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EN

This user manual describes the use of CardioSecur *pro* in conjunction with iPad 2, iPad (3rd generation), iPad 4, iPad Air and iPad Mini. For simplicity herein referred to collectively as “iPad”.

- iPad 2, iPad (3rd generation), iPad 4, iPad Air and iPad Mini. For simplicity herein referred to collectively as “iPad”.
- iPhone 4/4S, iPhone 5/5S/5C, iPhone 6/6Plus/6S/6SPlus and iPhone 7. For simplicity herein referred to collectively as “iPhone”.

Please note that CardioSecur *pro* runs the 30-Pin connector. In order to connect to an iPad with Lightning receptacle you require the neccessary adapter. This is not included in the scope of delivery.

1 Symbols

Packaging or instructions included in the scope of delivery may display the following symbols (color and size can vary):

Symbol	Meaning
	Use disposable electrodes before the displayed date of expiry.
LOT	Lot denomination
CE 0123	This product complies with the requirements of the directive for medical devices 93/42/EWG.
REF	Item number
	Warning A warning concerns information of high relevance. Take note of such information in the user manual.
	Information. Information concerns details that are worth knowing.
	Manufacturer’s data
	Store at indicated temperature with unbroken seal.
	For single use only
	Latex-free
	CardioSecur *pro* and its accessories - like any other electronic device – contain metal and plastic parts, which need to be disposed separately after operating life in order to prevent negative environmental impact. Send CardioSecur *pro* and its accessories with sufficient postage and if possible in its original packaging to Personal MedSystems GmbH for free of charge disposal.
	Application unit of type BF. An application unit of type BF grants protection against electric shock, in particular with regard to permissible discharge current, according to the requirements of norm EN 60601-1.

EN

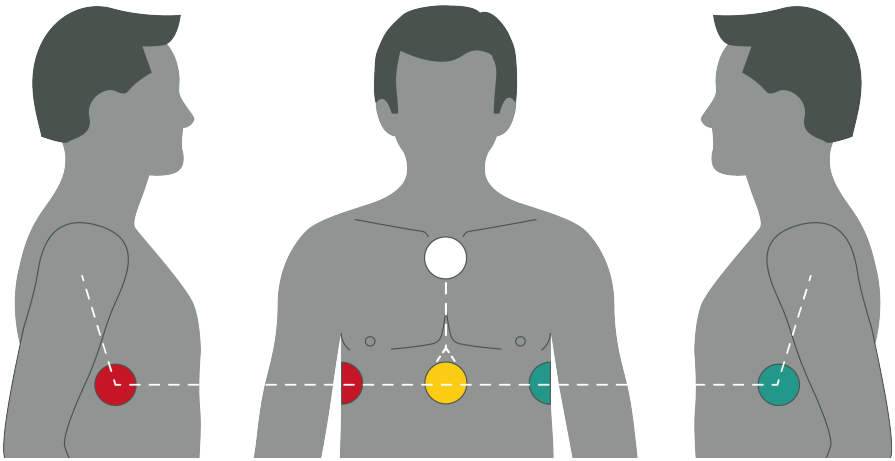
2 Intended Use

CardioSecur *pro* is intended to record, evaluate, document and diagnose a resting ECG of adults.

CardioSecur *pro* is a medical, electrical system comprising an ECG cable, an iPad and an app for an iPad. CardioSecur *pro* records a 22-lead ECG with four electrodes.

Only medically trained personnel may use CardioSecur *pro*.

In order to record an ECG with CardioSecur *pro*, the disposable electrodes need to be positioned on the patient's thorax according to the following diagram:



White electrode:	At the upper end of the sternum
Yellow electrode:	At the lower end of the sternum in the middle of the thorax
Red electrode:	In the middle of the right shoulder at the level of the lower end of the sternum (the same level as the yellow electrode)
Green electrode:	In the middle of the left shoulder at the level of the lower end of the sternum (the same level as the yellow electrode)

3 Safety Information

Take account of the following warnings and information. In case of your non-compliance you run the risk of causing malfunction, damage and injury.

⚠ **Warning:** CardioSecur *pro* is provided for the exclusive use of qualified physicians or personnel under their direct supervision. The numerical and graphical results from a recording must be examined with respect to the patient's overall clinical condition. It is the physicians responsibility to make the diagnosis or to obtain expert opinion on the results and to institute correct treatment if indicated.

⚠ **Warning:** In order to ensure sufficient signal quality and to prevent distorted results, only use disposable electrodes that are unused, have not expired and are at room temperature.

⚠ **Warning:** Remove all disposable electrodes after a reading from the skin, as prolonged adhesion may cause skin irritation.

⚠ **Warning:** Do not use CardioSecur *pro* in case of sensitive skin or allergies. This could cause rash, irritation of the skin or eczemas.

⚠ **Warning:** Do not use CardioSecur *pro* in combination with external defibrillators. CardioSecur *pro* is not defibrillator proof.

⚠ **Warning:** Do not perform readings in places exposing CardioSecur *pro* to high electromagnetic radiation (e.g. TV-sets, monitors, dish washers).

⚠ **Warning:** Do not expose CardioSecur to any electrostatics. Discharge any electrostatics out of your and your patient's body before touching CardioSecur *pro*.

⚠ **Warning:** Do not expose CardioSecur *pro* to any physical shocks or vibrations. Do not drop it on the floor or step on it.

⚠ **Warning:** Do not place anything onto CardioSecur *pro* or it might get damaged.

⚠ **Warning:** Do not open, take apart or repair CardioSecur *pro*. Do not transform CardioSecur *pro*. CardioSecur *pro* does not contain any parts that need to be maintained by its user.

⚠ **Warning:** Store and use CardioSecur *pro* only under the conditions described under section Technical Data.

⚠ **Warning:** Do not sterilize CardioSecur *pro* in a steam sterilizer (autoclave) or in a gas sterilizer (ethylene oxide, formaldehyde, ozone etc.).

⚠ **Warning:** Do not use CardioSecur *pro* in the vicinity of combustible anaesthetics, drugs or pressurized oxygen.

⚠ **Warning:** Only use CardioSecur *pro* if it has no apparent damage.

⚠ **Warning:** Note the information on care and maintenance.

⚠ **Warning:** CardioSecur *pro* utilizes an ECG method computing a 22-lead ECG from 3 leads read with 4 electrodes. Hence, deviations might arise in comparison to a 22-lead ECG read with 10 electrodes.

⚠ **Warning:** Do not perform ECG readings if the skin is wet at the attachment points of the disposable electrodes, e.g. due to sweat or after bathing.

⚠ **Warning:** Proper functioning of the disposable electrodes is influenced by intense body hair. Remove hair from the skin at the attachment points of the electrodes.

⚠ **Warning:** Ensure that your iPad is sufficiently charged in order to perform ECG readings.

⚠ **Warning:** During use of CardioSecur *pro*, do not connect any other device or computer via an adapter to your iPad and/or to the headset jack of your iPad.

⚠ **Warning:** During use of CardioSecur *pro* ensure that neither the patient nor any of the electrodes come into contact with other persons or conductive objects.

