CADScor® System

User Manual

Rx Only

1 Warranties and disclaimer

The CADScor®System is covered by a general 1-year warranty from date of purchase, that covers faulty hardware, including the CADScor®Sensor, the CADScor®Docking station and the external power adaptor.

Furthermore, Acarix guarantees that the CADScor®System will be operational for at least 1000 recordings in the warranty period.

If, however the CADScor®System does not operate properly, please first consult the "Troubleshooting guide"-section 11 in this manual describing possible errors.

Any claims on warranty should be addressed to Acarix directly or to the Acarix distributor in your country, who will initiate replacement or repair of faulty equipment.

1.1 Disclaimer

The information given in this document is adapted to an international market of healthcare professionals, based on illustrations, symbols and text. The document is giving no specific references to religious preference, ethnic origin, gender or political viewpoints. Any such relation is considered an interpretation of which Acarix cannot be held reliable. The information is intended to ensure the safe and accurate operation of the CADScor®System.

2 Copyright notice

3 Changes

This document is subject to change without notice and you are urged to contact Acarix to verify whether the document has been changed. The manual relevant to the specific equipment model can also be downloaded from the Acarix website. You can locate the specific model number (REF number) on the back of the aluminium frame of the CADScor®Docking station.

While every effort is made to ensure the correctness of the information provided in this printed manual Acarix disclaims any liability for errors and omissions herein.

The illustrations used in this manual may differ slightly from the appearance of the actual device, packaging materials or interface and reflects on-going efforts to improve safety, usability and clarify the overall instructions given.

4 Trademarks and Third-party software

CADScor® is a registered trademark owned by Acarix.

Third party software license agreements are listed in the back of this manual.

US-FDA revision 12.5, Mar. 20th, 2021.
From software version 4.0 US-FDA.

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5 Introduction

5.1 About this manual

This user manual is intended as a reference guide for the safe and correct use of the CADScor®System, after having been instructed in the proper operation of the CADScor®System.

This user manual contains both general and specific operating instructions, hereunder procedures for recording heart sounds, maintenance of the CADScor®System, troubleshooting, instructions and information of individual components.

To ensure optimal safety in operation and service of the CADScor®System, it is important to read this manual carefully and understand the use of the CADScor®System before starting to use the system professionally.

5.2 The CADScor®System and the environment

The Acarix CADScor®System has been designed to minimize the environmental impact from fabrication, transport and use.

The System- and Patch boxing and packaging is made from lightweight recycled paper and cardboard, which can be disposed of as paper-waste and recycled.

The used patch and pouch can be disposed of as normal household waste.

The CADScor®Sensor, docking station and power adaptor contains electronic components, and should not be discarded in normal household waste, but returned for recycling at a regulated facility, local distributor or shipped back to Acarix for recycling.

5.3 Product description

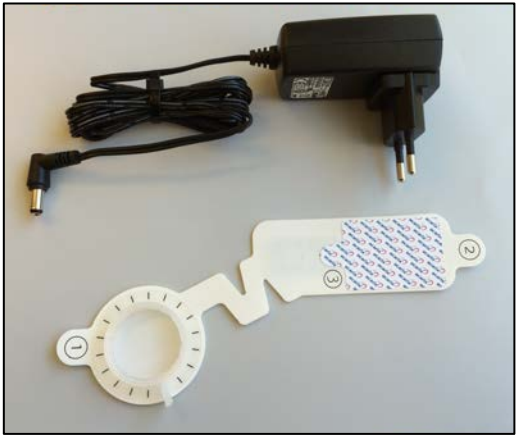
The CADScor®System is a device for recording and quantifying acoustic noise arising from coronary artery stenosis micro-turbulence and myocardial movement. These noises are usually described as "coronary murmurs".

The CADScor®System calculates a patient specific CAD-score by computational processing of a recording obtained from the chest surface of the patient and the patient risk factors present.

The CADScor®System consists of two physical units; the CADScor®Sensor and the CADScor®Docking station for charging and qualification of the sensor. A specific power adaptor powers the Docking station. The patch for anchoring the sensor to the chest of the patient is a necessary accessory for proper functioning of the CADScor®System (all shown at right). The CADScor®System is operated by a graphical user touch-screen interface.

CADScor®System; Docking station holding Sensor.

CADScor®Patch and power adaptor below.



5.4 Intended use

The intended use of the CADScor®System is to record heart sounds, i.e. murmurs and vibration for calculation of a patient specific score, the CAD-score, indicating the risk of coronary stenosis, as an aid in cardiac analysis and diagnosis.

5.5 Use of the CAD-score

The CAD-score is a patient specific heart murmur score indicative of Coronary Artery Disease (CAD)/Chronic Coronary Syndrome (CCS) for immediate risk stratification, prior to potential secondary evaluation.
The CADScor®System risk stratification can be applied to patients with symptoms suggestive of CAD/CCS, in compliance with the indications for use.
Using the CAD-score to risk stratify patients prior to further testing will reduce un-necessary evaluation and risk.
The CAD-score can thus aid the decision to initiate additional evaluations or not, or to observe the patient further prior to additional evaluations.
The presence of other patient risk factors or conditions may influence this decision.

Definitions of CAD:

Significant CAD	Insignificant CAD	Non-CAD
≥50% luminal diameter reduction by CAG.	<50% luminal diameter reduction by CAG or CCT calcium >0, or <70% luminal area reduction.	Negative (0) calcium by CCT or no evidence of luminal stenosis.
CAG: Coronary Angiography; CCT: Coronary Computed Tomography		

The CAD-score is thus indicating risk of having significant CAD, defined as having ≥50% luminal diameter reduction.
Two risk categories are defined using the CADScor®System:

CAD-score ≤20	CAD-score >20
Low risk	Elevated risk

The Negative (NPV) and Positive (PPV) predictive values vary with the prevalence

of significant CAD in the investigated population.

At lower significant CAD prevalence (e.g. 5-20%) in the investigated population, the NPV increases. The NPV of the CAD-score at or below 20, for ruling-out risk of significant CAD in the patient thus increases by falling prevalence, ranging from approximately 92.3-98.3% at 5-20% prevalence.
At higher significant CAD prevalence (e.g. 30-40%) in the investigated population, the NPV decreases. The NPV of the CAD-score for ruling out significant CAD thus decreases by increasing prevalence, ranging from approximately 87.5-81.8% at 30-40% prevalence.

A follow-up test, based on a CAD-score at or below 20, can be done after two to five years, if indicated.

At higher significant CAD prevalence in the investigated population, the PPV increases. The observed PPV of the CAD-score above 20 for predicting significant CAD is 14.4% (11.6-17.5%) in a 10.7% CAD prevalence population.

CADScor®System performance:
Significant CAD vs Other (Significant CAD versus insignificant CAD and non-CAD combined).
Algorithm ver. 3.2-US:
Sensitivity: 87.5% (79.2-93.4%)
Specificity: 37.5% (34.2-41%)
Validation data CAD-prevalence: 10.7%
NPV: 96.2% (93.4-98%)
PPV: 14.4% (11.6-17.5%).

CAD/CSS Prevalence %	NPV %* CAD-score ≤20
5	98.3
10	96.4
15	94.4
20	92.3
30	87.5
40	81.8
*modelled from Acarix clinical data for sensitivity/specificity above at threshold ≤20.	

5.6 Risk-Benefit for use

By using the CADScor®System for evaluating patient risk of Coronary Artery Disease, a CADScor low risk of significant CAD can help to direct other cause evaluation decisions and also remove unnecessary anxiety.
Patients with a CADScor elevated risk of significant CAD may be earlier recognized and thus be diagnosed and enter treatment earlier.

