call physician, availability by telephone, etc.). Depending on the purpose and pre-configuration of the device, the cards may already be in the device. If you receive the cards separately or would like to use your own SIM card, follow these steps:

1. Make sure the device is switched off!
   (Press and hold the on/off button for 3 seconds to open the power off menu and then press the power off symbol)
2. Open the cover on the upper edge of the case.
3. Insert the SIM card in the first card slot
   (with the rounded corner of the SIM card at the top left).
4. Insert the micro SD card in the second card slot.
   The contacts face toward the front.
   Gently press down on the edge of the card until the card clicks into place. Close the cover.

We recommend inserting the SIM card into the device before the first use. Cards may only be inserted or removed when the device is switched off.

Removing cards from the device
Tweezers can be used to remove the SIM card. To remove the micro SD card, press lightly on the edge of the card. The card automatically comes out (push-pull principle). Do not use force to remove the card.
03.5 Charging the custo kybe

IMPORTANT:
Fully charge custo kybe before the first use.

Charging the custo kybe
Connect custo kybe to the mains with the charging cable 1. The charging cable is connected to the micro USB connector on the device 2. Once the device is connected to the mains it switches on. During the charging process, three small arrows are displayed in the custo kybe battery symbol which indicates that the battery is charged. The display can be switched off by briefly pressing the on/off button. The battery is fully charged after four hours.

Always give the patient a newly and fully charged device for the recording.

Frequency of charging cycles
For a continuous ECG recording, custo kybe must be charged once per day or latest when the battery warning appears. Pay attention to the battery symbol of the custo kybe in the status bar (at the top of the screen). If the rechargeable battery is almost empty, no bars are visible in the battery symbol and the rechargeable battery turns red: 📈.

Information for Patients
During the charging process, custo kybe must be within radio range and have a clear line of sight connection to the fitted custo guard ECG transmitter so that the ECG recording is still possible. For example, the custo kybe can be charged during the night.
03.6 Charging the custo guard

**IMPORTANT:**
Fully charge the custo guard before the first use.

**Connect the charger**
Connect the charger to the mains with the power supply. The charger is ready for operation when the LED on the charger is orange. Only use the supplied power supply for the charger!

**Charge ECG transmitter**
Place the custo guard ECG transmitter on the charger. The direction of insertion is based on the shape of the device. The LED on the ECG transmitter provides information on the charging status:

- **RED:**........................................................... ECG transmitter is charging
- **GREEN:**..........................................................Charging complete

**IMPORTANT:** Only insert a clean and dry ECG transmitter in the charger. Dirty or damp ECG transmitters permanently damage the contacts of the charger. Do not allow any moisture to get into the charger.

**Frequency of charging cycles**
Depending on the model, custo guard must be charged every two or three days, latest when the custo guard warning appears on the custo kybe. The custo guard battery symbol in the status bar of the custo kybe (at the top of the screen) also shows the status of the battery. If the rechargeable battery is almost empty, no bars are visible in the battery symbol and the battery symbol turns red.

For an uninterrupted ECG recording, the patient can be given a second ECG transmitter, which can be fitted by the patient while charging the first one. In order to make it possible to record, the second custo guard ECG transmitter must be connected with the custo kybe, see Chapter 05.4.1 Connecting custo guard with the custo kybe.
03.7 **Switching custo kybe on and off**

**Start-up and Commissioning**
To start up the device, briefly press on the on/off button. The custo kybe logo appears on the display. After approximately 15 seconds the first screen is displayed. If custo kybe was switched on and configured already, the main menu is displayed. If you are commissioning the device, several entries are required before the main menu is displayed.

The first time the custo kybe device is started, the commissioning screens are automatically displayed in the proper order: Input of the PIN code, language selection for the interface, selection of an ECG transmitter. Follow the instructions on the screen, see Chapter 03.8 **custo kybe screens at commissioning**.

If the custo kybe is switched on and the display is on, the display can be switched off again by briefly pressing the on/off button. The device remains on.

**Using the custo kybe display**
In order to trigger a function on the custo kybe, touch the corresponding button on the display. If you have problems activating the buttons with your finger, you can also use a pen. Make sure that the pen is closed and only press lightly. The point of the pen must not be made of metal!

**Power Off (Decommissioning)**
If the ECG recording has ended or custo kybe is not in use, switch off the device. Hold down the on/off button for three seconds. The power off screen is displayed. Press the power off symbol. If the device does not switch off this way (error), press the on/off button for five seconds. Make sure that the storage location is dust-free, dry and away from direct sunlight.
03.8 custo kybe screens at commissioning

1. Enter the PIN code and confirm it with OK.

2. Select the Language for the user interface and confirm it with OK. The selected language is highlighted in green and marked with a check mark. After you select the language the device is restarted. If no language is selected (Cancel button), the currently selected language remains in effect and the next screen is displayed.

3. If custo kybe has not been connected and started with custo diagnostic yet, a message is displayed after restart that the device has not been configured yet. Confirm with OK.

4. Next, you can select the ECG transmitter to connect to the custo kybe. All ECG transmitters that are in radio range are displayed on the custo kybe. Select the desired ECG transmitter using the serial number (see the back of the device) and confirm with OK. The selected ECG transmitter is saved in the custo kybe and the selection dialogue is no longer displayed in future. The selection of the ECG transmitter can be also made at a later time (Cancel button).
03.9 custo kybe main menu, operating elements

The status bar (1 to 8) provides information about the condition of the devices:

1. “K” stands for custo kybe
2. custo kybe GSM reception (mobile telephony)
3. custo kybe battery status:
   During the charging process, three small arrows are displayed on the custo kybe battery symbol.
4. “G” stands for custo guard (ECG transmitter)
5. Quality of the connection between custo guard and custo kybe;
   if no custo guard is connected / in radio range, the red GUARD? symbol is displayed.
6. custo guard battery status
7. custo kybe device settings
8. Time and date
9. custo kybe main menu
   (available functionality depends on the configuration)

The functions in the Main menu (9) are activated by touching the corresponding buttons. If you are in a sub-menu, you can get back to the main menu with the Back or Cancel buttons.

If no action is performed for a longer period, the display switches off. The display is activated by pressing the on-off button on the top edge of the device.
03.10 **Overview of all custo kybe screens**

Depending on the type of application and the device configuration, some of the screens and functions shown here may not be available. The individual screens and their functions are shown on the next pages.
03.10.1 Show ECG
The ECG signal is displayed on this screen.

If a 3-channel ECG is recorded, you can switch between the channels with the Channel 1, Channel 2, and Channel 3 buttons.
The current heart rate (HR) is displayed in the box at the bottom left. The magnitude of the ECG signal can be changed with the “+” and “-” buttons. Use the Back button to return to the main menu.

03.10.2 Mark ECG
Events can be marked in this screen during the ECG recording. Events may include stress, discomfort, palpitations, taking medication, etc. To set a marker, the patient must press the Mark ECG button, and select a reason for the marker.

By pressing the OK button, the marker is saved in the ECG recording.

The marker texts can be set by the specialised medical staff when custo Kybe is configured and started in custo Diagnostic. This also applies to the texts for sending the ECG, see 03.10.3 Send ECG.
03.10.3 Send ECG

On this screen, ECG sections can be sent to the physician’s surgery. The length of the ECG sections is specified in custo diagnostic.

In order to send the ECG, the patient must press the Send ECG button on the main menu and then select a reason for transmitting the ECG data. By confirming with the OK button the ECG is transmitted to the physician’s surgery and saved in the database of the custo MCT system for evaluation. Depending on the type of event, the specialised medical staff can send feedback to the patient by contacting the patient by phone or by sending a text message.

03.10.4 Call physician

On this screen the physician’s surgery can be called. The telephone number of the contact person is transmitted to the custo kybe when the device is configured and started in custo diagnostic.

To call the physician’s surgery, the patient must press the Call physician button and then the green call button. In order to end the call, the red end call button must be pressed.

Only the telephone number saved in the custo kybe can be called from this screen.
03.10.5 Messages
This screen displays all messages that were sent from the custo MCT software to the patient.

Use the Arrow keys on the right side of the screen to page forward and backward. The list entries are used as buttons to open the individual messages.

03.10.6 Status information
With this button the current status of custo kybe and custo guard can be viewed. If the recording is completed as expected (sufficient battery capacity for custo kybe and custo guard; good ECG reception), there is a check mark on the Status information button.

In the event of an error (not enough battery capacity for one or both devices; poor ECG reception), there is a question mark on the Status information button. The user can display the error message by pressing the Button with the question mark in the custo kybe main menu. The error message contains information on how to solve the problem.
03 Description of device, basic instructions for initial operation

03.10.7 Functions in the settings menu
The settings can be opened with the Settings button on the upper edge of the screen. Use the Arrow keys on the right side of the screen to page forward and backward.