⚠ **Warning:** In case you cannot perform a firmware update, please contact Personal MedSystems' customer support.

⚠ **Warning:** Disinfect CardioSecur *pro* before each use. Please take account of warnings and information on care and maintenance in this user manual.

⚠ **Warning:** Perform regular data backups in order to prevent data loss (see chapter 5, Data Backup).

4 Getting Started

In order to run CardioSecur *pro* on your iPad, download the free **CardioSecur *pro*** app from the App-Store to your iPad:

5 Data Backup

You may perform a data backup in the following ways:

- Patient and ECG data may be stored together with the overall data on your iPad via iCloud or iTunes.
- ECG data may be exported in PDF format via E-Mail to other databases (e. g. PMDS, HIS) or storage media (e. g. hard drive, memory card).

6 ISP

The ISP (integrated service platform) offers the following possibilities:

- Platform to connect physician and patient
- Save, store and transfer data between different devices
- Enable new features for the user

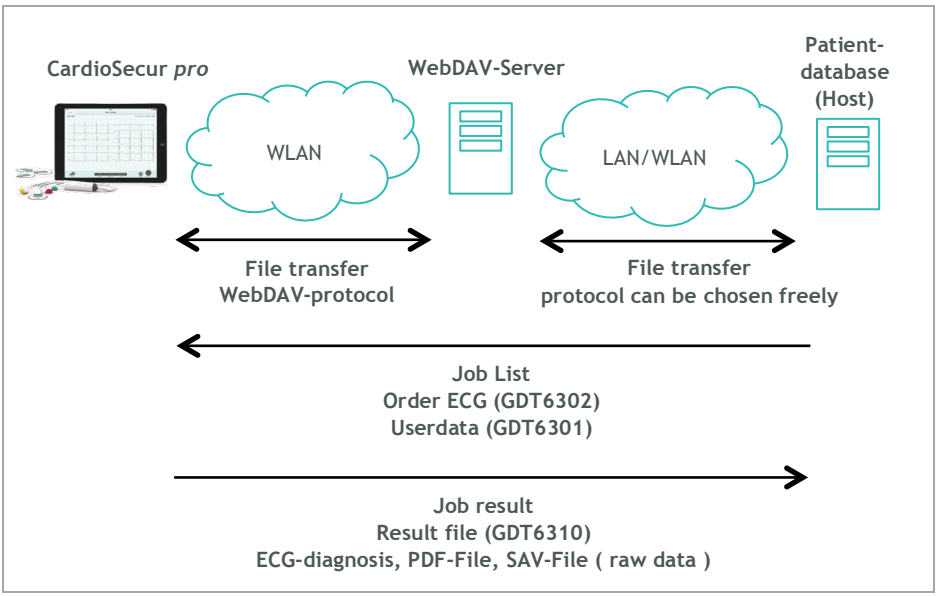
Different settings in the ISP are described in the following sections

- iPad:
- iPhone:

7 GDT-Interface

7.1 Overview

The GDT-interface can be used to transfer data between CardioSecur pro and an external database.



7.2 WebDAV-Server

The WebDav-Server needs directories with the following functions:

- Directory of jobs
- Directory of results

For this task there can be two separate directories or both functionalities can be placed in the same directory.

Setting up WebDav on Windows 7/8 Professional:

First, you must install the Internet Information Services (IIS) and WebDAV publishing features of Windows. In Windows 7, click Start, type "Windows features," and then click enter. In Windows 8, go to the Start screen, type "Windows features," select "Settings" on the right, and then select the shortcut that appears.

Make sure you select at least the following:

- Internet Information Services
- IIS Management Console
- WebDAV Publishing
- Windows Authentication

Next, to enable the WebDAV publishing you must open the IIS Manager. In Windows 7, click Start, type "IIS," and open the shortcut that appears. In Windows 8, go to the Start screen, type "IIS," and then select the shortcut that appears.

To configure the authentication, select the "Default Web Site" and double-click the "Authentication" icon. The list of authentication types displayed will depend upon which ones you installed earlier, but I'd suggest disabling "Anonymous" and enabling "Windows Authentication" if you will only be using IIS for WebDAV.

Next, select the "Default Web Site" site again and double-click the "WebDAV Authoring Rules" and then click "Enable" on the right. Now click "Add Authoring Rule" on the right to configure the permissions and make your desired selections.

To use https do a right click on the default website and add binding.

- Open IIS Manager and navigate to the level you want to manage. For information about opening IIS Manager, see Open IIS Manager (IIS 7). For information about navigating to locations in the UI, see Navigation in IIS Manager (IIS 7).
- In Features view, double-click Server Certificates.
- In the Actions pane, click Create Self-Signed Certificate.
- On the Create Self-Signed Certificate page, type a friendly name for the certificate in the Specify a friendly name for the certificate box, and then click OK.

Add WWW-Services to your firewall.

7.3 Data structures

Job list

The name of the GDT-files for jobs have the follwing structure: "MOBDSxxx.yyy".

xxx and yyy are parameters that can be chosen independently to identify files from the patient database that are ignored by CardioSecur pro. Job files are deleted by CardioSecur pro after they have been read.

CardioSecur pro is able to use following files:

- Write ECG (GDT 6502)
- Master data (GDT 6501)

The content of the files of CardioSecur pro uses the parameters of the following table.

CardioSecur pro also uses the master data if it is included in the write ECG file.

Description	dataset identifier	Style/Content
dataset identifier	8000	alphanumerical
patient identifier	3000	alphanumerical
Patient first name	3102	alphanumerical
Patient last name	3101	alphanumerical
Patient date of birth	3103	style: DDMMYYYY DD = day MM = month YYYY = year z. B. 3.10.2016 -> 03102016

Job Result

The name of the result GDT-file has the following structure: "DSMOBxxx"

xxx is a consecutive number to identify files that are provided by CardioSecur pro. Job requests are deleted by the receiver after they have been read.

Next to the GDT-file a PDF-report or a file with measurement data (SAV-file) in the SCP-format is created. The filename is included in the DSMOB.xxx file.

The result consists of two files:

- DSMOB.xxx with GDT-information
- binary files (PDF, SAV)

The content of the files is defined by the GDT-fields defined in the follwing table.

Description	Dataset identifier	Style/Content
Measurement identifier		„MOBEKG“
Device procedure identifier	8402	„EKG00“
Patient identifier	3000	= patient identifier of job list
Patient first name	3102	= patient first name from job
Patient last name	3101	= patient last name from job list
Date of the measurement	8432	format: DDMMYYYY DD = day MM = month YYYY = year z. B. 3.10.2016 -> 03102016
Time of the measurement	8439	format: HHMMSS HH = hour MM = minute SS = seconds e.g. 17:30:20s -> 170320
Archive identifier	6302	„1“
Format of the content	6303	• „PDF“ for PDF-Report • „SAV“ for raw data in the SCP-format
Description	6304	„mobile ECG“
File name Result file	6305	result file name

7.4 Process

- The host generates job files and stores these in the directory set up for the jobs
- CardioSecur pro reads the job files from the specified directory
- CardioSecur pro deletes the job file after the read process was successful
- These jobs are displayed in the patient database of the CardioSecur pro
- The physician writes ECGs for all patients that have a request in the patient database
- For completed jobs the GDT-file is stored in the directory specified for the results together with the PDF-file or the SAV-file.

