

User Manual ([EN](#)) applies to

CardioSecur Pace

Version 13.1
UDI-DI 4260334950068
26.03.2026

Index

1	Additional Information	3
2	Symbols	3
3	Intended Use	4
4	Safety Information	5
5	Connecting the CardioSecur ECG Cable	7
6	Disposable Electrodes	7
7	Data Backup.....	8
8	Care and Maintenance.....	8
9	Technical Data and Operating Conditions.....	9
10	Electromagnetic Compliance (EMC).....	9
11	Disposal.....	10
12	Labelling.....	11
13	Contact	11

1 Additional Information

This user manual applies to CardioSecur Pro and CardioSecur Aviation and describes their use of in conjunction with the following iOS devices (iPhone/ iPad/ iPod touch is a trademark of Apple Inc.):




Family	Model
iPad Air	2. Gen., 3. Gen., 4. Gen., 5. Gen.
iPad mini	3. Gen., 4. Gen., 5. Gen., 6. Gen.
iPad Pro 12.9"	1. Gen, 2. Gen., 3. Gen., 4. Gen., 5. Gen., 6. Gen.
iPad Pro 11"	3. Gen., 4. Gen., 5. Gen., 6. Gen.
iPad Pro 10.5"	2. Gen.
iPad Pro 9.7"	1. Gen.
iPad	5. Gen, 6. Gen., 7. Gen., 8. Gen., 9. Gen., 10. Gen.
iPhone 6	6, 6 Plus, 6s, 6s Plus
iPhone SE	1. Gen, 2. Gen. 3. Gen.
iPhone 7	7, 7 Plus
iPhone 8	8, 8 Plus
iPhone X	X, XS, XR, XS Max
iPhone 11	11, 11Pro, 11Pro Max
iPhone 12	12, 12 mini, 12 Pro, 12 Pro Max
iPhone 13	13, 13 mini, 13 Pro, 13 Pro Max
iPhone 14	14, Pro, Pro Max, Plus
iPod touch	6. Gen., 7. Gen.










The latest list is available for you at www.cardiosecur.com. For simplicity herein referred to collectively as iOS device and CardioSecur.

Additional information can be found at www.cardiosecur.com/en/pro-manual.

2 Symbols

Packaging included in the scope of delivery or this user manual may display the following symbols (colour and size can vary):

Symbol	Meaning
	Use disposable electrodes before the displayed date of expiry.
LOT	Lot denomination
	This product complies with the requirements of the directive for medical devices 93/42/EWG.
	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
REF	Item number

	Please read the user manual
	Warning Warning concerns safety-relevant information
	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 and its accessories - like any other electronic device – contain metal and plastic parts, which need to be disposed of separately after the operating life to prevent a negative environmental impact. Send CardioSecur and its associated accessories with sufficient postage, if possible, in its original packaging, to Personal MedSystems GmbH for disposal free of charge.
	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.

3 Intended Use

3.1 Intended purpose

CardioSecur is intended to record, display and document a resting electrocardiogram (ECG) for adult males and females.

CardioSecur is a medical electrical system comprising an ECG cable, an iOS device and an app for an iOS device. CardioSecur records a 22-lead ECG using 4 electrodes.

3.2 Indications

Diagnoses that can be made with the standard placement of a 10-electrode ECG (ischemia, rhythm disturbances).

3.3 Contraindications

Non-standard placement of electrodes (e.g. Brugada syndrome).

3.4 Intended User

The device is intended for use by healthcare professionals clinical settings such as hospitals, clinics, and medical practices.

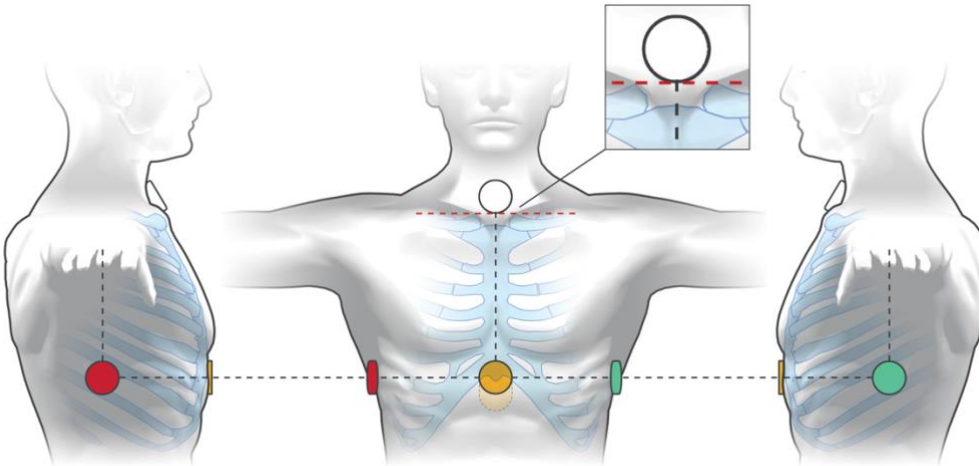
3.5 Intended Patient Population

Adult male and female

3.6 Information for use

Only medically trained personnel may use CardioSecur.