1. Patient and device information
2. Buttons to switch on/off sound
3. Volume control for the speaker of the device
4. Button to open the ECG transmitter selection,
5. Button to configure the Wifi connection (find network, enter password), only for devices with wireless functionality
6. Button to select the language for the user interface,
7. Button to switch on ECG live streaming (e.g. for monitoring patients within a wireless network), only with wireless functionality (optional)
8. Button to restart the device

---

**Image Description**

- **Patient and device information**:
  - Patient: Mustermann Franz
  - Phone No: +49151114084834
  - IMEI: 35389004002027-0
  - Serial: KU2013 00998 Version 88

- **Buttons to switch on/off sound**

- **Volume control for the speaker of the device**

- **Button to open the ECG transmitter selection**:
  - custo guard FW 1.1.4.0 HW: 2.2.0.0

- **Button to configure the Wifi connection**

- **Button to select the language for the user interface**

- **Button to switch on ECG live streaming**

- **Button to restart the device**

---

**Image Notes**

- **Settings 16:32 2013-09-04**
  - custo kybe settings
  - Language
  - Enable ECG-Livestream
  - Restart custo kybe

- **Settings 16:32 2013-09-04**
  - custo kybe settings
  - Sound
  - Mute
  - Select custo guard
  - Configure Wifi
03.11 custo diagnostic – basic program structure

The program is divided into three areas – User, Patient and Examination. This structure ensures that you can always recognise who (which user) is carrying out what type of examination with whom (which patient).
The main menus of each area can be reached by clicking on User, Patient or Examination.

In the User main menu, the user of the system can be selected. The actual administration of users takes place in the custo diagnostic service centre (for example, creating users, allocating user rights, user-specific settings).

The Patient main menu is used for patient management. Its most important functions include Search Patient, New Patient and Search Evaluation.

The Examination main menu lists all of the examination types which are possible with custo diagnostic. All the modules which you do not own are deactivated – this can be recognised by the light grey font.
This menu is also linked to the Settings area. This area is for making cross-program, examination-related and user-specific settings.
03.12 Functionality of the custo MCT system

**Physician, medical staff:**
- Requests the ECG
- Starts online monitoring
- Sends messages
- Performs remote configuration

**custo MCT software:**
checks every 30 seconds incoming ECG data in the custo kybe cloud, automatically downloads new ECG data (Internet access required!)

**custo kybe:**
- Stores ECG data of the patient
- Detects and sends ECG events
- Sends the HR Trend every 24 h
- Transfers the ECG data to the physician on request
- or the patient sends the ECG data

**External communication server**
for transmitting data between the physician and the patient

**Connection using mobile telephony**
*SIM card required!*

**Connection via mobile telephony,**
*SIM card required!*

**Patient calls the physician**
03.13 Commissioning of the custo MCT system

Your authorised custo med dealer performs the complete installation and configuration of the custo MCT system. Commissioning includes the following steps:

- Create a customer account in the custo kybe cloud. Access data is required for the configuration of custo diagnostic.
- custo diagnostic set-up at all work stations (incl. installation of Microsoft® SQL Server® - Express Edition and Windows Mobile Device Center).
- First custo diagnostic program start on the Master PC
- Configuration of the custo MCT software in custo diagnostic (Master PC)
- Configuration of additional work stations
- Commissioning of the custo kybe devices (PIN input, language selection, configure device with custo diagnostic)
03.14 Settings on the Master PC of the custo MCT system

To enable a connection between custo MCT system and custo kybe cloud, the access data for the custo kybe cloud must be entered in custo diagnostic. It is entered only once on the “Master PC”. This PC requires access to the Internet and Server access (see option 1) in order to download data from the custo kybe cloud and store it in the SQL database of the custo MCT system.

Open the screen Examination, Mobile Cardiac Telemetry, Settings, General, Server settings 0. Enter the custo kybe cloud access data 2 (these are provided by your authorised custo med dealer). Enable the option Server access 3. If the option Send trigger text message 4 is enabled, the custo MCT software sends a text message to the custo kybe as soon as new data for the custo kybe are available in the custo kybe cloud so that the commands contained therein are performed immediately (e.g., ECG request, remote configuration). Otherwise, the custo kybe checks for new data from the custo MCT software in the custo kybe cloud once every hour and runs the commands every hour.

Check whether the connection to the custo kybe cloud is working properly. Click on the Start test button. If the connection is successful, you will see the message “Login successful” 4. In the event of an error, you will be asked to check the access data and the Internet access. If error messages occur repeatedly, it is also possible to enter the connection using the proxy server data 5.

Next, enter the Telephone number that the patient can call with his custo kybe, if necessary. The specified phone number is automatically transmitted to the device and stored on the Call physician button when configuring a custo kybe.

If the medical facility with the custo MCT system is the contact point for patients, select the option Manual settings 7 and enter the Contact data 8 of the medical facility. If the medical facility with the custo MCT system is not the direct point of contact for patients, for example, if the custo MCT system works as a service provider for various surgeries, entering a phone number at this point makes no sense.

1) Patient-physician assignment: In the event that the medical facility with the custo MCT system provides services for different physician’s surgeries, the patients for whom ECG monitoring with a custo kybe is being performed must be assigned to the physicians that care for them.

For this, the contact data for the physicians are entered and stored in custo diagnostic on the Patient Edit database. New physician assignment screen. In the patient master data of a patient, the responsible physician can be selected in the “Assignment” area.

The patient-physician assignment can be made when starting the custo kybe if a patient is selected for the recording. The transmission of ECG events and reports to the physician can be made using email, fax or remote transmission.
Select the option Patient–physician assignment 1. Save your input. The settings on the “Master PC” are complete.

In order for the access data for the custo kybe cloud to be automatically set on all other workstations of the custo MCT system and receive access to the SQL database with the ECG data, all workstations must access the same database as the “Master PC” (your authorised custo med dealer configures this).

All workstations where online functions should be used (e.g., starting the custo kybe, online monitoring, sending text messages) require Internet access. Workstations without Internet access can only be used as viewing stations.

03.15 Print Settings (user–specific)

The printer settings are user-specific settings that can be set individually on each workstation of the custo MCT system. By default (out of the box) all content is printed. It is a good idea to adjust the content that will be printed to each workstation’s needs.

You can do this by opening the screen Examination, Mobile Cardiac Telemetry, Settings, Print, Settings 1. On this screen you can specify the content that should be printed in the daily profile of a patient such as only critical events or no artefacts 2. In addition, the ECG sample duration 3 can be changed and the print configuration (Print to paper and/or Print to PDF 4). If the option Print to PDF is selected, a storage location for the PDF files must be specified. Save your input.

To print a daily profile, click in custo MCT software on Print, Full day in the overview for a patient.
04 Hygiene

04.1 Cleaning and disinfection

Important notes

Use only cleaning agents and disinfectants approved by custo med. Unsuitable agents may damage the device.

The devices must never be immersed in liquid or cleaned with too much liquid. Make sure that no moisture gets inside the device (e.g. via interface contacts).

Clean and disinfect the devices after each recording. Make sure that the exterior of the devices is always aesthetic and clean.

custo kybe, custo guard ECG transmitter, cable adapter for adhesive electrodes

- Reprocessing type: Wipe disinfection

custo belt Elektrodengürtel, Tasche und Nackengurt für EKG-Sender Neoprentasche und Gürtel für custo kybe

- Reprocessing type: Washing with a disinfectant in a washing net

In addition to regularly washing with a disinfectant, we recommend a quick disinfection with alcohol after each use.

custo charger, charger for ECG transmitter

The charger may be wiped down with a dry, soft, lint-free cleaning cloth. The contacts must not be dirty or damaged. This can lead to a degradation of the charging function.

04.2 Approved cleaning agents and disinfectants

Wipe disinfection

Meliseptol® Wipes sensitive
Meliseptol® Foam pure (B.Braun)

- Note: Observe the manufacturer’s instructions

For more details and up to date information please visit our website www.customed.de
Washing with a disinfectant

Eltra 40® (ECOLAB)

- Note: Observe the manufacturer’s instructions

- Machine wash at 40°C in a washing net, (do not spin)
- Do not treat with harsh chemicals or bleach
- Do not iron
- Do not tumble dry

Due to the ingredients of the disinfectants, the product may be subject to visual changes. This does not, however, impair its functioning.

04.3 Disposing of the adhesive electrodes (single-use items)

Disposal of used adhesive electrodes (single-use items)

According to the Waste Catalogue Ordinance (WCO), contaminated adhesive electrodes are classified as waste whose collection and disposal is subject to special requirements in view of the prevention of infection and are categorised with waste code AS 18 01 03.

The disposal method also depends on the amount of contaminated waste.

- In clinics and medical practices which focus on treating patients with the corresponding diseases (i.e. not only in sporadic individual cases), the adhesive electrodes must be disposed of in a separate container (tear-resistant, labelled with the biohazard symbol). Note the Law on the Prevention and Control of Infectious Diseases (§17 IfSG: Objects tainted with notifiable pathogens).

- In principle, this requirement also applies in the case of small quantities of contaminated waste. However, disinfection of individual parts is possible (any disinfectant). You can then dispose of the electrodes with normal waste (domestic waste in a medical practice).

See the “Directive on the proper disposal of waste from health care facilities”.
05.1 Overview of steps

**START DEVICE**

- Connect the custo kybe to the PC and open the interface
- Start custo diagnostic, open custo Mobile Cardiac Telemetry
- If necessary, enter the GPRS connection data, set recording parameters
- Transmit recording parameters to the device (start device)
- Prepare the equipment for recording
- Connect custo guard ECG transmitter with custo kybe, fit the custo guard to the patient, check the ECG

**ECG MONITORING**

- Start custo diagnostic, open custo Mobile Cardiac Telemetry
- View ECG events for all patients:
  - Show patient list
- Display ECG events for an individual Patient:
  - Show patient
- Select patient from the list
- Evaluate/classify the ECG events for a patient, request ECG if necessary, start ECG live streaming, send message to patient

**READING**

- Connect the custo kybe to the PC and open the interface
- Start custo diagnostic, open custo Mobile Cardiac Telemetry
- Click the Read data from kybe button, tabular evaluation overview is displayed
- Complete evaluation: Show patient list or Show patient
05.2 Patient information, operating the device

For safe and uninterrupted ECG monitoring:

Instruct the patient on how to handle the device. The patient must master the following steps:
charge custo kybe, charge custo guard, connect custo kybe and custo guard, fit custo guard and, if necessary, how the ECG is transmitted and marked.

custo kybe must be protected from extreme cold, heat, moisture, dirt and mechanical damage. No showers, no swimming and no sauna visits.