By use of the CADScor®System no risks are associated directly from use, except in rare cases where a slight transient skin reaction towards the patch adhesive may be observed.

Inform patients who have CAD-score ≤20 to seek medical attention if symptoms persist or worsen after initial evaluation.

The risk of a false negative result for a true patient or a false positive result for a non-CAD patient should be taken into consideration when evaluating the patient.

5.7 Intended user profile

The CADScor®System is intended to be operated only by registered nurses, clinical/medical laboratory technicians, medical doctors/physicians after having been instructed in the proper operation of the CADScor®System.

⚠ Do not use the CADScor®System without the necessary qualifications, and only after instruction and having read and understood this User-Manual, due to risk of death or serious injury.

5.8 Intended patient population

The CADScor®System is intended to be used in males and females (by born gender) above 40 years of age.

⚠ The CAD-scores from patients in the 30-39-year group are currently outside the intended patient population. A warning triangle indicates the higher uncertainty of their CAD-scores (8.14).

5.9 Indications for use

The CADScor®System is indicated for use as a diagnostic aid in symptomatic patients suspected of stable Coronary Artery Disease/Chronic Coronary Syndrome.

Symptoms of CAD/CCS may manifest as*

Typical angina symptoms;
(all three below)

- Sub-sternal chest discomfort of characteristic quality and duration;
- Provoked by exertion or emotional stress;
- Relieved by rest and/or nitrates within minutes.

Atypical angina symptoms;
(Two of the above)

Non-anginal chest pain;
Lacks or meets only one or none of the above characteristics.

Dyspnea/breathlessness

* as defined by ESC Guidelines 2019 & NICE UK Guidelines CG95, 2019.

5.10 Contra-indications for use

Asymptomatic for angina or chest pain,
Implanted donor heart,
Previous Coronary Artery Bypass Graft (CABG),
Previous Coronary stenting or known CAD
Arrhythmia causing non-sinus rhythm,

Fragile or compromised skin,
or abnormal anatomy or significant operation scars in the fourth left Inter Costal (IC4-L)-recording area.

Implanted mechanical heart or mechanical heart pump,
Implanted Pacemaker or Cardioverter Defibrillator (ICD),
Other implanted active electronics or active electronic support equipment closer than 50 cm to the CADScor®System.

The CADScor®System has not been validated as a screening tool for Coronary Artery Disease/Chronic Coronary Syndrome in asymptomatic populations.

⚠ Do not use the CADScor®System on patients with implanted electronics like ICD, Pacemakers, heart-pumps or closer than 50 cm to similar active electronic support equipment, due to risk of equipment failure from CADScor®System electromagnetic RFID impulse.

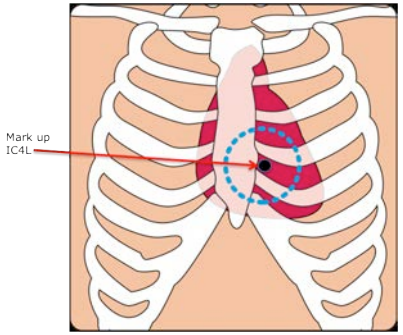
5.11 Intended conditions of use

The CADScor®System is intended to be used at medical clinics and hospitals, at room temperature and below 2500 meter above sea level.

The patient shall be lying on the back on an examination bed (supine position) during identification of the fourth left Inter Costal (IC4-L) space and recording of heart sounds. Mark the IC4-L position after location, approximately two centimetres of the sternum bone for placement of patch.

The CADScor®Sensor must only be used together with a CADScor®Patch. Patches are single-use only and should not be moved on the body after first adherence. If a patch has been misplaced a new patch must be used. The applied time of the CADScor®Sensor (including patch) is normally less than 15 minutes.

Use the CADScor®System below 2500 meters.



⚠ Train to identify left IC4 location. Wrong position may influence result.

⚠ Do not attempt to re-use a CADScor®Patch. The patch is single use only for hygienic reasons.

5.12 Symbols used

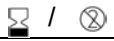
Definitions:
The CADScor®System user manual contains symbols, operational warnings and cautions, which are important and should be read and understood carefully before performing the related procedures.

Symbols and warnings are also found on the CADScor®System, the CADScor®Patch and the system packaging boxes.

5.13 Symbols on the CADScor® System and in User manual

Warnings: Describes a condition or a situation where risk of death or serious injury can occur.

Precautions: Describes a condition or a situation where a non-serious injury can occur to patient or user or damage the equipment or property.

Symbol	Explanation
	Product code number.
	Serial number
	Warnings and precautions. See description below (5.13-5.15).
	Instruction to Read user manual.
	Instruction to Consult user manual.
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Magnetic Resonance Imaging room unsafe
* /	Indication of a short diastole (*) result or a notice for result (⚠)
IPXX	Denotes liquid and dust ingress protection levels
	Defining the Sensor as the Applied part of CADScor®System
	Manufactured by
 /	Expiry date / single use of patches
	The CADScor®System, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements (Directive 2012/19/EU, WEEE).

5.14 Warnings

Warnings are alerts described to alert and reduce the risk of death or serious injury from use of the CADScor®System.

Warnings and precautions are labelled with a warning triangle and also refers to the relevant section in the User Manual.

Patient and user risk warnings:

⚠ Do not use the CADScor®System without the necessary qualifications, and only after instruction and having read and understood this User-Manual, including, symbols, contra-indications, warnings and precautions, due to risk of death or serious injury.

⚠ Do not use the CADScor®System on patients with implanted electronics like ICD, Pacemakers, heart-pumps closer than 50 cm to similar active electronic support equipment, due to risk of equipment failure from CADScor®System electromagnetic RFID impulse (5.10; 6.4).

⚠ Do not attempt to re-use a CADScor®Patch. The patch is single use only for hygienic reasons, to prevent possible cross contamination/infection between patients (5.11; 8.7).

⚠ The CADScor®System and patches are MRI-unsafe and should not be operated or placed in a Magnetic Resonance Imaging (MRI-) room, due to risk of skin burns and/or magnetic attraction and impact (7).

⚠ Never use other power adaptor than supplied with the CADScor®System, due to risk of electrical shock (5.17).

5.15 Precautions

Precautions are alerts to reduce potentially hazards situations or risks of non-serious

injury or reduced effectiveness from use of the CADScor®System.

Risk of incorrect CAD-score:

⚠ Incorrect placement of the CADScor® Sensor, outside patient IC4-L, may result in an incorrect CAD-score (8.4).

⚠ Inform patients who have CAD-score ≤20 to seek medical attention if symptoms persist or worsen after initial evaluation", due to the risk of a false negative CADScor result (5.6).

⚠ The CAD-scores from patients in the 30-39-year group are currently outside the intended patient population. A warning triangle indicates the higher uncertainty of their CAD-score (8.14).

Risk of damage to the CADScor®System:

⚠ Do not touch the charge-point terminals on the CADScor®System, due to risk of permanent damage to the electronics inside by electrostatic discharge (5.17-5.18)

⚠ Do not drop or exert excessive force to the CADScor®System since this may damage the CADScor®System permanently (6.1).

⚠ Do not expose the CADScor®System to liquids (water, oils, detergents or similar) or dust, since this may damage the CADScor®System permanently (10).

⚠ The CADScor®System cannot be heat- or radiation sterilized, or machine washed/cleaned, since this may damage the CADScor®System permanently (10).

⚠ Do not modify the CADScor®System or use or repair a defect CADScor®System, due to risk of malfunctioning. The CADScor®System must only be serviced by qualified Acarix personnel (10).

5.16 CADScor®System unboxing

Place the box on a table and open it as shown in figure below.