8 Care and Maintenance

Cleaning and Maintenance iPad

Take account of any information provided by Apple Inc. regarding cleaning and maintenance of your iPad.

Cleaning CardioSecur *pro*

Clean CardioSecur *pro* only with a slightly dampened towel. Usually cleaning with water and soap is sufficient. Ensure at any time that no liquids penetrate the casing. Any liquids on the casing instantly need to be dried off with a dry towel.

⚠ **Warning:** Clean CardioSecur *pro* never with benzene, benzine, paint thinner or concentrated alcohol.

Maintenance CardioSecur *pro*

⚠ **Warning:** Do not open CardioSecur *pro*. CardioSecur *pro* does not contain any parts that need to be maintained by the user.

Disinfection CardioSecur *pro*

To disinfect CardioSecur *pro* wipe it with a disinfectant. Use for disinfection only non-aggressive agents. Recommended disinfectants (for surface disinfection as recommended by the respective manufacturers of theses disinfectants in their user manuals) are:

- Helipur® H plus N
- Sagrotan® med concentrate

⚠ **Warning:** Never dip CardioSecur *pro* or parts of it into cleaning agents and do not sterilize it in a steam sterilizer (autoclave) or gas sterilizer (ethylene oxide, formaldehyde, ozone etc.).

9 Technical Data and Operating Conditions

Parameter	Description
Model	CardioSecur *pro*
Lead Method	Bipolar, 3 lead
Reading quality	22-lead ECG with 4 electrodes
Pulse range	18 to 256 beats/minute
Precision	Bandwidth: 0,05 to 40 Hz, sampling rate: 250 / 500 Hz
Type of protection	IP20 / IP22
Calculation heart rate	Evaluation of R wave across minimum of 3 beats, otherwise across 7 seconds
Filter	Selectable: muscle tension filter 35 Hz (-3 dB) and 50 Hz filter
Storage	External storage on iPad. Each gigabyte storage capacity: • 250 patients • 10.000 minutes total ECG reading capacity
Maximum duration of an ECG	1800 seconds = 30 minutes
Electrical safety	External power supply, application unit type BF
Power supply	External power supply via iPad
Temperature and humidity for operation	+5 to +45°C, 10 to 95 %, non-condensing
Temperature and humidity for storage	-20 to +45°C, 10 to 95 %, non-condensing
Air pressure for operation	700 - 1060 hPa
Electrodes	Disposable electrodes

⚠ **Warning:** Do not store or operate CardioSecur *pro* under the subsequent conditions:

- Direct sunlight
- Wet or damp places
- Dusty places
- Vicinity of fire or open flames
- Places subjected to strong physical shocks
- Places subjected to high electromagnetic radiation

ⓘ **Information:** During product lifetime no safety-related controls are necessary.

10 Electromagnetic Compliance (EMC)

⚠ **Warning:** Note important information on electromagnetic compliance (EMC). The growing number of electronic devices like PCs, displays, TV-sets, washing machines and mobile phones may subject medical devices to electromagnetic interference. This may cause malfunctioning of the medical device and create potentially unsafe situations. Equally medical devices should not interfere with other electronic devices. The norm IEC60601-1-2 was introduced to regulate the requirements for EMC and prevent unsafe product situations. This norm defines the degrees of immunity against electromagnetic interference and the maximum electromagnetic emission levels for medical devices. CardioSecur *pro* complies with norm IEC60601-1-2:2001 concerning immunity as well as emissions. Nonetheless special precautions should be taken: Do not use devices that cause strong electromagnetic fields in the vicinity of CardioSecur *pro*. A minimum distance of 2 meters is recommended. In case that the distance is less than 2 meters CardioSecur *pro* may not perform properly. In accordance with the norm IEC60601-1-2:2001 you may request our customer support (see chapter 13 Contact below) for further documentation.

DIN EN 550112
Industrial, scientific and medical high frequency devices (ISM devices)
Radio frequency interference – limit values and measuring procedure

Interference emission	Limit value class	Result
Interference voltage	--	n/a
RFI field strength (not accredited testing)	B	OK

DIN EN 60601 1-1-2
Medical electrical equipment
Part 1-2: General requirements for safety:
Collateral standard: electromagnetic compliance; requirements and testing

DIN EN 60601 1-2-47
Medical electrical equipment
Part 2-47: Specific requirements for safety including essential performance characteristics for outpatient electrocardiographic systems

Interference immunity against		Testing accuracy		Result
		normative	tested	
Static electrical discharge	air	8 kV	8kV	OK
	contact	6 (8) kV	8 kV	OK
High frequency electromagnetic fields (80 – 2500 mHz)	housing	3 V/m	10 V/m	OK
Fast transient disturbances (chest)	mains	2 kV	2 kV	n/a
	I/O	1 kV	-	n/a
Surge voltages	unsym.	2 kV	-	n/a
	sym.	1 kV	1kV	n/a
Conducted disturbances, induced by high frequency	mains	3 V	10 V	n/a
	I/O	3 V	-	n/a
Energy-related frequency – Magnetic field 50 Hz (Helmholtz coil)	housing	3 A/m	3 A/m	n/a
Voltage dips, short-term interruptions	mains UT	<5% 0,5 per.	<5% 0,5 per.	n/a
Test levels as % of UT duration in supply frequency periods	100 – 240V 50 / 60 Hz	40% 100 per.	40% 100 per.	n/a
All testing at 100 and 240V each 50 Hz		70% 500 per.	70% 500 per.	n/a
		<5% 5000 per.	<5% 5000 per.	n/a

11 Disposal

⚠ **Warning:** Ensure proper disposal of CardioSecur *pro* (electronic waste). Labelling on CardioSecur *pro*, its packaging and this user manual indicate, that after its lifetime CardioSecur *pro* must not be disposed together with ordinary household refuse. Dispose of CardioSecur *pro* separately, so that harm to the environment or human health is not caused by uncontrolled disposal.