For uninterrupted ECG monitoring, the custo kybe must always be switched on and charged in a timely manner. The custo guard ECG transmitter must always be worn at all times, also at night. Once the ECG transmitter is removed, an ECG recording is no longer possible. A second ECG transmitter can be used to bridge the gap while the custo guard ECG transmitter is being charged.

custo kybe must be in radio range of the custo guard ECG transmitter and have a clear line of sight connection to the custo guard.

Do not modify the device and do not make any changes to the interface contacts (e.g. removing the SD or SIM card).

Note for fitting the ECG transmitter:

If the ECG transmitter is removed during recording, be sure to pay attention to the orientation when refitting it: custo med logo (“C”) and text on the ECG belt must be oriented to be readable.
If it is incorrectly fitted, the direction of the ECG signal is not correct. The ECG transmitter must always be worn in the same direction.

Notes on custo kybe SIM card

The prepaid SIM cards distributed by custo med are supplied with 60 call minutes and 200 MB data volume (for the transmission of ECG data).
The SIM card contained in the custo kybe may not be inserted in any other devices. The SIM card may be used only for custo kybe.
05 Starting custo kybe recording

05.3 Preparing the custo kybe

Workstations where custo kybe devices are started and assigned with custo diagnostic require Internet access.

05.3.1 Connect device to the PC

Connect the custo kybe to the PC with the micro USB cable. The device switches on automatically. In the main menu of the custo kybe device, press the Settings button and press the Connect to PC button in the settings menu. The Windows Mobile Device Center starts on the PC. There are not steps required in this software.

05.3.2 Program start

Start custo diagnostic and log in with your user name and password if required. Click on Examination, Mobile Cardiac Telemetry, Start device. The patient search screen appears. Select a patient for the examination. Enter the patient’s name or the first letter of their name into the input fields of the patient search screen. Select the patient from the list below the input fields and confirm your selection by clicking on the Select Patient button. You can also select the patient by double clicking on the corresponding name.

If the patient does not yet exist in your database, click on the New Patient button. Enter the patient data. The fields marked with an asterisk are mandatory. Save the details so that the data is entered in your database.
The settings of the connected device are read. The “New device” dialogue appears. However, this only applies when a custo kybe is started for the first time with custo diagnostic or the custo kybe was previously deleted from the custo diagnostic device list (Ctrl+Q). In the “New device” dialogue mobile telephony service providers as well as GPRS connection data must be specified. The GPRS connection data can be obtained from the mobile telephony service provider or in the Internet (Search for “GPRS APN Provider”). Regularly check whether the GPRS connection data is still valid.

1) If the GPRS connection data change (e.g., new SIM card), the custo kybe must be created once again in custo diagnostic:
- Switch off the custo kybe, replace the SIM card, and restart the custo kybe.
- Wait for 1 to 2 minutes so that the custo kybe can read the new provider name.
- Delete the custo kybe from the custo diagnostic device list (Ctrl+Q).
- Restart the custo kybe in custo diagnostic. The “New device” dialogue reappears.

05.3.3 Setting analysis parameters, configure the device for patients
Select the desired analysis profile, e.g., Standard (includes device settings and ECG analysis parameters). In addition to the functionality of the device, ECG transmission and cursor texts can be specified in the left window pane (descriptions can be found on the following pages).

The ECG analysis parameters can be changed on the right half of the screen. Additional screens with ECG analysis parameters can be opened with the 1 to 3 buttons. In some cases it may be useful to reduce the transmission frequency of ECG events, e.g., only every tenth event. Changes on this screen are not permanently saved but are applied to the current patient.
05 Starting custo kybe recording

05.3.4 Specifying custo kybe functionality
In the “Base options” section you specify which functions are available to the patient on the custo kybe. The options listed below correspond to buttons that are displayed in the main menu of the custo kybe device. If an option is disabled at this point, it is no longer available after starting the device. Subsequent remote configuration of functionality is also possible, see 06.5.4 Make remote settings on the custo kybe.

1. **Show ECG**: The ECG display shows the ECG of the patient if the patient is wearing an ECG transmitter.

2. **Call physician**: The telephone number of the physician or custo MCT system is stored on the device. The patient can directly call the physician’s office with this button.

3. **Mark ECG**: The patient can set markers in the recording with this button, e.g., in the case of heart problems. Up to four **Marker texts** can be specified in custo diagnostic. The marker texts are transmitted to the device at start. If the patient uses the **Mark ECG** function, one of the pre-defined marker texts can be selected as the reason for the mark. This information is stored with the mark in the ECG recording.
**Send ECG**: The patient can send the ECG to the physician with this button. In addition, the patient can specify a reason for sending the ECG section, for example, “I have circulatory troubles”.

Up to four **send texts** can be created for the **Send ECG** function. The send texts are transmitted to the device at start. An ECG sent by patients is stored in the SQL database of the custo MCT system and can be opened and evaluated via the patient list.

Set **ECG send duration (min.)** for the time the patient can transmit with the **Send ECG** button (default: 6 minutes before and after pressing the button).

**Messages**: The messages (SMS) that are sent by the custo MCT software to the patient are stored in this menu.

**Settings**: In this section, the device settings such as the language, volume or selection of the ECG transmitter are specified. If the patient should not have access to the menu **Settings**, disable this option. After start-up, instead of the button **Settings**, the **Connect to PC** button is displayed so that the custo kybe can be connected later with custo diagnostic (e.g., read ECG, restart device, etc.).
05.3.5 Enter the telephone number of the SIM card
Enter the Phone number of the SIM card that is in the device. The telephone number absolutely must be entered correctly. Otherwise the custo MCT software can not contact the patient.

Make sure that the Time zone is set correctly. The time of the PC and the time zone are sent to the device at the Start.

05.3.6 Start, transmit data
The data are transmitted to the custo kybe device with the Start button. Confirm the start-up process.

At start up, a connection to the custo kybe cloud is established and an account with an ID number for the started custo kybe is created. The patient for whom the device has been started, is added to the patient list of the custo MCT software. This makes it possible to store the patient's ECG in the custo MCT software under the patient's name.

Finally, a message appears in custo diagnostic that the device was successfully assigned. Confirm this message and disconnect the device from the PC (remove the micro USB cable).

After the custo kybe is started with custo diagnostic, an automatic restart of the device is performed. Next, a confirmation text message is received on the recently started custo kybe. This text message contains the patient data of the previously selected patient. This allows you to verify which device has been assigned to which patient. The device is ready for the recording.
05.3.7 Equipment for the recording

Give the patient the equipment for the recording and explain how to use the device.

- custo kybe including micro SD card and SIM card with carrying case and belt
- Charging cable for custo kybe
- custo guard 1 with custo belt 1
- custo guard 3 with custo belt 3
- custo charger single (charger for ECG transmitter) and power supply

If the electrode belt can not be used, the ECG transmitter can be worn in a case around the patient’s neck, see 05.4.5 Fitting custo guard with cable adapters and adhesive electrodes.
05.3.8 Device management

In order to manage multiple devices and make settings, select Examination, kybe Center, Device management 1. Here you will find the overview with the serial number, patient name, kybe account, start date, firmware version, GPRS profile and the status of the available devices 2 which can be selected individually.

Under GPRS Profiles 3 the mobile provider’s data can be entered or changed 4. To access the device details 5, click on the respective device and then on Show device 6. The current battery run times of custo guard and custo kybe can be viewed there. The status of custo kybe can be updated and the profile of the respective device can be changed.

Starting custo kybe recording
05.4 Receiving custo guard ECG

05.4.1 Connecting custo guard with the custo kybe

The work steps described here should be performed before the custo guard ECG transmitter is fitted to the patient.

In order for the custo kybe to be able to receive the ECG signal of a custo guard ECG transmitter, the custo kybe and custo guard must be connected to each other. The connection from the custo kybe and custo guard are set up on the custo kybe. This step may have already been performed during commissioning of your system and predefined device pairs may be defined.

If that is not the case (red GUARD? symbol), press the Settings button and then Select custo guard or in the status bar on the red GUARD? button. All of the ECG transmitters that are within range are listed with their serial numbers. Select the ECG transmitter using the serial number (on the back of the device) and confirm your selection with OK. The red GUARD? symbol disappears and the quality of the wireless connection as well as the status of the battery of the custo guard is displayed.

If a custo guard is already connected to the custo kybe, you can check whether the custo guard is actually selected that the patient should receive for the recording on the Settings, Select custo guard screen. If necessary, change the selection and confirm it with OK.
05.4.2 Checking ECG on the custo kybe

On the custo kybe main menu press the Show ECG button in order to check the ECG signal.

If the custo guard ECG transmitter is not yet fitted to the upper body of the patient, only noise or a straight line is displayed instead of the ECG signal. If the ECG transmitter is correctly fitted to the upper body of the patient, the ECG signal is displayed. For the description of how to fit the ECG transmitter see Chapters 05.4.3 to 05.4.5.