Establish the content of the CADScor®System box (one each):

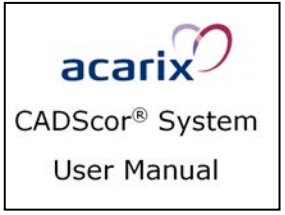
- CADScor® Sensor.
- CADScor®Docking station.
- A box containing a power adaptor plus country specific plug.
- A box in the lid holding;
- a User Manual,
- a separator tool to separate the back plate from the top part of the Docking station and
- a drilling template for mounting the Docking station on the wall.

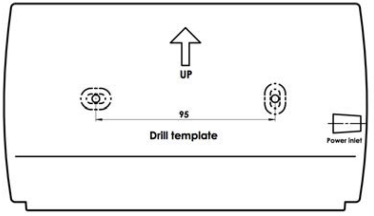
The CADScor®System is pre-assembled in desktop position.
Lift the CADScor®System from the system box by holding the system at the edges of the aluminium plate of the Docking station.

Place CADScor®System on steady surface.
Inspect the CADScor®System for possible transport damages.
Take out the box containing the power adaptor and supplied plug. Assemble power adaptor unit by pressing the plug firmly onto the power adaptor until clicked securely into place. No voltage adjustments are needed for the power adaptor.

⚠ Never use other power adaptor than supplied with the CADScor®System, due to risk of electrical shock.

Finally take out the lid box containing the user manual, separation key and drill template.





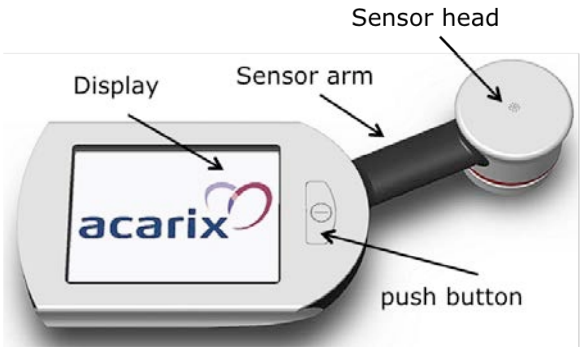
5.17 The CADScor® Sensor

The CADScor®Sensor is the part to record heart sounds at the fourth left Inter Costal region and to calculate the CAD-score based on the acoustic recording.

The sensor has one physical button, a touch display and a sensor head extending on a flexible arm from the sensor body (see figure at right).
The push button has several functions when pressed or pressed and held for extended time.

Press	Function	Beep
1x	Turn sensor on	-
2x	Cancel on-going recording	Triple beep
3x	Enter Settings menu	-
Hold> 4 sec	Forced qualification	Single beep
Hold> 8 sec	Sensor off and reset	Double beep

Main components of the CADScor®Sensor, top/side view.



Red assembly indicator ring

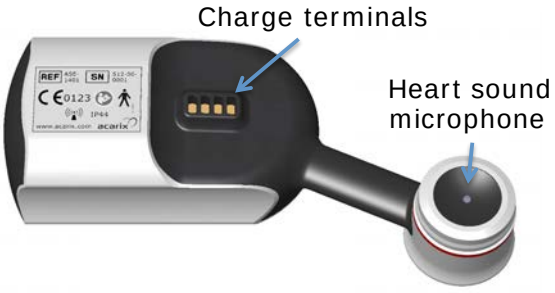
The sensor LCD touch display shows a user interface to guide you through a recording session. Also, the sensor status and the CAD-score are shown on the display when it is calculated.

The flexible sensor arm connects the sensor body to the sensor head.
Within the sensor head a heart microphone and an ambient microphone are placed.

Inside the sensor body is a built-in speaker that generates auditory cues for guiding the patient to pause breathing.

The sensor charge/contact point terminals are used to re-charge the sensor battery, when the sensor is placed in the Docking station (See figure at right).

Main components of the CADScor®Sensor, bottom-side view and labelling at right (SN refers to CADScor®Sensor serial number).



⚠ Do not touch the charge-point terminals on the CADScor®System, due to risk of permanent damage to the electronics inside by electrostatic discharge.

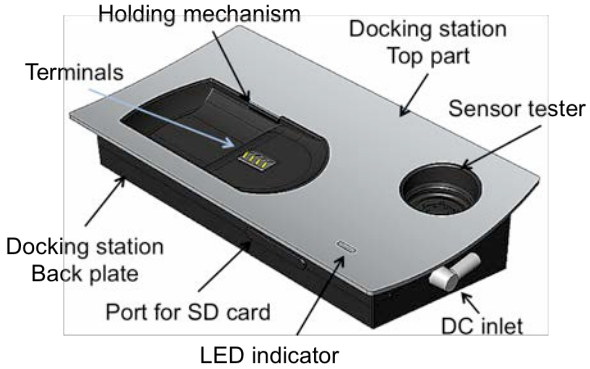
5.18 CADScor® Docking station

The Docking station serves as a "home" for the sensor to which the sensor is mated specifically from the factory.
In the Docking station the sensor is recharged and qualified. A specific sensor can only be qualified in its home Docking station.

⚠ Do not touch the charge-point terminals on the CADScor® System, due to risk of permanent damage to the electronics inside by electrostatic discharge.

The Docking station LED shows the current status of the CADScor® System when the sensor is docked and powered (Colour codes in section 6.1).
The Docking station can be wall mounted for easy access and saving desk space (see section 6.2 below).

Parts identification	
Top view	Bottom view
Indicator LED	Back plate
Sensor tester	Product information marking
Contact terminals	
DC-in	



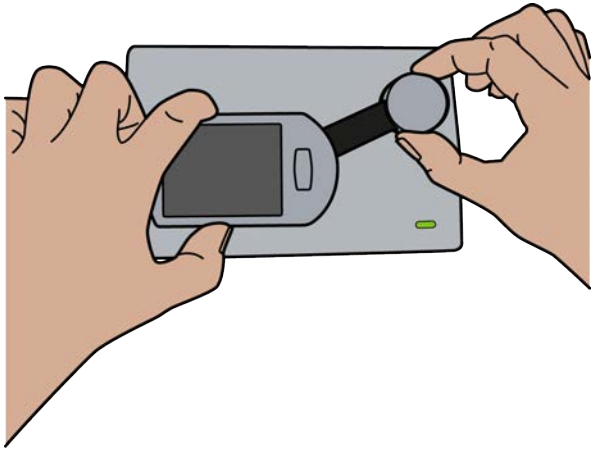
6 Installation of CADScor®System

6.1 Desktop model

Place the Docking station on a stable surface (desktop/table). Desktop position is the pre-set operating mode of the Docking station.

Insert the CADScor®Sensor in the Docking station using both hands. Make sure that the sensor head is fully inserted into the sensor tester and that the red indicator line on the sensor head is completely hidden. A spring action mechanism will hold the sensor-body firmly in the Docking station.

Insert the small power plug to the Docking station on right hand side and the power adaptor into a 100-240 VAC power outlet. Turn on wall outlet power.



The LED on the Docking station lower right corner should light up.

Three different colours are used to indicate system status (table at right).

If no colour is lighting up the Docking station LED, wall outlet power has not been turned on or the power adaptor is faulty.

See troubleshooting guide section 11.

⚠ Do not drop or exert excessive force to the CADScor®System since this may damage the CADScor®System permanently.

LED indicator	Sensor status
Constant YELLOW	Power on docking station
Constant GREEN	Sensor fully charged; ready for use
Flashing GREEN	Ongoing charging of sensor battery above minimum level
Constant RED	Error in Sensor or Docking station; Not ready for use (in sensor display).
Flashing RED	On-going qualification (in sensor display)
Flashing RED	Low on Battery (in sensor display)
The LED is off	Power not applied.