12 Labelling

www.cardiosecur.com
Personal MedSystems GmbH
Hansaallee 154
D-60320 Frankfurt am Main
Made in Germany 201x

13 Contact

Personal MedSystems GmbH
Hansaallee 154
60320 Frankfurt am Main
Germany

Phone: +49-(0)69-907477-81
Fax: +49-(0)69-907477-84
E-mail: kb@personalmedsystems.com
Website: www.cardiosecur.com

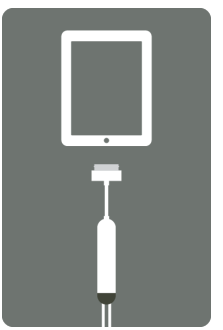
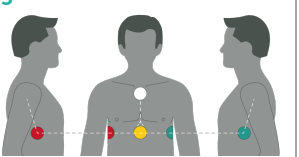
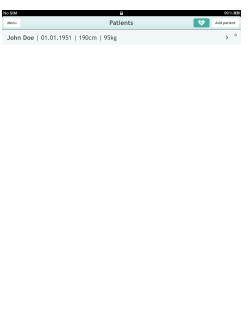
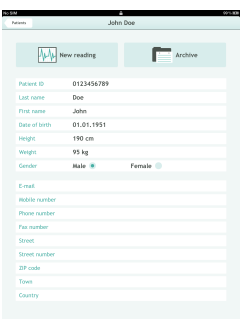
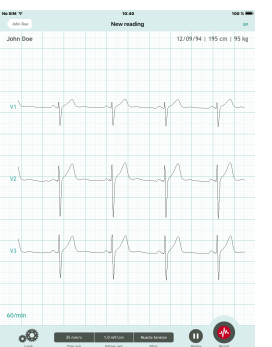
HRB 114144 B
USt.-Id.-Nr.: DE 260540641

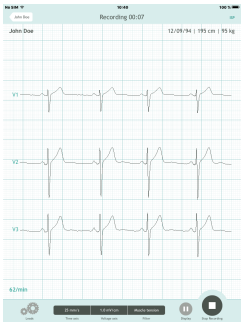
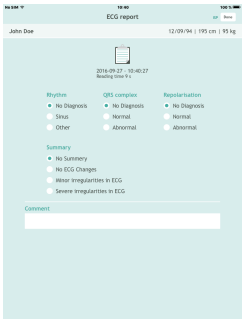
Refer to our customer support in case of queries regarding CardioSecur *pro*.
Phone: +49-(0)69-907477-81
e-mail: kb@personalmedsystems.com

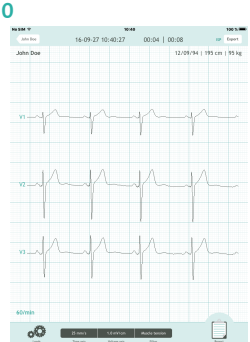
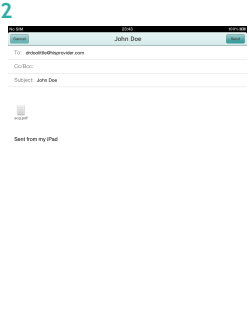
14 iPad

14.1 ECG Recording

The following flow diagram shows the steps on how to perform an ECG recording. Details to each step can be found in the chapters 14.4 Patient Administration, 14.5 Patient Details, 14.6 ECG Display and Functions and 14.8 Export.

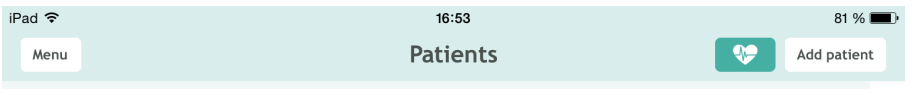
1  Start the CardioSecur *pro* app.	2  Connect the CardioSecur *pro* ECG cable to your iPad.	3  Attach the disposable electrodes to the patient's body according to the diagram.
4  Create a new patient file by touching the icon Add patient.	5  Enter the patient's personal data and start a reading by touching the icon New reading.	6  Start an ECG recording by touching the icon .

7	8	9
		
Stop an ECG recording by touching the icon ⏹. When a recording is stopped it is stored automatically in the archive.	Create a report by touching the icon 📋. You may also edit a report later by selecting the recording form the archive.	Complete your report entries by touching the icon Done.

10	11	12
		
Send an ECG report as PDF-file via e-mail by touching the icon Export.	Select the preferred display of the ECG recording and attach it to the e-mail by touching the icon E-Mail.	Enter the recipient's e-mail address and start the transmission by touching the icon Send.

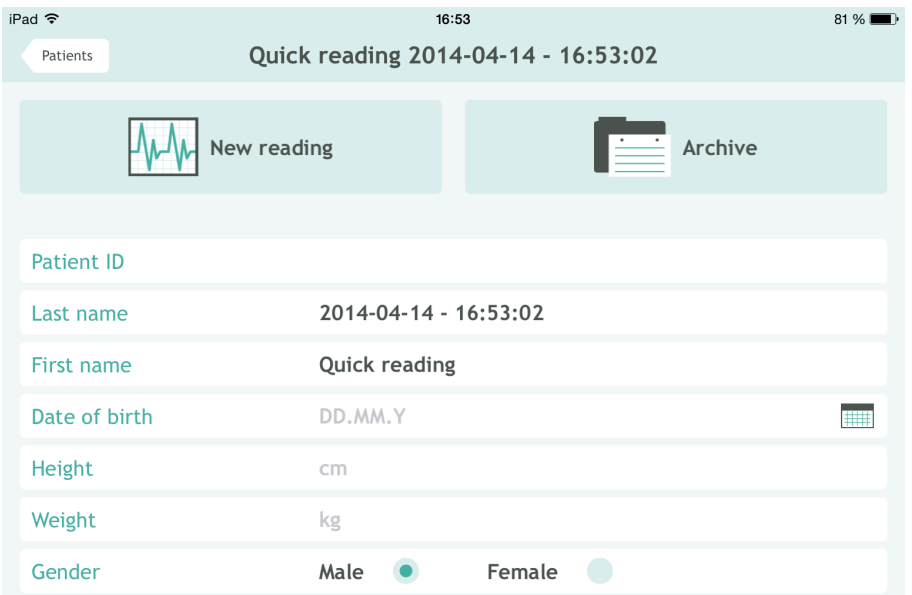
14.2 Emergency ECG Recording

In an emergency you have the possibility to perform an ECG recording fast and without need for entering the patient's personal data. This may save in some cases valuable time. To commence an emergency recording touch the icon in the patient administration window:



CardioSecur *pro* thereupon creates by default a patient with the following properties:

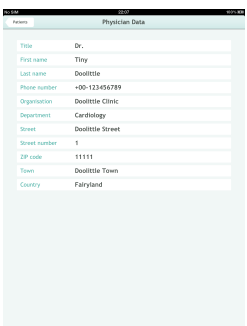
- Last name: current date and time (format: YYYY-MM-DD - hh:mm:ss)
- First name: Emergency
- Gender: male



An ECG reading will commence instantly without need for entering further input. In order to perform an ECG recording in emergency cases, follow the instructions given in chapter 14.1 ECG Recording starting at step 6.