Check the ECG signal. Make sure that the basic shape of the ECG signal is approximately the same as the shape shown here so that the individual heart beats are recognisable. If the ECG signal is too low or there is too much interference, change the position of the ECG transmitter. Wait a few seconds until the contact between the skin and the electrode belt has been established.

The ECG is already recording. Close the ECG view with the Back button. The main menu is displayed again. The backlight goes off after a few seconds. The patient can store the device (for example, in a pocket or carrying case) and take it with them.
05.4.3  Fitting the custo guard with the custo belt electrode belt

Using the custo belt, the ECG transmitter is fitted to the upper body of the patient. The skin must be free of oil and any body care products.

The electrode belt must be adjusted so that it fits snugly and the surface of the contacts fit well, but the patient is not impaired and their breathing is not hindered. The contact surfaces on the inside of the electrode belt must not get dirty. Impurities impede the ECG quality.

If you do not receive a good signal with one of the belt positions shown, you can change the position of the ECG transmitter. For example, move the ECG transmitter slightly to the left or right while watching the ECG signal.

CAUTION: The electrode contact surfaces must always have contact with the skin. Otherwise, completing the ECG recording will not be possible. Make sure that no textiles are between the electrode and the skin (e.g., excess length of the electrode belt or retraining loop).

Proper positioning of the ECG transmitter

If the ECG transmitter is removed during recording, be sure to pay attention to the orientation when refitting it: custo med logo ("C") and text on the ECG belt must be oriented to be readable (frontal view as shown above). If it is incorrectly fitted, the direction of the ECG signal is not correct. The ECG transmitter must always be worn in the same direction.
05.4.4 custo belt 3 length adjustment (for 3-channel ECG)
Practice adjusting the length with a custo belt 3 in advance. Proceed as described in the steps 1 to 4.

2 Initial minimum length position
The length adjustment slider is located directly next to the point where the material becomes wider on the custo belt. The elastic excess length is completely pulled through the slider so that the slider is directly next to the black plastic hook.

3 Initial minimum length position
The length adjustment slider is located directly next to the point where the material becomes wider on the custo belt. The elastic excess length is completely pulled through the slider so that the slider is directly next to the black plastic hook.

4 Adjustment from minimum length to medium length
Hold the slider with your right hand. The upper layer of material, next to the slider on the left, is pulled through the slider until there is no more elastic excess length. The black plastic hook is then pulled to the left.

5 Adjustment from medium length to maximum length
Hold the slider or the upper layer of material next to the slider on the left with your left hand and pull the material next to the slider on the right to the right until the slider is situated next to the black plastic hook.
5 Adjustment from maximum length to medium length
Hold the slider with your right hand, grasp the lower layer of material to the left of the slider and pull it through the slider up to the wide point.

6 Adjustment from medium length to minimum length
Hold the slider with your left hand and pull the elastic excess length completely to the right through the slider until the slider is back between the black plastic hook and the wide material point.

7 Extension with the custo belt extender
If the maximum length is not sufficient, use a custo belt extender (extension piece). The custo belt extender is adjusted to the minimum length when the slider is located next to the material loop. The maximum length is reached when the slider is next to the black plastic hook. There is no limit on the number of custo belt extenders that can be used.

8 Movable back electrode
For petite patients the back electrode is fitted towards the front electrode (see Figure) so that the back electrode does not rest on the spine. Open the Velcro fastener and turn the electrode module to the desired position. Close the Velcro fastener again. The electrodes must always be in full contact with the patient's skin.
05.4.5  Fitting custo guard with cable adapters and adhesive electrodes

If the electrode belt cannot be used, the ECG transmitter can be worn in a case around the patient’s neck.

1) Attach the cable adapters to the ECG transmitter.
   For custo guard 3, three cable adapters are fitted 1  
   (on the snap fastener contacts with the designations R, L, and 3) 1).
   For custo guard 1, two cable adapters are fitted 1).
   2) Attach the electrodes (e.g. custo sensitive) to the cable adapters.
   3) Place the ECG transmitter in the case 2 and close it.
   4) Fasten the neck strap to the case.
   5) Adjust the strap to the desired length.
   6) Clean the electrode contact points, the skin must be free of oil and any body care products.
   7) Remove the protective foil from the electrodes.
   8) Stick the electrodes on the chest of the patient, see figure 3 and 4.

For the preparation of the electrode contact points, we recommend the custo prep ECG preparation cream. Lightly rub off the areas of the skin where the electrodes are located. In addition, we recommend the usage of custo sensitive ECG electrodes (latex-free, PVC-free, skin-friendly, air and moisture permeable). Es können alternativ auch die Klebeelektroden anderer Hersteller verwendet werden, vorausgesetzt, sie sind vom jeweiligen Hersteller für diesen Verwendungszweck freigegeben.

1) The two snap fastener contacts of one cable adapter have different diameters. Only one end of the cable adapter fits on the contacts of the ECG transmitter. When attaching try out both ends if necessary. Do not press with force.

2) Lösen sich während der Aufzeichnung Elektroden ab, sind diese wieder anzubringen. Ansonsten ist die EKG-Aufzeichnung nicht möglich. Der Patient sollte sich zur Wiederanlage an die Arztpraxis wenden.

---

1. custo guard 1 with 2 cable adapters (1-channel ECG)
2. custo guard 3 with 3 cable adapters (3-channel ECG), pay attention to placement R, L, 3!
05.5 Creating and storing individual recording profiles

The previously described start of the device was carried out with the standard recording parameters. Additional recording profiles can be created for different requirements in the custo MCT software.

To create a new recording profile, open the screen Examination, Mobile Cardiac Telemetry, Profile management. Click on New profile, assign a Name for the new profile and click on Confirm.

Select the newly created profile in the menu Analyse profile. Make the desired changes. In the example shown, the function Show ECG was disabled in the custo kybe main menu. The transmission frequency for tachycardia has been set higher. Only every tenth tachycardia is transmitted to the custo kybe with this setting. In any case, the full ECG is stored in the custo kybe device with all the events. Click on Save, so that the changes are saved in the profile.
## 06.1 Procedures for ECG monitoring

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ECG recording is in progress, custo kybe stores the patient’s ECG</td>
</tr>
<tr>
<td>2</td>
<td>custo kybe sends ECG to the MCT software (event in the ECG, HR trend, ECG request)</td>
</tr>
<tr>
<td>3</td>
<td>Patient sends ECG to the MCT software (for physical complaints, for controlling, etc.)</td>
</tr>
<tr>
<td>4</td>
<td>The ECG is stored in the database of the custo MCT software and displayed as an entry in the patient list</td>
</tr>
<tr>
<td>5</td>
<td>The entries for the patient list are opened individually in order to view the ECG</td>
</tr>
<tr>
<td>6</td>
<td>ECG is evaluated directly by the physician (status is set to confirmed, specify further procedures)</td>
</tr>
<tr>
<td>7</td>
<td>ECG is set to classified by trained staff (artefact/critical/non-critical) Objective: Make work easier – later it is possible to filter based on the classification</td>
</tr>
<tr>
<td>8</td>
<td>A classified ECG is evaluated by the physician, for example, only critical ECG (review of the classification, status set to confirmed, specify further procedures)</td>
</tr>
<tr>
<td>9</td>
<td>Possible approach to critical events: Online monitoring, ECG request, notify patient (appointment, instruction, etc.)</td>
</tr>
</tbody>
</table>

### What effects do the classification and diagnosis in the software have?

As soon as an ECG section is classified and/or confirmed, the corresponding entry is removed from the patient list (filter: non-classified/non-confirmed). Using this method it is immediately evident how many entries must still be processed.

Whether classification or pre-sorting of the ECG sections is useful depends on your work processes. Example: If many patients are being monitored, the evaluation is normally performed by several people. In order to ensure that all ECG sections are evaluated and to avoid double evaluation, it is necessary to classify and identify the ECG sections accordingly.

If only individual patients are monitored and if the evaluation of the ECG sections are only made by one person, confirmation and classification usually take place in one step and are optional.
06.2 **Structure and navigation in the custo MCT software**

Starting point: **Patient list**  
(List of all recordings and events)

**Selection of a list item**  
(e.g., **Patient** or **Event**)

**Overview screen** of the selected patient:  
List of all events for the patient with HR trend, ECG, classification, comment field

**Monitoring** (online ECG) during a recording, the physician can connect to the custo kybe ECG receiver and view the ECG of the patient in real time

**kybe control** during a recording, the physician can connect to the custo kybe ECG receiver and perform these functions:

- **Send message**  
(text message to patient)

- **Request ECG**  
(desired ECG section is selected in the custo MCT software and the request sent)

- **Remote settings**  
(subsequent modification of the functionality of ongoing custo kybe devices)

**Targeted selection of a single patient:**  
**Show patient**

---

**Note about navigating in the custo MCT software**

As soon as you are in the **Patient list** or in the **Overview** screen for the patient, you can return to the higher-level screen by pressing the **End** button (lower right of the screen).  
Example: You are on the **Send message** screen. With the **End** button you return to the **Overview** screen for the patient. If the **Overview** screen of the patient was opened via the **Patient list**, the **End** button returns you to the **Patient list**.
06.3 Transmission of the ECG data to the custo MCT software

When starting a custo kybe device in custo diagnostic, a connection to the custo kybe cloud is established and an account with an ID number is created for the custo kybe. The ECG data of a patient are stored temporarily in the corresponding account in the custo kybe cloud. The ECG data are regularly called from custo MCT software and stored in the database of the custo MCT software. The ECG data can then be opened via the patient list of the custo MCT software.