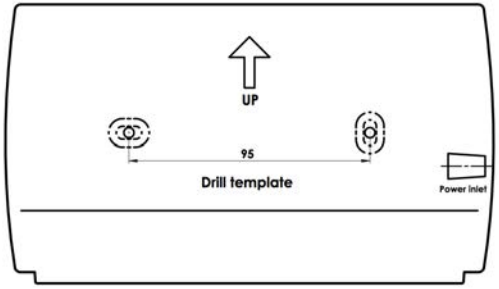
6.2 CADScor®System wall mounting

The CADScor®System can be wall mounted to save desktop space or for increased general visibility.

Determine suitability of the wall material and items in the wall before mounting.

To unlock the back plate from the top part of the Docking station, hold the Docking station by the aluminium plate, one end resting on a table. Place the separator tool into the two small holes in the edge and press gently using the index fingers of both hands and separate slowly (see figure at right). Do not apply strong force since slipping grip may happen and lead to injury.

Use drill template and a pencil to mark up the wall position. Ensure horizontal level using a spirit level or similar.



Drill two holes (Ø 4mm) through the centre of marks and mount back plate (thinner rim facing up) using appropriate screws and plugs.

Place the top part of the Docking station on the back plate, sensor tester placed at upper right corner, and click into locking position.

Ensure that top plate has engaged at all four corner positions.

Place CADScor®Sensor in the Docking station and apply power.

6.3 CADScor®Patch box opening

Place the CADScor®Patch box on a table and open along the perforated line at the box front and top sides (see figure at right).

Each CADScor®Patch box contains 20 patches individually packaged in peel-pouches. The pouch is opened at one-end, by holding and separating the two layers.

Additionally, an assembly tool is provided to ensure the correct alignment and assembly of the patch to the sensor head and body.

On the paper backing of the patch peel-pouch, instructions are given for the assembly. Follow these instructions carefully to obtain high quality heart recordings (see section 6.5-6.6).

Patch box with assembly tool and labeling:

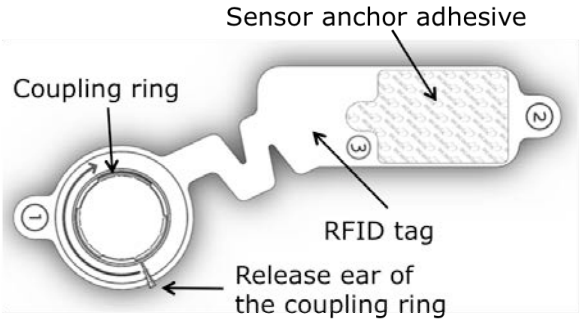
6.4 The CADScor®Patch

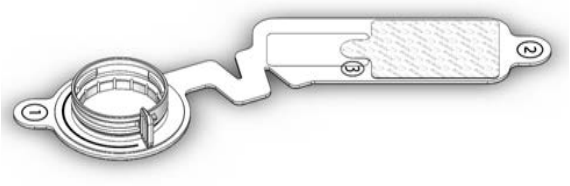
The disposable patch is used for anchoring the sensor onto the chest of the patient and provides optimal recording conditions (see figures at right).
The CADScor®System cannot be operated without a valid patch.

The CADScor®Patch has adhesive material on both sides and a coupling ring where the sensor head has to be inserted.
On the patch is furthermore a numbering sequence to follow when applying the patch and sensor onto the patient's chest.

A Radio-frequency identification chip (RFID) can be seen under the top foil, used to validate the patch before use.

Upon removal of the sensor from the patch a pull-string is drawn to open the coupling ring for easier disassembly.





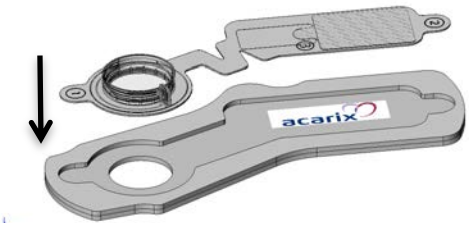
6.5 The CADScor®Patch, assembly

Place the cardboard assembly tool on an even hard surface (e.g. table top).

Align the un-packed patch on top of the assembly tool, so that the patch is within the outline on the tool. Make sure the coupling ring is situated correctly on top of the hole cut-out in the assembly tool (See figure at right).

Place the sensor on top of the patch, aligning to the axis of the patch. The sensor head shall be placed in the coupling ring of the patch.

Press the sensor head gently and evenly into the coupling ring, using the palm of your hand.
The sensor head will then correctly snap into the coupling ring.

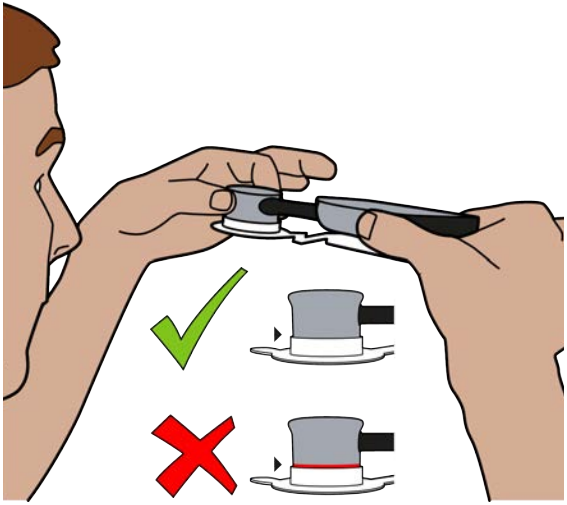


6.6 Confirming correct sensor-patch assembly

The red colored assembly indicator ring on the sensor head must now be hidden in the coupling ring, when looked from the side.

Visually confirm the disappearance of the red colored indicator ring all around the sensor head (see figure at right).

From the patch underside a slight protrusion of the sensor head through the patch can be observed.



7 Setting up the CADScor®System prior to use

7.1 CADScor®Sensor

The CADScor®Sensor is the part of the CADScor®System to record heart sounds at the left IC4 region, and to display the calculated CAD-score.

7.2 First time configuration of the CADScor®Sensor

Connect the power adaptor to the Docking station and turn on supply voltage.
Place the sensor in the Docking station, if not already docked, to charge the battery.

The sensor will automatically detect the Docking station and power on, showing the Acarix logo (as shown at right).

⚠ The CADScor®System and patches are MRI-unsafe and should not be operated or placed in a Magnetic Resonance Imaging (MRI-) room, due to risk of skin burns and/or magnetic attraction and impact.

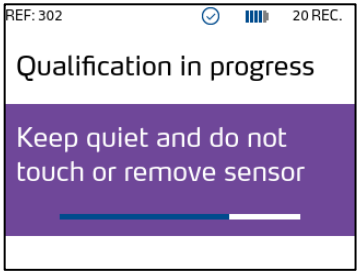
As part of the power-on sequence an information display will show current software version and user relevant warnings and instructions (REF:101).

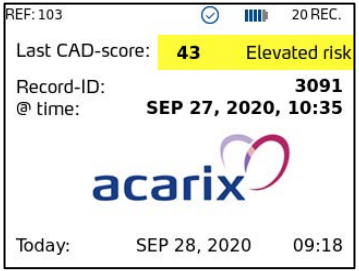
Since qualification of the sensor is needed every 23rd hours, a display message will show that qualification is in progress (REF:302).

Follow the instructions to keep quiet and not touching or removing the sensor from the Docking station.
After qualification and first time the sensor is powered-on, configuration is needed.

While the sensor is "docked" in the Docking station, the "last-recording" display (REF:103) is shown.

Take out ("un-dock") the sensor from the Docking station to enable configuration.