14.3 Menu

Physician Data	Under this menu item you may enter all physician data. When creating an ECG report your data will be added automatically to the report. Physician data comprises the following information: • Title • TitleFirst name • Last name • Phone number • Organisation • Department • Street • Street number • ZIP code • Town • Country



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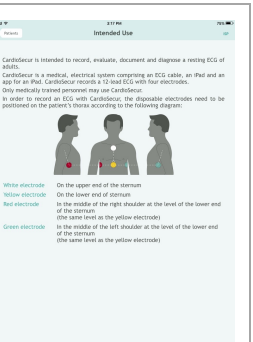
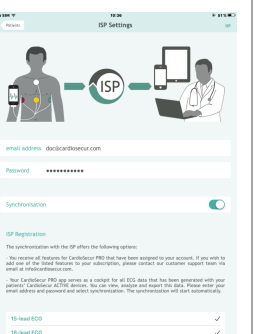
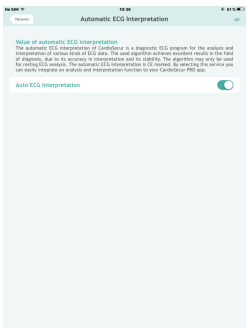
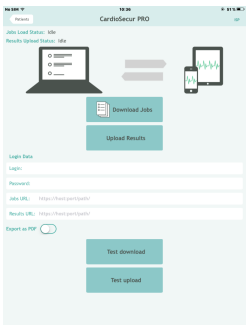
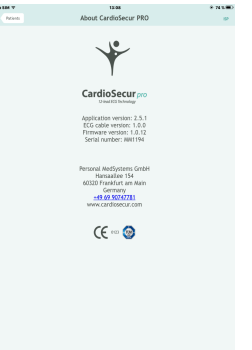
Intended Use	You will find the Intended Use in the app as well as in this user manual:	
ISP Settings	Connecting to your personal user account on the ISP (Integratet Service Platform) allows you to use all your CardioSecur features. The ISP also is the center point of your connection to patients that use the CardioSecur active.	

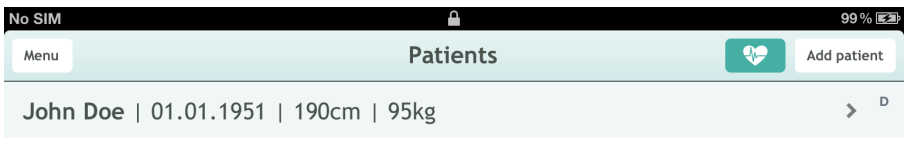
Automatic ECG Interpretation	The automatic interpretation is a complete diagnostic tool that enables you to perform a full automated diagnostic analysis on a 10 second measurement. The interpretation also holds measurement values for characteristic ECG parameters as QRS duration and QT-time.	
GDT worklist	The GDT interface holds the possibility to integrate CardioSecur in your IT-System. Patients from your database can be synchronized into your CardioSecur app. ECGs taken for these patients can then be synchronized to your patient files of your IT system as PDF or as raw data.	
Safety Information	You will find the safety information in the app as well as in this user manual: ➢ See chapter 3 Safety Information	

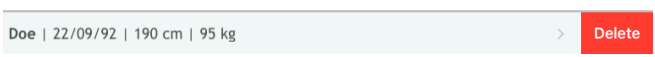
EN

About **CardioSecur *pro***	Information about CardioSecur *pro* comprises the following Data: • Serial number • Version of the application • Version of the ECG cable • Version of the firmware • Contact information of Personal MedSystems • Labelling



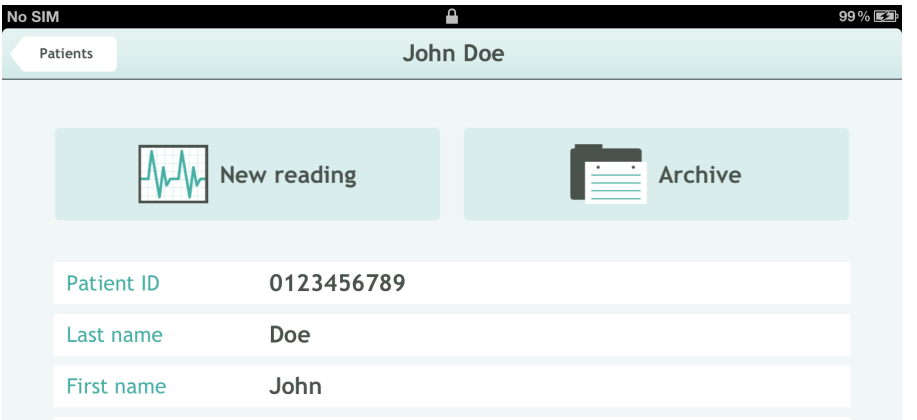
14.4 Patient Administration



Menu	➢ See chapter 14.3 Menu
	Performing an emergency recording ➢ See chapter 14.2 Emergency ECG Recording
Touch a patient entry in the list	Access a patient's details ➢ See chapter 15.5 Patient Details
Add Patient	Create a new patient ➢ See chapter 15.5 Patient Details
With one finger swipe from right to left across the patient entry (delete gesture)	Delete a patient entry by touching the icon Delete. 

EN

14.5 Patient Details

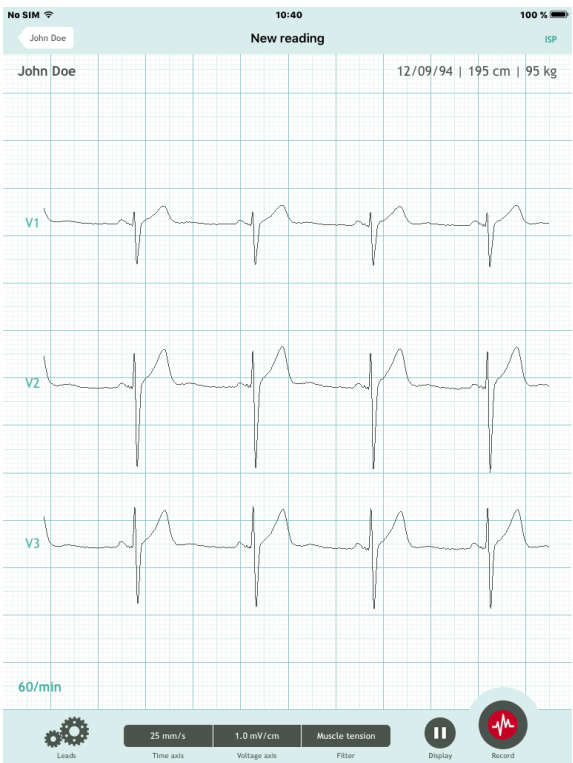


New reading	Commence a new ECG reading for a patient ➢ See chapter 14.6 ECG Display and Functions
Archive	List of all ECG recordings of a patient
Data fields	You may enter personal data of the patient. The patient's data will be added to each performed ECG recording. Data concerning the patient comprises the following information: • Patient ID • Last name • First name • Date of birth • Height • Weight • Gender • E-mail address • Mobile phone number • Phone number • Fax number • Street • Street number • ZIP code • Town • Country

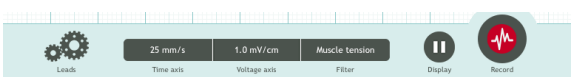
14.6 ECG Display and Functions

ECG display may be performed in the following modes:

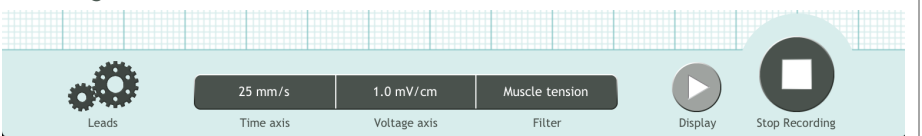
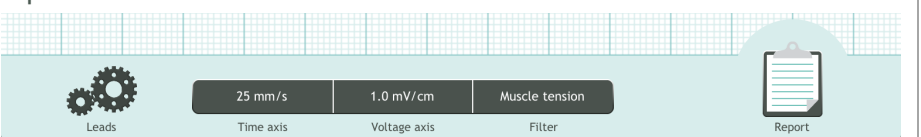
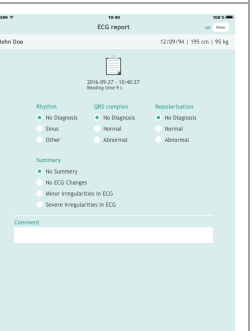
- **Viewing mode:** In viewing mode ECG readings can be viewed. You have the option to halt the running ECG reading and resume it again. ECG readings are merely displayed not recorded in this mode.
- **Recording mode:** In recording mode ECG readings can be recorded and stored in the local memory of your iPad.