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



- White electrode: Position the white electrode precisely in the depression above the breastbone, never below the collarbone level.
- Yellow electrode: On the lower, bony end of the sternum or slightly below.
- Red electrode: In the middle of the right axillary line at the same level as the yellow electrode.
- Green electrode: In the middle of the left axillary line at the same level as the yellow electrode.

4 Safety Information

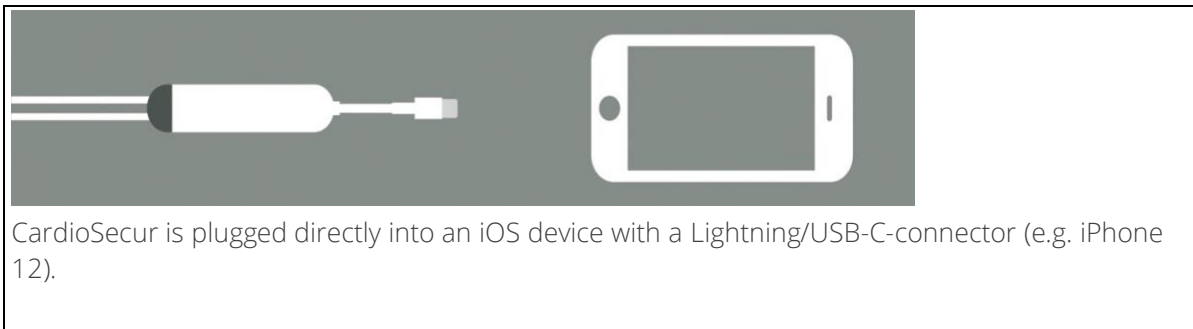
Take account of the following warnings and information. In case of your non-compliance you run the risk of causing malfunction, damage or bodily injury.

- Warning:** The numerical and graphical results from a CardioSecur recording must be examined with respect to the patient's overall clinical condition. It is the physician's 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 from the skin after a reading, as prolonged adhesion may cause skin irritation.
- Warning:** Do not use CardioSecur in case of sensitive skin or allergies. This could cause rash, irritation of the skin or eczema.
- Warning:** Do not use CardioSecur when using an external defibrillator (CardioSecur is not defibrillator proof).
- Warning:** Do not perform readings in places exposing CardioSecur to high electromagnetic radiation (e.g. TV sets, monitors, dishwashers, dimmer).
- Warning:** Do not expose CardioSecur to any electrostatics. Discharge any electrostatics from your and your patient's body before touching CardioSecur.
- Warning:** Do not expose CardioSecur to any physical shocks or vibrations. Do not drop it on the floor or step on it.
- Warning:** Do not open, take apart or repair CardioSecur. Do not transform CardioSecur. CardioSecur does not contain any parts that need to be maintained by its user.
- Warning:** Store and use CardioSecur only under the conditions described in section 9, Technical Data and Operating Conditions, otherwise proper function cannot be guaranteed.
- Warning:** Do not sterilize CardioSecur in a steam sterilizer (autoclave) or in a gas sterilizer (ethylene oxide, formaldehyde, ozone etc.).

- Warning:** Do not use CardioSecur in the vicinity of combustible anesthetics, drugs or pressurized oxygen.
- Warning:** Only use CardioSecur if it has no apparent damage.
- Warning:** Note the information in section 8, Care and Maintenance.
- Warning:** CardioSecur utilizes an ECG method computing up to 22-lead ECG from 3 leads read with 4 electrodes. Hence, deviations might arise in comparison to a 12-lead ECG read with 10 electrodes.
- Warning:** Do not place anything onto CardioSecur as this may damage it.
- 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 large amounts of body hair, lotion or oily skin. Regularly remove hair from your skin at the attachment points of the electrodes and ensure that your skin is free of lotion and fat. Do not clean your skin with alcohol.
- Warning:** Ensure that your iOS device is sufficiently charged in order to perform ECG readings.
- Warning:** During use of CardioSecur, do not connect any other device or computer via an adapter to your iOS device and/or to the headset jack of your iOS device.
- Warning:** During use of CardioSecur 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 (see section 13, Contact).
- Warning:** Please take account of warnings and information in section 8, Care and Maintenance.
- Warning:** Perform regular data backups in order to prevent data loss (see section 7, Data Backup).
- Warning:** CardioSecur does not guarantee data transmission.
- Warning:** If email export is intended, please ensure before use, that your email account is configured on your smart phone or tablet and fully functional.
- Note:** CardioSecur is suitable for use with pacemakers.