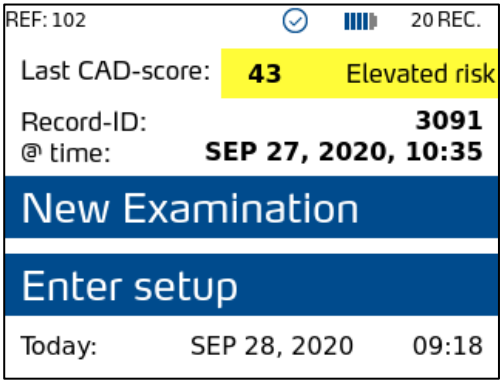
The sensor will automatically go to the sensor "home" display (REF:102).

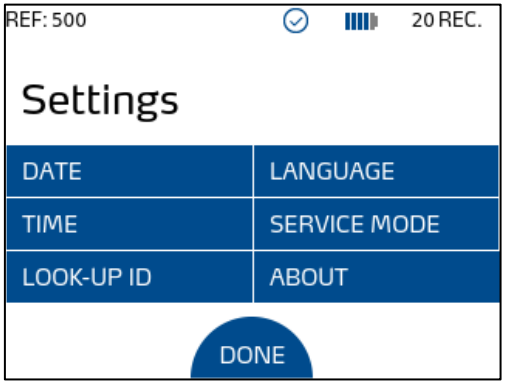
Press "Enter setup" on the "home" display to configure the sensor (REF:102) or triple-click the push button.

A sub-menu will appear, allowing adjustment of Date, Time and Language (REF:500).
Follow the instructions below to do the correct adjustments.

The SERVICE MODE option is intended for Acarix authorized personnel to e.g. install new software and is not accessible in normal use.

⚠ Do not modify the CADScor®System or use or repair a defect CADScor®System, due to risk of malfunctioning. The CADScor®System must only be serviced by qualified Acarix personnel (10).





7.3 Setting language

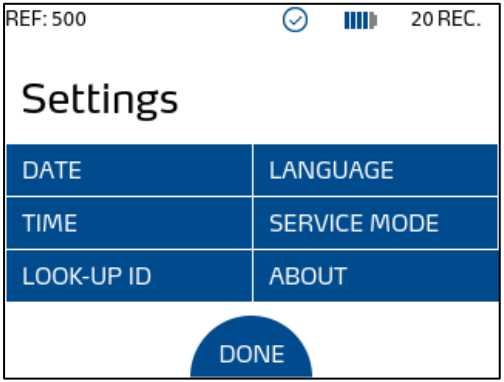
Press LANGUAGE on the Settings display (REF:500) to change user interface language.

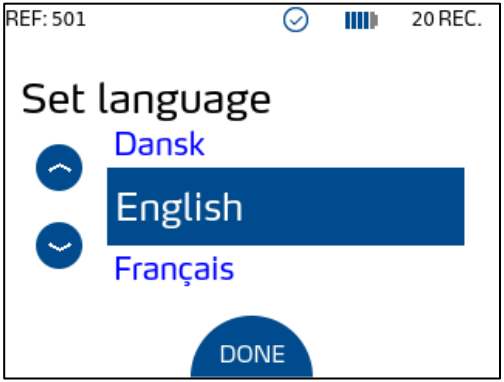
The default language is English.

In the "Set language" display (REF:501),

Press or to select a user interface language.

Press "DONE" to save language choice and exit "LANGUAGE" menu.





7.4 Setting time

Press "TIME" to set the correct time.

Time format is international 24 hours, and cannot be changed.

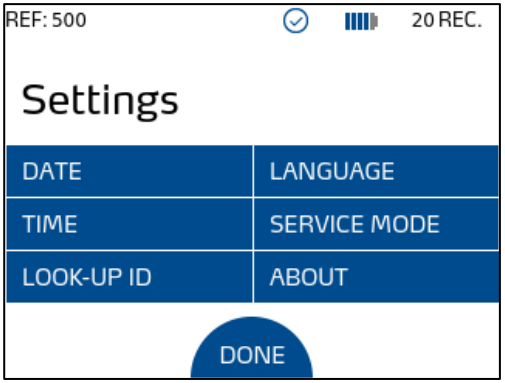
In the "Set time" display (REF:502),

Tap the hours (HH) or minutes (MM) fields individually to activate the wanted field.

Press or to change time (HH:MM)

Press "DONE" to save time setting and exit "TIME" menu.

When TIME has been changed, a re-qualification is automatically required.



7.5 Setting date

Press "DATE" to set the correct date.

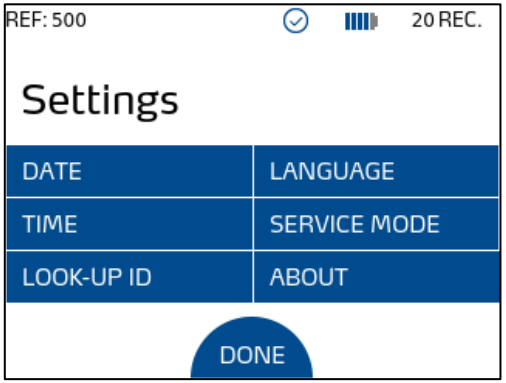
Date format is Month: Day: Year, where month is given by three letter abbreviations.

The date format cannot be changed.

In the "Set date" display (REF:503),

Tap the month, day or year fields individually to activate field.
Press or to change date (M/D/Y).

Press "DONE" to save and exit "DATE" menu.
When DATE has been changed, a re-qualification is automatically required.



7.6 Finishing Sensor SET-UP

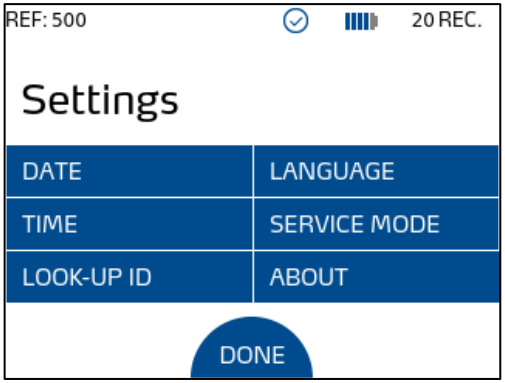
Press "DONE" to exit "Settings" display. The sensor will return to the "home" display (REF:102).

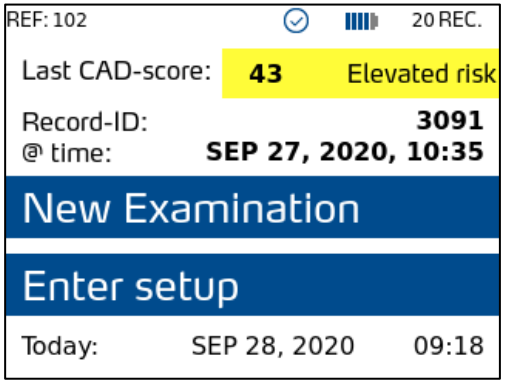
The sensor will turn off automatically after five minutes of inactivity.

7.7 Universal access

A functionality to enter the set-up menu directly is available by pushing the push button three times in succession. This cannot be done during a recording session. This functionality is also enabled while the sensor is in the Docking station.

In case an unknown language has been chosen, triple-push the button and select the upper right blue quadrant to enter language settings. Choose relevant language and press "DONE" to finish language selection.





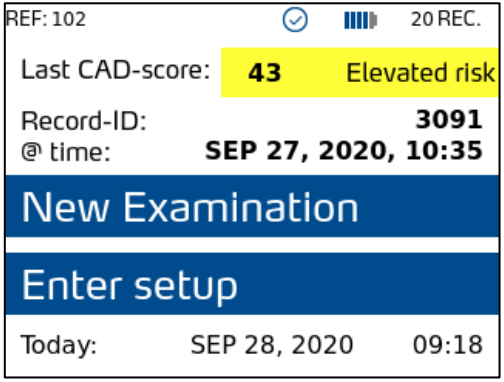
While the sensor is docked, a pause display ("Last recording") will be shown (REF:103).