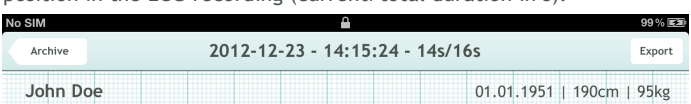


Viewing mode



	Halt a running ECG reading. This icon appears, while the ECG reading is

	running (not in recording mode).
	Resume a running ECG reading. This icon appears, when a running ECG image was halted.
	Start an ECG recording. This icon appears after activating a new reading.
Recording mode 	
	Stop an ECG recording. This icon appears, when an ECG recording was commenced. By stopping an ECG recording it will be stored in the archive.
Report Function 	
	Either after performing an ECG recording or when selecting a recording from the archive you may create a report attaching to the recording. Reports allow you to edit the following options: • Rhythm • QRS complex • Repolarisation • Summary • Comment 
General Functions	

	Display options: • Number of columns • Lead block selection • Individual leads • Cabrera display 
Time axis	Selection of time axis scaling: • 5 mm/s • 10 mm/s • 25 mm/s • 50 mm/s
Voltage axis	Selection of voltage axis scaling (amplitude): • 0.5 mV/cm • 1 mV/cm • 2 mV/cm • 5mV/mm
Filter	Selection of ECG filters: • No filter • 50 Hz filter • Muscle tension filter
Swipe with one finger (scrolling gesture)	Scrolling on the time axis. The header displays the current view position in the ECG recording (current/total duration in s). 
Narrow and widen space between two fingers (zoom gesture)	Zooming in and out the current view.

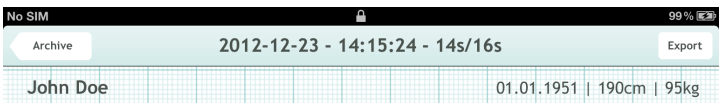
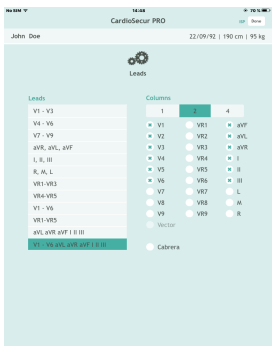
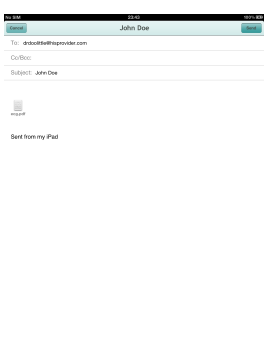
14.7 Archive

Touch an entry	Activate the display of an archived ECG recording. ➢ See chapter 14.6 ECG Display and Functions.
Swipe with one finger from right to left across an entry (delete gesture)	Delete an archived ECG recording with the icon Delete. 

14.8 Export

Every ECG may be exported via e-mail after recording or from the archive. In order to do so an e-mail account must be installed on your iPad. The ECG report attaches to the e-mail as PDF-file. The alignment of an ECG report is by default and unalterable in landscape view.

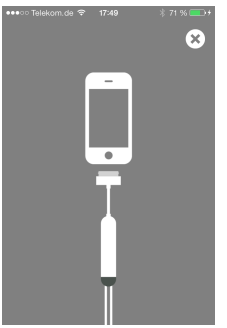
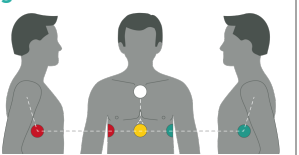
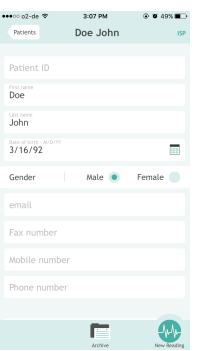
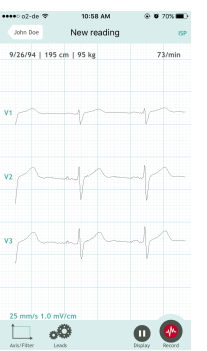
Follow the subsequent steps to export an ECG recording:

Export	Every ECG recording that is new or selected from the archive may be exported. To do so touch the Export icon in the header. 
E-mail	Before exporting you may select how the ECG recording is displayed in the PDF-file. Displaying options: • Number of columns • Lead block selection • Individual leads • Cabrera display • Rhythm strip • Entire ECG or current view Complete your selection by touching the E-Mail icon and the e-mail send dialog will appear. 
Send	The ECG report will be attached to the e-mail as PDF-file. The e-mail subject will contain the patient's name. You may change the subject and content of the e-mail. In order to send the e-mail you need to enter the e-mail address of the intended recipient. Send the e-mail by touching the icon Send the e-mail will be sent. 

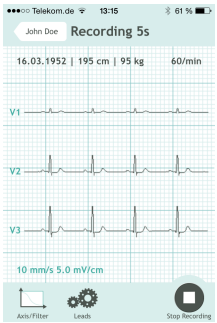
15 iPhone

15.1 ECG Recording

The following flow diagram shows the steps on how to perform an ECG recording. Details to each step can be found in the chapters 14.4 Patient Administration, 14.5 Patient Details, 14.6 ECG Display and Functions and 14.8 Export.

1  Start the CardioSecur *pro* app.	2  Connect the CardioSecur *pro* ECG cable to your iPad.	3  Attach the disposable electrodes to the patient's body according to the diagram.
4  Create a new patient file by touching the icon +.	5  Enter the patient's personal data and start a reading by touching the icon .	6  Start an ECG recording by touching the icon . 

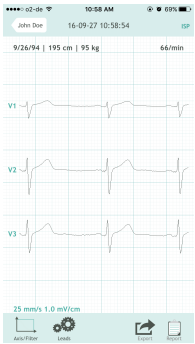
7



Stop an ECG recording by touching the icon .

When a recording is stopped it is stored automatically in the archive.

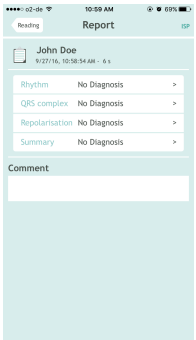
8



Create a report by touching the icon .

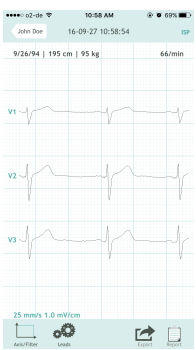
You may also edit a report later by selecting the recording form the archive.