The transmission of the recording data occurs ...

➤ if the custo kybe recognises an event in the ECG signal of the patient. An ECG section will be automatically transmitted to the physician or the custo MCT software, for example, 6 minutes before and after the event. The transmission is made via mobile telephony (the device must have a SIM card).

➤ If the patient feels the need to send an ECG section to the physician, for example, when feeling physical discomfort or taking medication. Sending of the ECG section is triggered manually when the patient presses on the Send ECG button on the device.

➤ After one day has passed. Every day at 00:00 (midnight) the heart rate trend of the previous day is automatically transmitted from the custo kybe to the custo MCT software (daily storage). Based on the HR trend, the physician can subsequently request ECG sections, e.g., if any anomalies are visible in the HR trend.

06.4 Open and evaluate ECG data

06.4.1 Access via the patient list (List of all patients and events)
The ECG data are managed in the patient list in the custo MCT software and can be opened and evaluated by the physician or specialised medical staff. To monitor and check the ongoing recordings, you start custo diagnostic and open the Examination, Mobile Cardiac Telemetry, Show patient list screen.
The Patient list has several different Sorting filters (on the left below the list). Depending on which filter is set, the patient list is used to select a patient or as a working list. The filter that is chosen depends on your work method.

- **Current patient**: all ongoing recordings
- **All patients**: all completed and ongoing recordings
- **Non-classified events**: ECG sections that have not been opened and classified in the software yet. The classification of ECG sections is made based on the criteria artefact, critical and non-critical. If a preliminary classification is performed, the physician no longer has to open all ECG sections to check them, but can selectively process the critical events.
- **Non-confirmed events**: ECG sections that are already classified (artefact, critical or non-critical) are automatically stored with the status “non-confirmed” in the custo MCT software. In this manner the physician can display all classified but not yet confirmed ECG sections via the patient list.

To evaluate ECG data, click on a List entry (patient or event). You access the Overview screen of the previously selected patient. All ECG events of the patient are displayed on this screen.
06.4.2 Access via targeted selection of a patient

If you want to see the events of a specific patient without having to open the Patient list, start custo diagnostic and open the Examination, Mobile Cardiac Telemetry, Show patient 1.

The patient search screen appears. Select a patient. Enter the patient's name or the first letter of their name into the input fields of the patient search screen 2. Select the patient from the list below the input fields 3 and confirm your selection by clicking on the Select Patient button 4. You can also select the patient by double clicking on the corresponding name.

The patient master data of the current patient can be processed using the Edit patient button 5. The physician assignment can be set on this screen, for example, if the custo MCT software is the service provider for several physicians' surgeries 1). Using the Save button, your modifications are saved and the screen is closed with the Cancel button.

After the patient has been selected, you can reach the overview screen 6 of the previously selected patient. All events for the patient are displayed as a list on this screen.
06.4.3 Overview screen of a patient

The overview screen of a patient is used to evaluate the ECG events of the patient and to contact the patient if needed.

- List of all ECG events for a patient with:
  - Sorting filter (e.g., all events, non-classified, critical, etc.)
  - Time of the event
  - Who triggered the transmission of the ECG data (device, patient, software)
  - Type of event
  - Processing status of the event, e.g., classified, confirmed

New list entries are identified with bold type

In order to view the stored ECG to a list entry, click on the desired list entry.

- ECG section to classify the event

  Preliminary confirmation based on the criteria Artefact, non-critical, critical

  Confirmation status: the property confirmed can be selected if, for example, a classified event is evaluated by the physician and is confirmed

- Change ECG view (move the cursor to the blue area)

  Heart rate trend of the previous recording

- Text field for entering comments about the selected event

2) Procedures for classification: If an event was classified, it is pre-confirmed and is removed from the category “Non-classified event” in the Patient list as well as in the Overview of the patient. A classified event is automatically considered “Non-confirmed” and can be found with the search filter “Non-confirmed events”. This makes it possible to always see how many events still need to be classified/confirmed, and the physician can filter the pre-confirmed events based on the classification (e.g., only critical).

3) Processes for assigning the confirmed status: Classified events are given the “Non-confirmed” status. Events that already have the status set to “Confirmed”, are no longer displayed in the Patient list and are considered to be completed. Non-classified events can also be marked as “confirmed” without prior classification. In this case, an event is considered classified as well as confirmed and is no longer displayed in the patient list.

4) Consisting of the daily HR trend and HR trend of the events received. The time and heart rate of the current cursor position are displayed on the lower end of the red cursor.
06.5 Control options, communication with the patient

06.5.1 Online monitoring

It is possible to view the ECG of a patient in real time, for example, if critical events were previously observed.

Select the patient whose ECG should be checked. Click on the Monitoring button on the overview screen of the patient. Click Yes on the “Online ECG” dialogue to start online monitoring. Wait until the connection to the custo kybe of the patient has been established.

Once the connection is established the ECG of the patient is displayed. Above the ECG signal, the amplitude and write speed can be changed. The ECG is only displayed, not stored. Online monitoring is terminated automatically after five minutes. Even if the screen is closed with the End button before the five minutes have expired, the custo kybe remains in online monitoring mode and can not perform any other actions requested by the custo MCT software.

![Online ECG interface](image)
06.5.2  Send a message to the patient

In the custo MCT software you can send text messages (SMS) to the patients such as a reminder to make an appointment or feedback to an event.

Select the patient that you would like to send a message to. Click on the **custo kybe control** in the patient overview screen and select **Send text** in the menu that opens.

Enter the message in the “Message for Patient” section. In order to be able to use the text for future messages, click on **Save as text module** button. The saved text appears in “Text modules for messages” section. In order to use a text in this area, click on the + button next to the desired entry. In order to send a message, click on **Send message**. All messages sent to the patient are displayed in the “Text Messages” list. You return to the overview page with the **End** button.
06.5.3 Request ECG from the patient

Every day at 00:00 (midnight), the custo kybe automatically transmits the heart rate trend of the prior day to the custo MCT software (daily storage). The HR trend is stored in the custo MCT database and is displayed as an ECG event in the patient list. Based on the HR trend, the physician can request ECG sections from the patient at a later time, for example, if there are anomalies in the HR trend.

Select the patient whose HR trend should be checked. Click on the **kybe control** button in the patient’s overview screen and select **Request ECG** in the menu that opens.

The HR trend of the patient is displayed in the upper half of the screen. The red area is used to select the ECG section. In order to change the selection, click on the edge of the red area with the left mouse button and drag the line to the desired location on the HR trend. The red selection area can be moved using the **Arrow key** above the grid. The selected time period can also be entered manually in the fields below the red HR trend area. Once the selection of the ECG section is completed, click on **Send request**. In the table labelled “ECG Requests” you will see the status of the data transfer. Depending on the amount of data this process can take a few minutes. You return to the overview page with the **End** button.

---

1) The transfer of the data is delayed when
the option **Send trigger text message** is not enabled. In this case, it can take up to an hour until the custo kybe reads the request that is in the queue in the custo kybe cloud.

... custo kybe has no mobile telephony reception. The data transfer (sending and receiving) becomes available once mobile telephony reception possible.
06.5.4 Make remote settings on the custo kybe

The functionality and configuration of custo kybe devices that are already started can be changed later via the custo MCT software (remote setting).

Select the patient on whose device a remote settings should be made. Click on the kybe control button in the patient's overview screen and select Remote settings in the menu that opens.

In the “Profile page” area, the functionality of the custo kybe device can be changed. The options in the “Base options” section are the buttons that are displayed in the main menu of the custo kybe device. If an option is not selected, the corresponding button will not be available later on the custo kybe. Furthermore, the length of the ECG sections that are sent by the patient can be changed. New Send texts and Marker texts can be set and the ECG analysis parameters can be adapted (detailed description of the functions, see 05.3 Preparing the custo kybe).

The changes to the custo kybe device are sent with the Send command button. Confirm the changes. The remote setting modification is finished.

2) The transfer of the data is delayed when... the option Send trigger text message is not enabled. In this case, it can take up to an hour until the custo kybe reads the request that is in the queue in the custo kybe cloud.

... custo kybe has no mobile telephony reception. The data transfer (sending and receiving) becomes available once mobile telephony reception possible.
06.5.5 Create printout

The print function is located on the overview screen for the patient (Examination, Mobile Cardiac Telemetry, Show patient list, Select patient).

Open the Print menu and select the content of the printout in the overview screen of the patient – Cursor position, Full day or Current event. The printout is done on the default printer (settings on the screen Examination, Mobile Cardiac Telemetry, Settings, Print, Settings).