After a period of inactivity, the sensor will automatically power-down to save energy and the screen will go black.

The sensor will then only perform automatic qualification, every 23rd hour.

The sensor will power-on again after pressing the push button or taking the sensor out of the Docking station.

When powered on again, the sensor will return to its "last recording" display while in the Docking station (REF:103) or return to the "home" display outside the Docking station (REF:102).



7.8 CADScor® Docking station

The Docking station is used for:

- Holding the sensor and charge the sensor battery when docked.
- Qualify the sensor at regular intervals or on request.
- Indicate the CADScor® System status by LED light.
- Transfer of data from the sensor to a removable memory card (only available in clinical trials through arrangement with Acarix).
- Update the sensor software.

7.9 Connecting/disconnecting power adapter to Docking station

The CADScor®Docking station has a dedicated external universal power adaptor (100-240 VAC/50-60Hz).

To supply the Docking station, connect the small power adaptor plug into the jack on the side of Docking station.

7.10 Charging of the sensor battery

In the Docking station, charging of the sensor battery is initiated through the charging contact terminals of the Docking station.

Approximately 30 minutes are needed to charge the sensor battery allowing for approximately 5-10 standard recordings and CAD-score calculations.

⚠ Never use other power adaptor than supplied with the CADScor®System, due to risk of electrical shock (5.17).

7.11 Docking station indication LED light

When the sensor is placed in the Docking station, an LED on the aluminium front indicates the present status of the CADScor®System.

More information on the sensor status can be found in the display of the sensor if turned on in the Docking station.

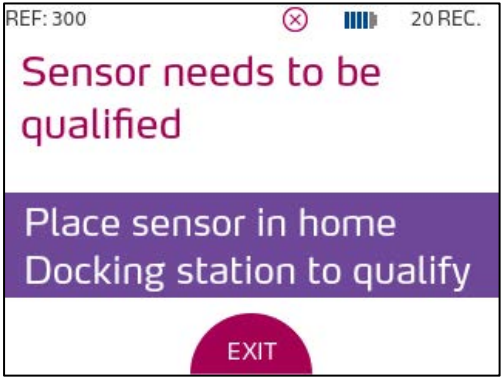
LED indicator	Sensor status
Constant YELLOW	Power on docking station
Constant GREEN	Sensor fully charged; ready for use
Flashing GREEN	Ongoing charging of sensor battery above minimum level
Constant RED	Error in Sensor or Docking station; Not ready for use (in sensor display).
Flashing RED	On-going qualification (in sensor display)
Flashing RED	Low on Battery (in sensor display)
The LED is off	Power not applied.

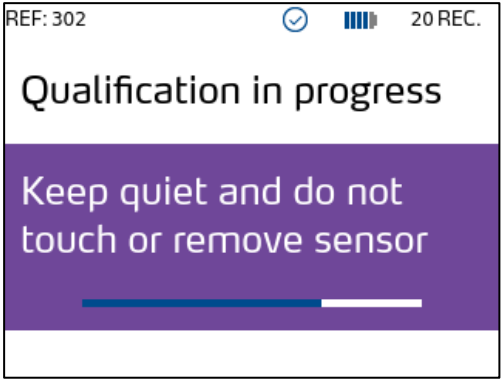
7.12 Qualification of sensor

The CADScor®System is qualified at regular intervals to ensure safe operation. During qualification, a series of tones are played from the Docking station to the sensor.

The qualification procedure is automatically carried out every 23 hours, if the sensor is placed in the Docking station. If the sensor qualification has expired outside the Docking station, a display message will ask for sensor to be placed in the home Docking station (REF:300).

It is important that the sensor head is pressed firmly down into the built-in sensor tester.
The red indicator ring on the sensor head should be invisible when inserted correctly. When the qualification is on-going a display message is shown (REF:302).





7.13 Forced qualification

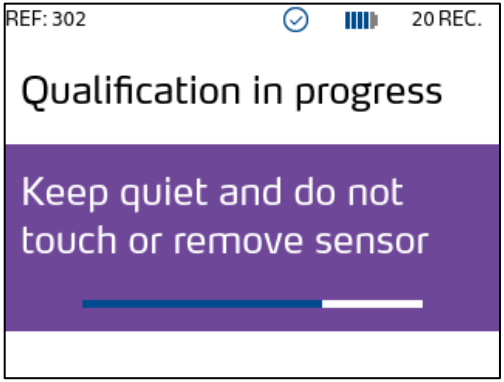
If you are bringing the CADScor®Sensor along and suspect qualification will expire before returning, a forced qualification can reset expiration clock by 23 hours.

Place the sensor in the home Docking station

The sensor will power-on automatically in the powered-on Docking station.

Press and hold the push button for 4 seconds (a single beep feedback will be given) to activate sensor qualification procedure (REF:302).

The sensor display will return to the "last recording" display when qualified (REF:103).

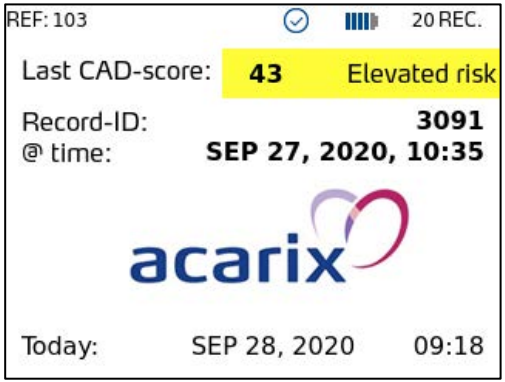


7.14 Re-setting sensor

The CADScor®Sensor operating system can be reset in the event of unresponsive software failure. The re-setting will force the sensor to reload sensor-software and also re-qualify the sensor.

Procedure:
Press and hold the push button for 8 seconds (beyond the 4 seconds single beep, until a double beep signal feedback is given) to power off the sensor.
The sensor will automatically turn on again while in the powered Docking station or by button press.
The sensor will then reload operating software and qualify automatically.

The sensor will display the start-up display (REF:101) followed by the "last recording" display (REF:103) when the qualification has finished, and sensor is docked.



8 Detection of heart sounds

8.1 Preparing the examination room

The CADScor®System records very weak heart murmurs. Reducing external or environmental noise will increase the likelihood of a successful recording.

Close doors and windows to reduce noise from outside sources like traffic noise, talk, construction work and similar.

Turn off indoor noisy or unused electrical equipment (e.g. noisy PC, mobile telephones, ventilators, fans, air-condition).
Unplug power to patient bed if available.

Keep quiet (both user and patient) during the heart sound recording.

Reduce room noise!

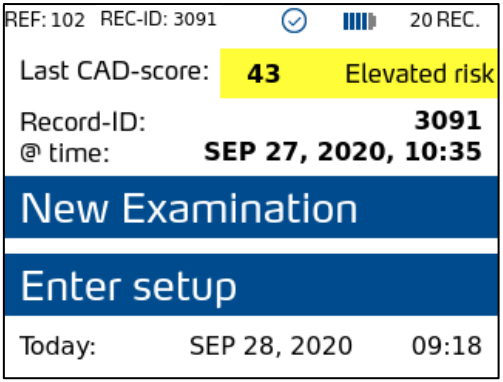
⚠ The CADScor®System and patches are MRI-unsafe and should not be operated or placed in a Magnetic Resonance Imaging (MRI-) room, due to risk of skin burns and/or magnetic attraction and impact.