9



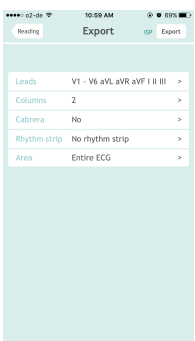
Complete your report entries by touching the icon Reading.

10



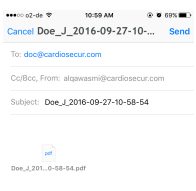
Send an ECG report as PDF-file via e-mail by touching the icon .

11



Select the preferred display of the ECG recording and attach it to the e-mail by touching the icon Export.

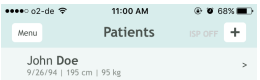
12

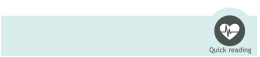


Enter the recipient's e-mail address and start the transmission by touching the icon **Send**.

15.2 Quick reading

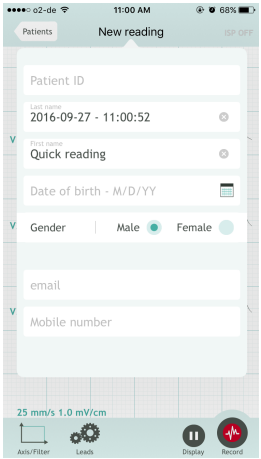
In an emergency you have the possibility to perform an ECG recording fast and without need for entering the patient's personal data. This may save in some cases valuable time. To commence an emergency recording touch the icon  in the patient administration window:



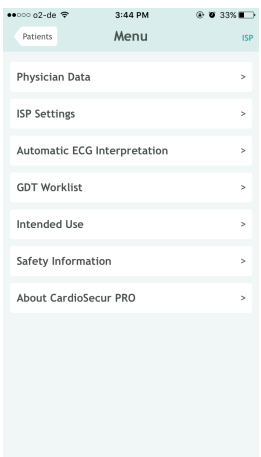


CardioSecur *pro* thereupon creates by default a patient with the following properties:

- Last name: current date and time (format: YYYY-MM-DD - hh:mm:ss)
- First name: Emergency
- Gender: male



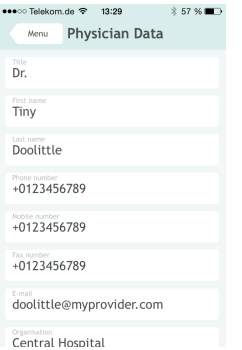
An ECG reading will commence instantly without need for entering further input. In order to perform an ECG recording in emergency cases, follow the instructions given in chapter 14.1 ECG Recording starting at step 6.

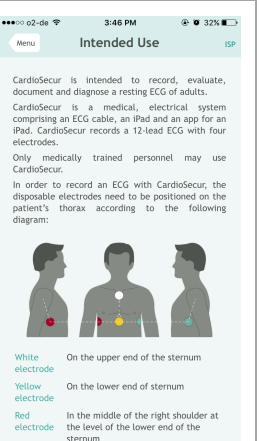


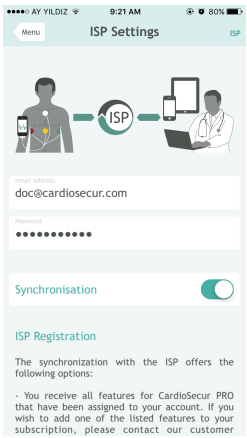
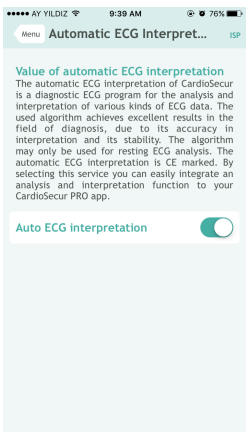
EN

15.3 Menu

Physician Data	Under this menu item you may enter all physician data. When creating an ECG report your data will be added automatically to the report. Physician data comprises the following information: • Title • First name • Last name • Phone number • Mobile number • Fax number • E-mail • Organisation • Department • Street • Street number • ZIP code • Town • Country
Intended Use	You will find the Intended Use in the app as well as in this user manual:





ISP Settings	Entering the personal data and synchronizing will allow you to use ISP. Using the ISP features can be added or removed, and ECG data generated by patients can be viewed.	
Automatic ECG interpretation	This allows you to activate/deactivate the automatic interpretation, which is a diagnostic ECG program of the analysis of different ECG data.	

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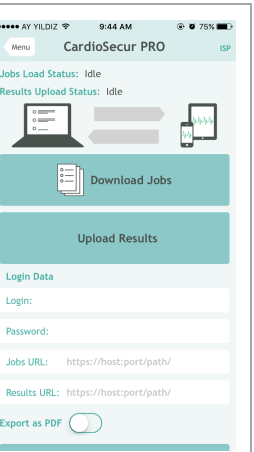
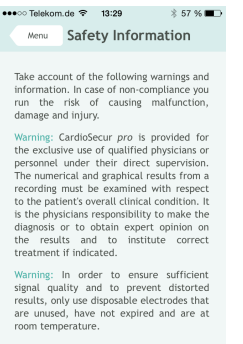
GDT Worklist		
Safety Information	You will find the safety information in the app as well as in this user manual: ➢ See chapter 3 Safety Information	

About CardioSecur *pro*	Information about CardioSecur *pro* comprises the following Data: • Serial number • Version of the application • Version of the ECG cable • Version of the firmware • Contact information of Personal MedSystems • Labelling	

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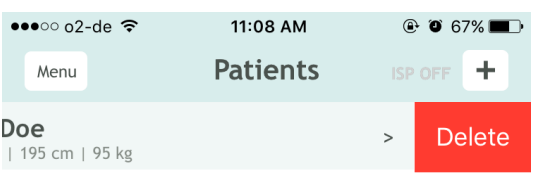
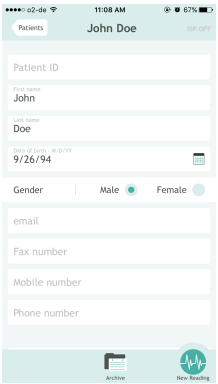
15.4 Patient Administration

Menu	➢ See chapter 14.3 Menu
	Performing an emergency recording ➢ See chapter 14.2 Emergency ECG Recording
Touch a patient entry in the list	Access a patient's details ➢ See chapter 14.5 Patient Details
Add Patient	Create a new patient ➢ See chapter 14.5 Patient Details
With one finger swipe from right to left across the patient entry (delete gesture)	Delete a patient entry by touching the icon . 