If a PDF file is created, custo diagnostic saves them in the preset storage location on your hard drive or in the network. The printer settings can be changed at any time and adjusted to your work method, see chapter 03.15 Print settings (user-specific).
Example of a daily printout

<table>
<thead>
<tr>
<th>Date, Time</th>
<th>Type</th>
<th>Initiator</th>
<th>Information</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>07.11.2013 00:01:46</td>
<td>ECG Analysis Algorithm</td>
<td>Bigeminy</td>
<td>Bigeminy</td>
<td>Not classified</td>
</tr>
<tr>
<td>07.11.2013 00:01:28</td>
<td>ECG Analysis Algorithm</td>
<td>Bigeminy</td>
<td>Bigeminy</td>
<td>Not classified</td>
</tr>
<tr>
<td>07.11.2013 00:01:11</td>
<td>ECG Analysis Algorithm</td>
<td>Bigeminy</td>
<td>Bigeminy</td>
<td>Not classified</td>
</tr>
<tr>
<td>07.11.2013 00:00:53</td>
<td>ECG Analysis Algorithm</td>
<td>Bigeminy</td>
<td>Bigeminy</td>
<td>Not classified</td>
</tr>
<tr>
<td>07.11.2013 00:00:35</td>
<td>ECG Analysis Algorithm</td>
<td>Bigeminy</td>
<td>Bigeminy</td>
<td>Not classified</td>
</tr>
<tr>
<td>07.11.2013 00:00:17</td>
<td>ECG Analysis Algorithm</td>
<td>Bigeminy</td>
<td>Bigeminy</td>
<td>Not classified</td>
</tr>
<tr>
<td>07.11.2013 01:22:49</td>
<td>Kybe Daily save (HR Trend)</td>
<td></td>
<td></td>
<td>Not classified</td>
</tr>
</tbody>
</table>

07.11.2013

Heart frequency

Bigeminy 07.11.2013 01:22:22 classified by: Supervisor
06 ECG monitoring, reading the recording

06.5.6 Export ECG by email or fax

The print function is located on the overview screen for the patient (Examination, Mobile Cardiac Telemetry, Patient list, Select patient).

On the overview screen for the patient, open the Options menu and select where the patient's ECG should be exported – to an e-mail address (Mail...) or to a fax number (Fax...). The export dialogue is then opened. Select which content should be exported (Full day, Current event, Current cursor position or Custom timespan). Enter the recipient's e-mail address or fax number. Select Confirm to send the ECG to the specified e-mail address or fax number.
06.6  Reading ECG recording

06.6.1  Read and store ECG in the custo MCT software

During a recording, only the daily HR trends and individual ECG sections are stored in the custo MCT database. In order to receive the entire ECG recording, the custo kybe device must be read in with custo diagnostic.

- Connect the custo kybe to the PC with the micro USB cable. The device switches on automatically. In the main menu of the custo kybe device, press the Settings button and then press the Connect to PC button in the settings menu. The Windows Mobile Device Center starts on the PC. There are not steps required in this software.
- Start custo diagnostic and log in with your user name and password if required. Click on Examination, Mobile Cardiac Telemetry, Read data from kybe. The data that are saved in this device are imported and stored in the custo MCT database. Confirm the individual steps to start importing the data. The import process can take a few minutes.
- The evaluation overview is displayed next.

CAUTION: Large volumes of data (long recordings) should be read directly from the micro SD card using a card reader. Switch off the custo kybe, remove the micro SD card and insert it into the card reader. Click on Examination, Mobile Cardiac Telemetry, Read data from kybe. Then you are prompted to enter the import directory. Select the directory of the micro SD card and confirm the operation.

The imported ECG data can be opened via the patient list of the custo MCT software (Examination, Mobile Cardiac Telemetry, Patient list, Select patient). The imported ECG data are not displayed as an entry in the event list. Events that have not yet been saved are added to the patient list as new entries and the ECG is added in between the events.

The new events and the added ECG can be viewed on the patient overview screen.
06.6.2 Open recording data as Holter evaluation in custo tera

With the custo MCT software, the stored ECG can be displayed as a Holter evaluation in the custo tera software module. If necessary, read the complete ECG recording into the custo MCT software or just export ECG events that are already stored. During export, the ECG data of the previously selected day (24 h) is saved as a Holter evaluation.

To export the data you open the overview screen in the custo MCT software for the patient whose evaluation you would like to export as a Holter evaluation (Examination, Mobile Cardiac Telemetry, Show patient list, Select patient).

Select the desired event in the patient overview screen, open the Options menu and click the Holter button. Specify when the recording should be processed – Immediately or Later. If you select the option Immediately, the ECG recording is exported and the Holter evaluation is displayed. If you select the option Later, the ECG recording is stored in the job list for later analysis and is not displayed.

The Holter export gives you the opportunity to perform detailed analysis and processing of the ECG. A final overall report can be entered and stored in custo tera. An export of the Holter recording can be re-opened using the Holter main menu (Examination, Holter, Show evaluation).

1) In order to perform task in the job list, click on Examination, Task and then on Execute or Execute all.
06.6.3 Anfordern von Aufzeichnungsdaten als Langzeit-EKG
Im custo kybe center gespeichertes EKG kann als Langzeit-EKG Auswertung im Softwaremodul custo diagnostic angefordert werden. Wählen Sie die gewünschte Zeitspanne und klicken auf Bestätigen, damit das EKG, sobald genügend Daten vorhanden sind, abgeholt und angezeigt wird.

![Image of custo kybe center](image)

06.7 custo kybe EKG Aufzeichnung abschließen

When the recording with the custo kybe has ended, take all of the recording equipment from the patient:
- custo kybe with charging cable;
  - ensure that the micro SD card and SIM card are in the device.
- Carrying case and belt for custo kybe
- custo guard with charger and power supply
- custo belt or bag, neck strap and cable adapters

Clean and disinfect the equipment, see Chapter 04 Hygiene.

Fully charge the custo kybe and custo guard, see Chapter 03.5 Charging the custo kybe and 03.6 Charging the custo guard.

**Note on data storage on the micro SD card**

The entire ECG recording of a patient is stored on the micro SD card of the custo kybe device. Reading the full ECG recording is optional since all recognised ECG events for the patient are already saved in the custo MCT database. Reading the full ECG recording is useful for finding additional information or if the data should be exported as a Holter evaluation. The data stored on the micro SD card will be automatically deleted the next time the device is started.
07 Product information

07.1 custo kybe – possible malfunctions and countermeasures

The battery is not charging
The battery symbol on the left in the custo kybe display remains red while charging. Make sure that the charging cable is properly connected to the power supply and is supplied with voltage. If the rechargeable battery is completely empty, custo kybe should be connected to the power supply for about four hours.

No ECG signal on the custo kybe
Check whether a custo guard is connected to the custo kybe, see custo guard information in the status bar of the custo kybe. If that is not the case, a connection must be established using the corresponding menu. Furthermore, the custo guard must be charged. In addition, you should check whether the ECG magnification on the custo kybe screen “Show ECG” is set to a normal value or is minimised.

custo kybe battery life is less than 16 hours
In the event of an intensive or long-term and continuous use of the device, a shorter duration is normal and is due to battery wear. If the mobile telephony reception is not adequate, the device also consumes more power than normal, because it is searching for a mobile signal. If this is not the case, the custo kybe should be charged for at least four hours. If the battery life is still too short, the rechargeable battery must be replaced.

custo kybe does not react to inputs
If the custo kybe does not react to inputs from the user, the device should be restarted. To do this, press and hold the on/off button for at least five seconds so that the custo kybe switches off. Then switch on the device with the on/off button.

custo kybe can not be switched on
The rechargeable battery is empty. The custo kybe must be recharged. Connect the device to the power supply with the charging cable and charge it for at least four hours. Once the device is connected to the power supply it switches on.

custo kybe switches itself off
The rechargeable battery is empty. The custo kybe must be recharged. Connect the device to the power supply with the charging cable and charge it for at least four hours. Once the device is connected to the power supply it switches on.
The time on the custo kybe is incorrect
Either the custo kybe will update the time itself after a certain period of time, or the
device must be restarted with custo diagnostic.

The SIM card can not be inserted in the custo kybe
If there is a ridge at the end of the SIM card that has to be inserted, this edge should
be rounded with a file. Do not use force to insert the SIM card.

No connection between custo MCT software and custo kybe.
Check whether there is mobile telephony reception in the status bar of the custo
kybe. In the custo MCT software, check whether the correct telephone number was
entered for the SIM card that is in use. If necessary, update the GPRS connection
data. Check whether the Master PC of the custo MCT system has access to the
Internet.

Configuration text message is not received by the custo kybe
If a custo kybe is started in the custo MCT software, the custo MCT software trans-
mits a configuration text message to the custo kybe.
Configuration text messages are not received by the custo kybe if a SIM card is used
that does not request a PIN code. The PIN code request can be activated using a
conventional mobile phone.

The device has become damp and no longer works
Immediately switch off the device and contact your authorised custo med dealer or
custo med.

The back of the device gets warm
This is normal when charging the battery as well as by heavy use of the device.

Telephone function not available
Check whether the custo kybe contains a SIM card. The telephone function (Call
physician button) can not be used during transmission of ECG data. Telephoning will
not be possible until data transmission is completed.
07.2 Technical data and system requirements

custo kybe

<table>
<thead>
<tr>
<th>Interfaces</th>
<th>USB 2.0</th>
<th>Micro USB (Host-Host)</th>
<th>custo wireless connection 2.4 GHz</th>
<th>Micro SD card</th>
<th>SIM card</th>
<th>WLAN (optional)</th>
<th>Bluetooth (optional)</th>
<th>GSM/GPRS/UMTS (upload 384kbit/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data storage</td>
<td>Micro SD card, up to 64 GB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage capacity 3-channel ECG</td>
<td>1 GB 29 days</td>
<td>2 GB 58 days</td>
<td>32 GB 2.5 years</td>
<td>64 GB 4.7 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows Embedded CE 6.0 R3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power supply</td>
<td>Rechargeable lithium polymer battery 3800 mAh</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery run time</td>
<td>24 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery charging time</td>
<td>approx. 4 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| max. number of charging cycles | > 350 cycles (= service life) 1)
depending on the type of use and the previous charging cycles |
| Display | 3.5 inch QVGA 65K colour display |
| Operating elements | Resistive Touch  | On/off button |
| Dimensions | approx. 135 x 70 x 23 mm (L x W x H) |
| Weight | approx. 230 g |
| Operating conditions | Temperature +5°C ... 40 °C |
| Humidity | 15 ... 95% RH non-condensing |
| Air pressure | 700 ... 1060 hPa |
| Transport and storage conditions | Temperature -20°C ... +70°C |
| Humidity | 10 ... 95% RH non-condensing |
| Air pressure | 700 ... 1060 hPa |
| Classification | Device with internal power supply, Class IIa, Type BF |

1) The service life duration is a result of the capacity loss (80% of the specified capacity) of the rechargeable battery. If the maintenance interval specified by the manufacturer (24 months or 350 charging cycles, whichever occurs first) is observed, the service life duration is extended by a further 350 charging cycles.