8.2 *Preparing the sensor*

Press the push button to turn on the sensor in the Docking station or take out the sensor from the Docking station. After power-on (and eventual qualification) the display will return to the "home"-display (REF:102) if sensor is ready, and outside Docking station.

The sensor battery status and the number of remaining recordings on current battery level is shown in the display, top right (20 REC). Battery level low: Charge the battery if the level is below minimum (red battery icon).

Qualification status is shown by circled blue check mark in upper display information line. Qualification expired: Qualify the sensor if the previous qualification has expired (red cross in circle).



Icon	Icon descriptions
REF:	Display reference number
REC-ID:	Recording identification number
/or	Sensor qualification status icon : Qualification valid.
	: Qualification expired.
/or	Battery level icon : Full battery level
	: Low battery level.
REC.	Remaining capacity recording icon

8.3 Preparing the patient

Always use a paper/linen bedcover between patient and examination-bed to avoid rubbing noise. This will reduce situations potentially requiring a second recording.

Hair removal

Also, to obtain high-quality heart sound recordings and to reduce secondary recordings, body hair at the IC4-L region has to be removed as well as hair in the area of the applied patch.
The extended shaving area will ensure better anchoring of the CADScor®Sensor and easier removal of patch after recording.

Shaving can be done using surgical clipper or standard single use shaving tool.

Greasy or moist skin should be cleaned using standard alcohol skin wipes.

Always conduct proper skin cleaning and hair removal in patch area for optimal patch adhesion and high-quality heart sound recordings.

8.4 Identifying the fourth left Inter Costal space (IC4-L)

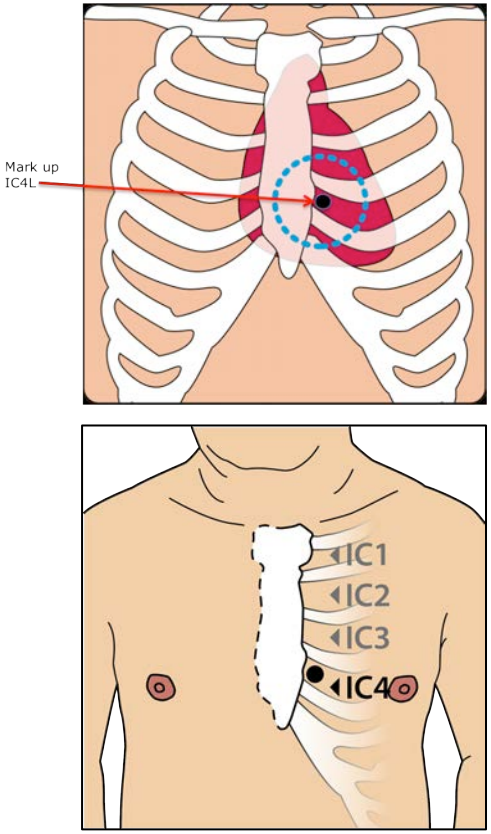
Establishing the correct recording position on the patient is very important for obtaining a valid heart sound recording.

The fourth left Inter Costal space is most reliably identified using a simultaneous four-finger palpation on the patient's chest.

This method is also known as the "finger-method" for IC4-L identification, picture at right.

Un-dress the patient in the thorax area. It is important that clothing will not rub against the sensor during recording.

Place the patient flat on the examination bed in supine position (chest facing upwards).



Standing on the patients' right side, spread your left-hand fingers approximately 1.5 centimeters, and place your left-hand little finger up against the collar bone (clavicular). Just under the collarbone costa number one (C1) is found.

Press the other fingers against the chest left side and massage the fingers into the intercostal spaces at the sternum border.

A moderate to high palpation pressure is needed to recognize the costa and the intercostal spaces.

When each of the four fingers has found their intercostal spaces, mark up the fourth left Inter costal space under your index finger.

Mark the position of IC4-L, approximately two centimeters from the sternum border into the fourth Inter Costal space.

Use a clearly visible pen marker, to later reliably locate the established recording position to avoid repositioning the sensor-patch assembly and thereby reduce skin adherence.

The marked IC4-L spot indicates the centre of the recording site for the sensor head.

The sensor head should rest free of the sternum border.

Train to be able to identify the IC4-L position correctly.
The IC4-L position is equivalent to the electrode V2 position in a standard 12-lead ECG.

Train and counsel with a colleague to identify and establish the correct position for the IC4-L location, using the finger technique. Train on a number of patients until safe IC4-L locating experience has been obtained.

Train to obtain IC4-L locating experience.

⚠ Incorrect placement of the CADScor® Sensor, doing recording outside IC4-L on the patient, may result in an incorrect CAD-score.

8.5 Attachment of patch to sensor

An assembly tool is provided with the patches to mount the patch correctly to the sensor (see also section CADScor®Patch assembly).

Place the CADScor®Patch on top of the assembly tool as outlined on the tool (see figure at right).

Then place the CADScor®Sensor on top of the patch.

Press sensor head carefully into coupling ring by using the palm of your hand. Make sure that the sensor head is secured at the stop position and that the red indicator ring on the sensor head is now not visible. The sensor and patch assembly is now ready for attachment to the patient.

8.6 Explaining of the recording procedure to patient

Explain the recording procedure to patient. Being generally relaxed and pausing breathing at correct intervals is important for recording of high-quality heart sounds. Observe at least 5 minutes of patient resting to ensure hemodynamic balance before doing CAD-scoring and blood pressure readings.

The recording sequence is less than three minutes long and divided into a pre-recording and 4 recording loops.
During each recording loop, the patient should pause his breath for 8 seconds.
A sound will be heard when it is time to pause breathing. The sound will be demonstrated to the patient before starting.

Instruct patient to relax respiration and do belly breathing instead of thorax breathing. Show belly breathing by patient hand on belly, including inhalation, exhalation and natural breathing pause after exhalation.

Procedure	Step	Time (s)	Actions
Resting phase		>300	Patient lies in bed.
Recording phase	Pre-recording	30 + 30	Analysing recording conditions
	Loop Nr. 1 Breathing	18	No recording
	Breathing pause	8	Recording
	Loop Nr. 2 Breathing	18	No recording
	Breathing pause	8	Recording
	Loop Nr.3 Breathing	18	No recording
	Breathing pause	8	Recording
	Loop Nr. 4 Breathing	18	No recording
	Breathing pause	8	Recording
Result phase	Post recording	60-120	Calculation of CAD-score
Approx. Total time		524-564	

Before Recording phase

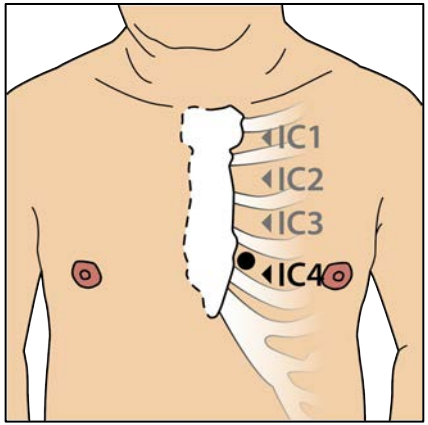
Summary
Check examination room for acoustic and electrical noise. Check sensor readiness.

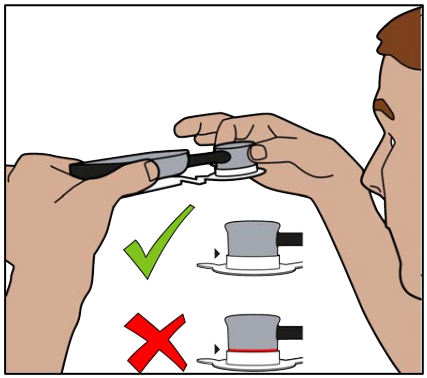
Ask patient to remove clothing from the waist-up and lie on the back on the examination bed (supine position) and rest.
Identify the IC4-L region and do hair removal in IC4-L/patch region if needed.