15.5 Patient Details



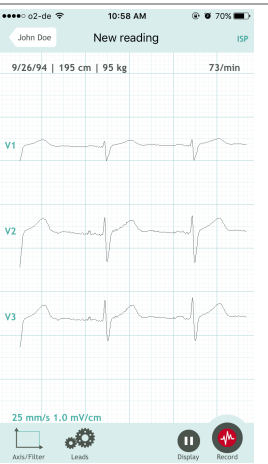
	Commence a new ECG reading for a patient ➢ See chapter 14.6 ECG Display and Functions
	List of all ECG recordings of a patient
Data fields	You may enter personal data of the patient. The patient's data will be added to each performed ECG recording. Data concerning the patient comprises the following information: • Patient ID • Last name • First name • Date of birth • Height • Weight • Gender • E-mail address • Mobile phone number • Phone number • Fax number • Street • Street number • ZIP code • Town • Country

EN

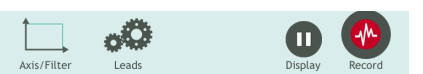
15.6 ECG Display and Functions

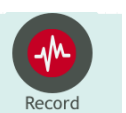
ECG display may be performed in the following modes:

- **Viewing mode:** In viewing mode ECG readings can be viewed. You have the option to halt the running ECG reading and resume it again. ECG readings are merely displayed not recorded in this mode.
- **Recording mode:** In recording mode ECG readings can be recorded and stored in the local memory of your iPad.



Viewing mode



	Halt a running ECG reading. This icon appears, while the ECG reading is running (not in recording mode).
	Resume a running ECG reading. This icon appears, when a running ECG image was halted.
	Start an ECG recording. This icon appears after activating a new reading.

Recording mode

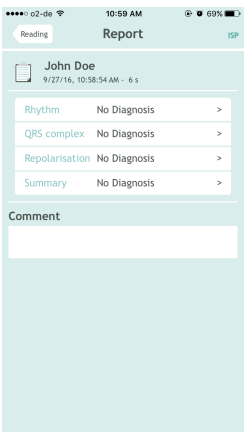
	Stop an ECG recording. This icon appears, when an ECG recording was commenced. By stopping an ECG recording it will be stored in the archive.

Report Function

Either after performing an ECG recording or when selecting a recording from the archive you may create a report attaching to the recording.

Reports allow you to edit the following options:

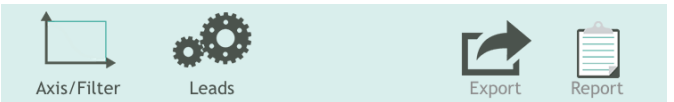
- Rhythm
- QRS complex
- Repolarisation
- Summary
- Remarks



EN

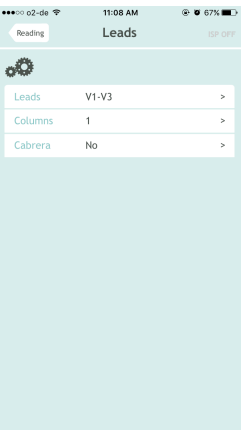
15.6.1.1.1.1 **Report Function**

15.6.1.1.1.2



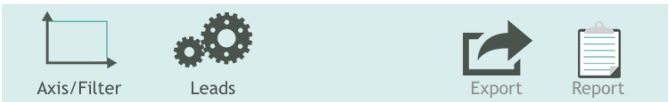
Display options:

- Number of columns
- Lead block selection
- Individual leads
- Cabrera display

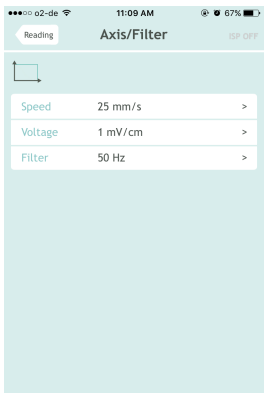


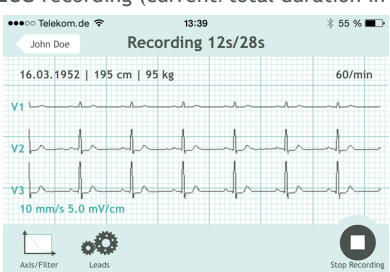
15.6.1.1.1.1.3 Axis/Filter

15.6.1.1.1.1.4

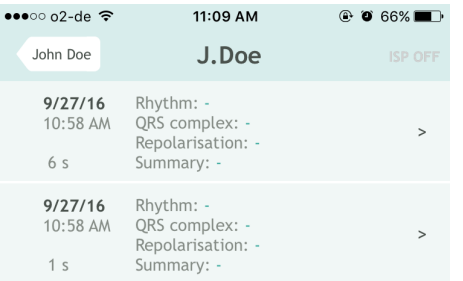
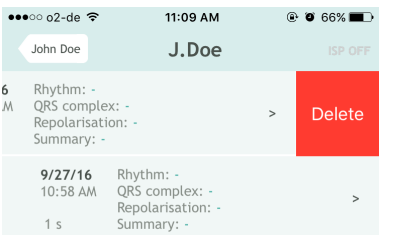


Time axis	Selection of time axis scaling: • 5 mm/s • 10 mm/s • 25 mm/s • 50 mm/s
Voltage axis	Selection of voltage axis scaling (amplitude): • 0.5 mV/cm • 1 mV/cm • 2 mV/cm • 5mV/cm
Filter	Selection of ECG filters: • No filter • 50 Hz filter • Muscle tension filter



General Functions	
Swipe with one finger (scrolling gesture)	Scrolling on the time axis. The header displays the current view position in the ECG recording (current/total duration in s). 
Narrow and widen space between two fingers (zoom gesture)	Zooming in and out the current view.

15.7 Archive

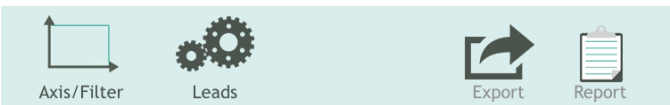
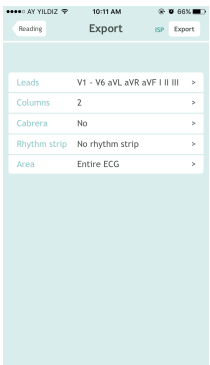
<table>
<tr><td colspan="2"> 
</td></tr>
<tr><td>Touch an entry</td><td>Activate the display of an archived ECG recording.
➢ See chapter 15.6 ECG Display and Functions.</td></tr>
<tr><td>Swipe with one finger from right to left across an entry
(delete gesture)</td><td>Delete an archived ECG recording with the icon .
 
</td></tr>
</table>

15.8 Export

Every ECG may be exported via e-mail after recording or from the archive. In order to do so an e-mail account must be installed on your iPhone. The ECG report attaches to the e-mail as PDF-file. The alignment of an ECG report is by default and unalterable in landscape view.

Follow the subsequent steps to export an ECG recording:

EN

Export	Every ECG recording that is new or selected from the archive may be exported. To do so touch the Export icon in the footer. 
E-mail	Before exporting you may select how the ECG recording is displayed in the PDF-file. Displaying options: • Number of columns • Lead block selection • Individual leads • Cabrera display • Rhythm strip • Entire ECG or current view Complete your selection by touching the E-Mail icon and the e-mail send dialog will appear. 15.8.1.1.1.1.1 

Send	The ECG report will be attached to the e-mail as PDF-file. The e-mail subject will contain the patient's name. You may change the subject and content of the e-mail. In order to send the e-mail you need to enter the e-mail address of the intended recipient. Send the e-mail by touching the icon Send the e-mail will be sent.