ECG transmitter custo guard 1/3

| Number of ECG channels | 1 or 3 (no pacemaker detection) |
| Sampling rate | 125 Hz, 250 Hz, 500 Hz, 1 kHz |
| Resolution | 10 bit |
| 3 dB bandwidth ECG amplifier | 0.5 Hz – 150 Hz |
| Measuring range ECG | 10 mV |
| Minimum perception level | 10 µV |
| Radio frequency band | ISM 2.4 Ghz |
| Radio transmission power | 1 mW maximum |
### Radio performance
- **Stationary frequency**

### RF modulation
- GFSK

### RF transmitting rate
- 2 Mbps / 1 Mbps / 250 kbps

### Connection to the PC
- Via custo com RF (radio receiver unit)

### Power supply
- Lithium-ion battery (190 mAh)

### Battery run time
- 1-channel ECG: approx. 5 days, 3-channel ECG: approx. 3 days, approx. 100 days on standby (73 µA standby current)

### Charging time of battery
- approx. 3 hours (when fully discharged)

### Display and control elements
- LED display for the charging status

### Dimensions
- **Approx. 70 * 42 * 12 mm (L * W * H)**

### Weight
- 30 g

### Ingress protection rating
- IP65

### Operating conditions
- **Temperature**: +10°C ... +45°C
- **Air humidity**: 10 ... 95% rH
- **Air pressure**: 700 ... 1060 hPa

### Transport and storage conditions
- **Temperature**: -20°C ... +40°C
- **Air humidity**: 10 ... 95% rH
- **Air pressure**: 700 ... 1060 hPa

### Electrode belt custo belt
- **1-channel model**: Length (not stretched) 570 mm – 840 mm, Width 30 mm
- **3-channel model**: Length (not stretched) 680 mm – 1400 mm, Width 30 to 50 mm
- **Composition**: PA, biocompatible according to EN ISO 10993-1, Oeko-Tex ® Standard 100
- **Alternative to custo belt**: ECG cable adapter, length approx. 300 mm

### Charging device custo charger
- **Single**: Power supply 5 V, max. charging current 80 mA, Dimensions (L * W * H) approx. 80 * 49 * 33 mm, Operating conditions Temperature +10°C ... +40°C, Humidity 10 ... 95% rH without condensation, Air pressure 700 ... 1060 hPa
- **Multi**: Power supply 5 V, max. charging current 6 x 80 mA = max. 480 mA, Dimensions (L * W * H) approx. 279 * 80 * 33 mm, Operating conditions Temperature +10°C ... +40°C, Humidity 10 ... 95% rH without condensation, Air pressure 700 ... 1060 hPa

---

2) The battery run time is dependent among other things on the mode of reception of the receiver, the distance and obstacles between the receiver and transmitter (condition of the transmission path) and the age and condition of the battery. After 300 or more charging cycles, the battery has a capacity of 80% of the initial capacity.

**Definition of charge cycle:**
During a charge cycle the entire battery power is used, however, this does not have to occur in a single charging operation. For example, you can use a device for several hours on a particular day, use approximately half the capacity, and then fully charge it again. If the same procedure is repeated on the following day, this is equal to just one charging cycle and not two charging cycles. It can therefore take a few days for a charge cycle to be fully completed.

---

Telemetric ECG Monitoring with custo Kybe and custo diagnostic | GEB 0195 – DK 1634 | 10/01/2017 | custo med GmbH
# Product Information

## General System Requirements

<table>
<thead>
<tr>
<th>Operating System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Windows 7 (32-bit and 64-bit operating system)</td>
</tr>
<tr>
<td>Windows 8 (32-bit and 64-bit operating system)</td>
</tr>
<tr>
<td>Windows 8.1 (32-bit and 64-bit operating system)</td>
</tr>
<tr>
<td>Windows Server 2003 (32-bit and 64-bit operating system)</td>
</tr>
<tr>
<td>Windows Server 2008 (32-bit and 64-bit operating system)</td>
</tr>
<tr>
<td>Windows Server 2008 R2</td>
</tr>
<tr>
<td>Windows Server 2012</td>
</tr>
<tr>
<td>Windows Server 2012 R2</td>
</tr>
</tbody>
</table>

Older versions are not supported.

### PC

The PC hardware should meet the minimum requirements of the operating system used.

Provide additional RAM (1 GB) for custo diagnostic. Please ensure that there is sufficient free space on the hard disk for the custo diagnostic evaluations.

The PC must meet the requirements of the safety standard DIN EN 60950 for information technology equipment.

<table>
<thead>
<tr>
<th>File Sizes of the Evaluations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holter: approx. 15 MB (60 MB max.)</td>
</tr>
<tr>
<td>ABPM: approx. 128 KB (512 KB max.)</td>
</tr>
<tr>
<td>Holter-ABDM: approx. 20 MB (25 MB max.)</td>
</tr>
<tr>
<td>Resting ECG: approx. 200 KB (approx. 10 sec. of ECG)</td>
</tr>
<tr>
<td>Stress ECG: approx. 6 MB (approx. 20 min. of ECG)</td>
</tr>
<tr>
<td>CPET: refer to Stress ECG</td>
</tr>
<tr>
<td>Spirometry: approx. 50 KB (256 KB max)</td>
</tr>
<tr>
<td>Rehabilitation: approx. 6 MB (approx. 45 min. of training)</td>
</tr>
<tr>
<td>custo kybe center: approx. 10 – 15 MB for a 24h ECG</td>
</tr>
</tbody>
</table>

### Hardware & Connections

- DVD or CD-ROM drive
- USB port
### Recommended system requirements

**Computer**
- Intel Core i3-CPU with HD Graphics 4400
- 4 GB RAM
- 256 GB SSD or SSHD (for single-user systems 2TB HDD)
- 1 GBit network connection (not for single-user systems)
- Fanless Dual-DVI (or DP) graphics card (for CPET)
- Windows 8.1 x64 (PRO version for joining a domain)

**Connections**
- One USB 2.0 port per USB device (preferably not USB 3.0)
- One COM port for each ergometer and treadmill (serial)
- in case of installed Bluetooth at least version 4.0, otherwise can be deactivated in the BIOS

**Monitor**
- 20" TFT with DVI or DP port
- Full HD resolution
- Dual-TFT for CPET

**Printer**
- 600 dpi resolution
- Monochrome (colour recommended for CPET)
- USB 2.0 port or network connection
- PCL-enabled (increases printing speed with the suitable driver)

---

### 07.3 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](http://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.
07 Product information

07.4 Manufacturer’s Declaration regarding EMC (electromagnetic compatibility) according to IEC 60601-1-2:2007

Cable lengths for the sensors and accessories: USB cable 2m

WARNING!
The use of longer cables could result in increased emissions or decreased immunity. The use of sensors and cables other than those listed above is prohibited.

Manufacturer’s Declaration – electromagnetic emissions
custo kybe is designed for operation in the electromagnetic environment specified below. The customer or user of the custo kybe should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emission Measurements</th>
<th>Compliance</th>
<th>Electromagnetic Environment – Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF emissions according to CISPR11</td>
<td>Group 2</td>
<td>custo kybe must emit electromagnetic energy in order to properly perform its intended function. Nearby electronic equipment may be affected.</td>
</tr>
<tr>
<td>HF emissions according to CISPR11</td>
<td>Class B</td>
<td>custo kybe is suitable for use in all establishments, including domestic areas and areas that are directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Emission of harmonics according to IEC61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Emission of voltage fluctuations/flickers according to IEC61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

Manufacturer’s Declaration – electromagnetic immunity
custo kybe is designed for operation in the electromagnetic environment specified below. The customer or user of the custo kybe should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Tests</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) according to IEC 61000-4-2</td>
<td>± 6 kV contact discharge ± 8 kV air discharge</td>
<td>Group 2</td>
<td>Floors should be made of wood or concrete or be equipped with ceramic tiles. If the floor is provided with synthetic material, the relative air humidity must be at least 30%.</td>
</tr>
<tr>
<td>Fast transient electric interference factors/bursts according to IEC 61000-4-4</td>
<td>± 2 kV for net wires ± 1 kV for input and output wires</td>
<td>Group 2</td>
<td>The quality of the supply voltage should correspond to the one of a typical business or clinical environment.</td>
</tr>
<tr>
<td>Surges according to IEC 61000-4-5</td>
<td>± 1 kV push-pull voltage ± 2 kV push-push voltage</td>
<td>Not applicable</td>
<td>The quality of the supply voltage should correspond to the one of a typical business or clinical environment.</td>
</tr>
<tr>
<td>Voltage drops, short-time interruptions and fluctuations in the supply voltage according to IEC 61000-4-11</td>
<td>&lt; 5 % U_t for 0.5 period (&gt; 85 % drop) 40% U_t for 5 periods (60 % drop) 70% U_t for 25 periods (30 % drop) &lt; 5 % U_t for 5 s (&gt; 95 % drop)</td>
<td>Not applicable</td>
<td>The quality of the supply voltage should correspond to the one of a typical business or clinical environment. If the user of the custo kybe system requires continued functioning, even if interruptions in the energy supply occur, the use of an interruption-free power supply to supply the custo kybe system is recommended.</td>
</tr>
<tr>
<td>Magnetic field with supply frequency (50/60 Hz) according to IEC 61000-4-8</td>
<td>3 A/m</td>
<td>10 A/m</td>
<td>Magnetic fields with net frequency should correspond to the typical values, as they can be found in the business and clinical environment.</td>
</tr>
</tbody>
</table>