5 Connecting the CardioSecur ECG Cable

5.1 Cable CardioSecur Pro MFI



5.2 CardioSecur Wireless



6 Disposable Electrodes

Disposable electrodes constitute the link between your body and CardioSecur. They are of critical importance for the technology's proper function. Personal MedSystems cooperates with highly specialized manufacturers for disposable electrodes, in order to ensure optimal signal quality.

F9067/4/CARDIOSECUR are disposable electrodes designed for recording electrocardiograms (ECG).

Warning: Use disposable electrodes only if the expiry date has not passed. **Warning:** Use disposable electrodes only if they have reached room temperature.

Warning: Store disposable electrodes only with unbroken seal and at temperatures between 10°C and 25 °C.

Warning: Please be aware of the instructions on the back of the disposable electrode packaging.

Manufacturer Information

FIAB SpA
Via P. Costoli, 4
50039 Vicchio (FI)
Italy

"manufactured and imported"
F9067/4/CARDIOSECUR



Ambu A/S

Made in Malaysia



7 Data Backup

You may perform a data backup in the following ways:

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

8 Care and Maintenance

8.1 Cleaning and Maintenance of iOS device

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

8.2 Cleaning and disinfection of CardioSecur

Clean CardioSecur with a slightly dampened towel only. Cleaning with water and soap is usually sufficient. Any liquids on the casing need to be dried off with a towel immediately.

Warning: Never clean CardioSecur with benzene, benzine, paint thinner or concentrated alcohol. To disinfect CardioSecur, wipe it with a disinfectant. Only use non-aggressive agents for disinfection. Recommended disinfectants (for surface disinfection as recommended by the respective manufacturers of these disinfectants in their user manuals) are Helipur® H plus N and Sagrotan® med concentrate.

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

8.3 Maintenance of CardioSecur

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

9 Technical Data and Operating Conditions

Parameter	Description
Model	CardioSecur Pace
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 125 Hz, sampling rate: 250 Hz
Heart rate calculation	Evaluation of R wave across minimum of 3 beats, otherwise across 7 seconds
Type of protection	IP22
Filter	Selectable: muscle tension filter 35 Hz (-3 dB) and 50 Hz filter
Storage	External storage on iOS device. Each gigabyte capacity is 10,000 min ECG readings
Maximum duration of an ECG	1800 seconds = 30 minutes
Applied-Part protection class	External power supply, application unit type BF
Protection class	External power supply via iOS device
Temperature and humidity operation	+5 °C to +40 °C, 10 % to 93 %, non-condensing
Temperature and humidity storage	-25 °C to +70 °C, 10 % to 93 %, non-condensing
Air pressure for operation	700 - 1060 hPa
Electrodes	Disposable electrodes
Environmental use	Clinical Setting

Warning: Do not store or operate CardioSecur under the following 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: Safety-related controls are not necessary during the product's lifetime.

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 degree of immunity against electromagnetic interference and the maximum electromagnetic emission levels for medical devices. CardioSecur 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. A minimum distance of 2 meters is recommended. In case that the distance is less than 2 meters CardioSecur may not perform properly. In accordance with the norm IEC60601-1-2:2001 you may contact our customer support (see section 13, Contact) for further documentation.

10.1 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

10.2 DIN EN 60601 1-1-2

Medical electrical equipment

Part 1-2: General requirements for safety:

Collateral standard: electromagnetic compliance; requirements and testing

10.3 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	8 kV	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	1 kV	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 Test levels as % of UT duration in supply frequency cycles All testing at 100 V and 240 V each 50 Hz	mains UT 100 – 240V 50 / 60 Hz	<5 %	<5 %	n/a
		0,5 Per.	0,5 Per.	
		40 %	40 %	n/a
		100 Per.	100 Per.	
		70 %	70 %	n/a
		500 Per.	500 Per.	
		<5 %	<5 %	n/a
		5000 Per.	5000 Per.	

11 Disposal

Warning: Ensure proper disposal of CardioSecur (electronic waste).

Labelling on CardioSecur, its packaging, and this user manual indicate that CardioSecur must not be disposed together with ordinary household refuse after its lifetime. Dispose of CardioSecur separately, so that harm to the environment or human health is not caused by uncontrolled disposal.

12 Labelling

www.cardiosecur.com

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13 Contact

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Website: www.mobile-ecg.com / www.cardiosecur.com

Refer to our customer support in case of queries regarding CardioSecur and to request a printed version of the user manual.

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