NOTE: U_t is the net AC voltage before applying the test levels
Manufacturer’s Declaration – electromagnetic immunity

custo kybe is designed for operation in the electromagnetic environment specified below. The customer or user of the custo kybe should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Tests</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted HF transients</td>
<td>3 V&lt;sub&gt;effective value&lt;/sub&gt;</td>
<td>[U&lt;sub&gt;1&lt;/sub&gt;] V</td>
<td>Portable and mobile radio transmitters should not be used at a closer distance to the custo kybe and its lines than the recommended protective distance which is determined according to the equation for the transmitting frequency.</td>
</tr>
<tr>
<td>according to IEC 61000-4-6</td>
<td>150 KHz to 80 Mhz</td>
<td>Not applicable</td>
<td><strong>Recommended protective distance:</strong></td>
</tr>
<tr>
<td>Radiated HF transients</td>
<td>3 V/m</td>
<td>E&lt;sub&gt;1&lt;/sub&gt; = 10 V/m</td>
<td>d = [3.5/U&lt;sub&gt;1&lt;/sub&gt;] V√P for 80 MHz to 800 MHz</td>
</tr>
<tr>
<td>according to IEC 61000-4-3</td>
<td>80 MHz to 2.5 GHz</td>
<td></td>
<td>d = [3.5/E&lt;sub&gt;1&lt;/sub&gt;] V√P for 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>with P as the nominal power of the transmitter in watt (W) according to the indications of the transmitter manufacturer and d as the recommended protective distance in meters (m).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>According to an examination on-site a) the field strength of stationary radio transmitters should be inferior to the compliance level b) with regard to all frequencies.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>In the vicinity of devices carrying the following symbol, interferences are possible:</td>
</tr>
</tbody>
</table>

**COMMENT 1:**
With 80 MHz and 800 MHz the higher frequency range is valid.

**COMMENT 2:**
These guidelines may not apply in every case. The propagation of electromagnetic variables is influenced by absorptions and reflections of buildings, objects and people.

a) The field strength of stationary transmitters, such as e.g. base stations of mobile phones and mobile transmitting stations, amateur radio stations, AM and FM broadcasting as well as television networks cannot be exactly predetermined theoretically. In order to determine the electromagnetic environment regarding the stationary transmitters, a study of the location should be considered. If the measured field strength exceeds the above-mentioned compliance levels at the location where the device is used, the device should be watched in order to prove the intended functions. If unusual performance features are observed, it may be necessary to take additional measures, for example reorienting or relocating the device.

b) Over the frequency range from 150 kHz to 80 MHz the field strength should be inferior to 10 V/m.
Product information

Recommended protective distances between portable and mobile RF telecommunication devices and custo kybe

custo kybe is designed for the operation in an electromagnetic environment in which the RF transients can be controlled. The user of the custo kybe can help avoid electromagnetic interferences by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the device – depending on the initial performance of the communication device, as indicated below.

### Protective distance depending on the transmitting frequency in m

<table>
<thead>
<tr>
<th>Nominal power of the transmitter W</th>
<th>150 kHz to 80 MHz ( d = \left[3.5/U_1\right] \sqrt{P} )</th>
<th>80 MHz to 800 MHz ( d = \left[3.5/E_1\right] \sqrt{P} )</th>
<th>800 MHz to 2.5 GHz ( d = \left[7/E_1\right] \sqrt{P} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.04</td>
<td>0.04</td>
<td>0.08</td>
</tr>
<tr>
<td>0.1</td>
<td>0.11</td>
<td>0.11</td>
<td>0.22</td>
</tr>
<tr>
<td>1</td>
<td>0.35</td>
<td>0.35</td>
<td>0.70</td>
</tr>
<tr>
<td>10</td>
<td>1.11</td>
<td>1.11</td>
<td>2.22</td>
</tr>
<tr>
<td>100</td>
<td>3.50</td>
<td>3.50</td>
<td>7.00</td>
</tr>
</tbody>
</table>

For transmitters whose maximum nominal power is not indicated in the above table, the recommended protective distance \( d \) can be determined in meters (m), using the equation affiliated with the corresponding column. \( P \) is the maximum nominal power of the transmitter in watt (W) according to the indications of the manufacturer of the transmitter.

---

COMMENT 1:
With 80 MHz and 800 MHz the higher frequency range is valid.

---

COMMENT 2:
These guidelines may not apply in every case. The propagation of electromagnetic variables is influenced by absorptions and reflections of buildings, objects and people.
07.5 EC Declaration of Conformity

EG-Konformitätserklärung
EC Declaration of Conformity

Hersteller / manufacturer: custo med GmbH | Maria-Merian-Str. 6 | 85521 Ottobrunn, Germany

Wir erklären in alleiniger Verantwortung, dass das
We hereby declare under our sole responsibility that the

Telemedizinische Systeme  custo diagnostic
Telemedical Systems  custo kybe
custo guard 1/3

auf das sich diese Erklärung bezieht, mit den grundlegenden Anforderungen,
gemäß Anhang I der Richtlinie für Medizinprodukte 93/42/ EWG, übereinstimmt.

The conformity assessment procedure is based on Annex II (excluding section 4).

Die Konformitätsbewertung entspricht dem Verfahren von Anhang II (ohne Abschnitt 4),

Medical Device Directive 93/42/EEC.

Die Produkte gehören zur Klasse IIa nach der Richtlinie für Medizinprodukte 93/42/EWG, Anhang IX, Regel 10.

All units are class IIa according to MDD 93/42/EEC appendix IX rule 10.

Benannte Stelle / Notified Body:
TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339 München, Germany

Kenn-Nummer / ID number:
0123

EG Zertifikat Nr. / EC Certificate no.:
G1 16 10 12998 007

Ausstellungsdatum / Date of issue:
01.12.2016

Ablaufdatum / Expiry date:
30.05.2019

Ort / City

Peter Müller
Geschäftsführer / Director
07.6 Decommissioning, storage and transport

Decommissioning and storage

Clean and disinfect the custo kybe and its components before decommissioning it.

Make sure that the storage location is dust-free, dry and away from direct sunlight.

Transport

Clean and disinfect the custo kybe and its components before transport.

Use the original packaging for transport. This is a sensitive piece of electronic equipment. If unavailable, pack the device so that the device is protected against impact, moisture and dust.

The device must comply with the operating conditions when it is put into operation again, e.g. operating temperature (see 07.2 Technical Data...).

07.7 Disposal

The device and all its 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 device must not be disposed of as normal domestic waste. The manufacturer can dispose of the lithium polymer rechargeable battery.

The original packaging is recyclable (cardboard/paper).
07.8 Keyboard navigation and shortcuts in custo diagnostic

Use the quick links in the main navigation, the keyboard navigation and the keyboard shortcuts to enable fast and convenient working.

Quick links in the main navigation

**LEFT-CLICK**
- User master data
- Call last patient
- Examination main menu

**RIGHT-CLICK**
- Evaluation search
- Call last patient
- Evaluation last displayed

Keyboard navigation

When you press the Alt key, the initial letter of all the buttons on a screen page will be underlined. Pressing an initial letter in combination with the Alt key triggers the corresponding button.
Generally accepted keyboard shortcuts

- Esc: End, Cancel
- Ctrl I: Confirm, continue
- Ctrl U: Program Information
- Ctrl H: User main menu
- Ctrl P: Patient main menu
- Ctrl F: Examination main menu
- Ctrl S: Patient master data for the selected patient
- Ctrl A: All examinations of the selected patient
- Ctrl G: List of most recently opened evaluations (same as clicking on the arrow button at top right)
- Ctrl F: List of most recently opened evaluations
- Ctrl L: Evaluation search
- Ctrl W: Waiting room list
- Ctrl Q: Device list
- Ctrl M: Switching to Metasoft
- Ctrl F1: Create system report, service e-mail
Generally accepted keyboard short cuts for open evaluation

- **Ctrl N**: Report dialogue
- **Ctrl K**: Medication input dialogue
- **Ctrl R**: Call comparison ¹)
- **Ctrl T**: Call trend ¹)
- **Ctrl D**: Call print ¹)
- **Ctrl E**: Call settings ¹)
- **Ctrl O**: Call Options menu ¹)

¹) Keyboard shortcuts will only work if the corresponding button is available on the screen.
Manufacturer’s contact details:
custo med GmbH
Maria-Merian-Str. 6
85521 Ottobrunn, Germany
Germany
Phone:  +49 (0) 89 710 98 - 00
Fax:  +49 (0) 89 710 98 - 10
Email:  info@customed.de
Internet:  www.customed.de