Observe at least 5 minutes of patient resting to ensure hemodynamic balance before doing CAD-scoring and blood pressure readings.

Assemble new CADScor®Patch and sensor using assembly tool. Note absence of red indicator ring around sensor head in coupling ring of patch.

Instruct patient in recording sequence, breathing mode and instruction sounds.

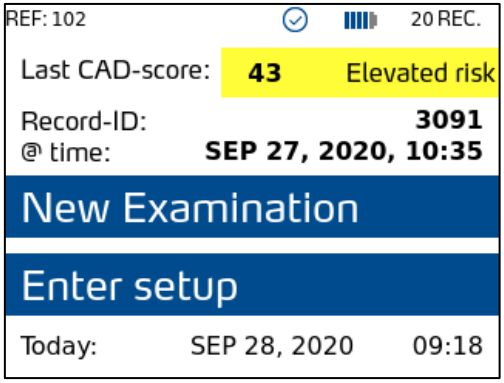




8.7 Recording phase, patient risk factors

Initiating the recording sequence:
If not already powered-on press push button once to activate sensor. The Acarix start-up display (REF:101) will be shown during sensor self-test. Choose "New examination" on the "home"-display (REF:102), shown when sensor is un-docked.
Whenever “New Examination” is chosen a new REC-ID will be assigned.

Four patient specific risk factors are required to initiate the recording and are included in the calculation of the CAD-score:
Patient Gender
Patient Age-group
Patient Symptom and
Patient hypertension status

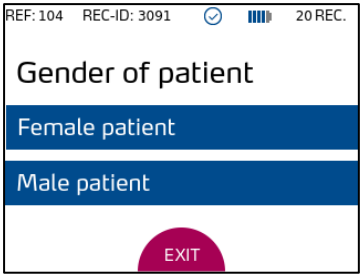


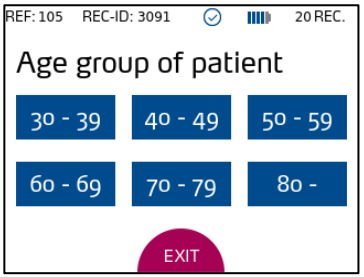
The risk factors are entered sequentially and summarized for confirmation.

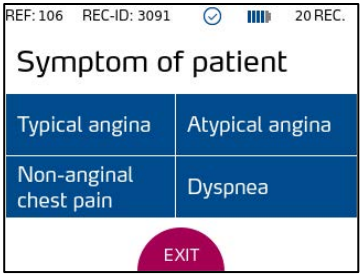
Patient birth Gender should be entered on display (REF:104).
If the entered data should be corrected press EXIT, to return to New Examination display (REF:102).

Patient Age-group, represented as 10-year intervals, should be registered as age on the day of the examination on display (REF:105).
If the entered data should be corrected press EXIT, to return to New Examination display (REF:102).

Patient symptom, as defined by ESC and NICE UK Guidelines (refer to section 5.9) should be entered in (REF:106).
If the entered data should be corrected press EXIT, to return to New Examination display (REF:102).





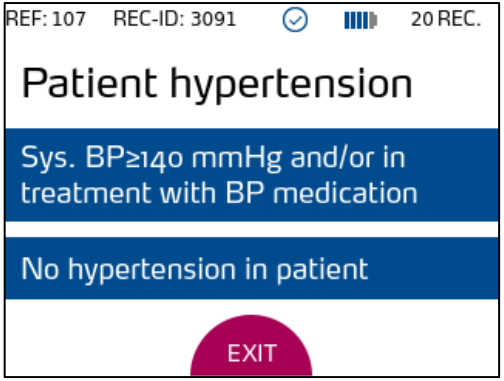


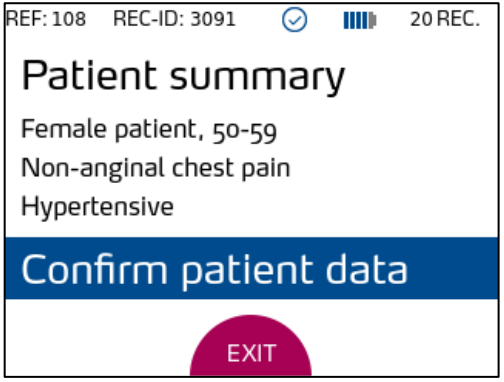
Presence (or not) of Patient hypertension should be entered in display (REF:107). Hypertension is defined as patient having systolic blood pressure equal or above 140 mmHg or being in medical treatment for systolic hypertension.

If systolic blood pressure is unknown and patient is not in medical treatment for hypertension, a standard blood pressure reading after the resting period and prior to the CADScor measurement, should be done to establish hypertension status. Observe at least 5 minutes patient rest to ensure hemodynamic balance before doing CAD-scoring and blood pressure readings.

If the entered data should be corrected press EXIT, to return to New Examination display (REF:102).

After entering hypertension status, a patient data summary display (REF:108) is shown. Confirm the patient data to continue or EXIT to re-enter data.

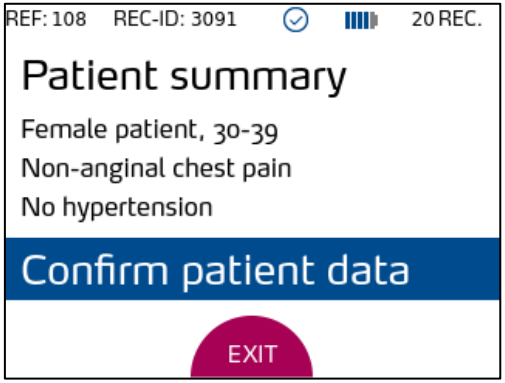


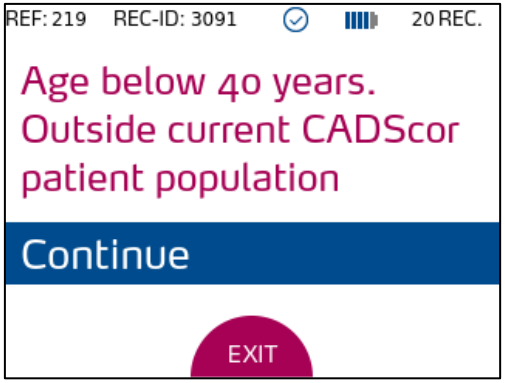


If the patient age entered is within the patient age-group 30-39 years, a notice display (REF:219) is shown to indicate that the patient age is below the current intended patient population for the CADScor®System.

A warning-sign (⚠) behind the resulting CAD-score will indicate the higher uncertainty of the CAD-score from this group.

If the information of the patient was correct and approved, press Continue to acknowledge the information and proceed to Patch assembly and patient murmur recording or press EXIT to change the patient details or abort the current CADScor measurement.





Attaching sensor/patch assembly to patient

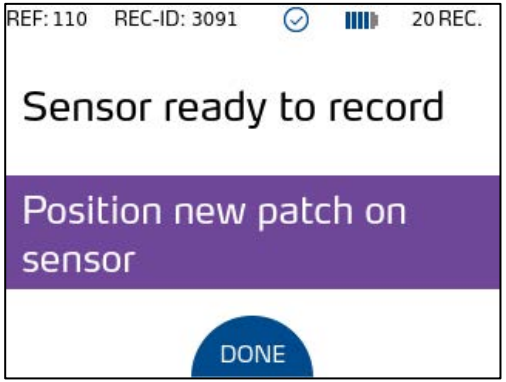
If sensor is ready to record, the sensor will ask for new patch (REF:110).

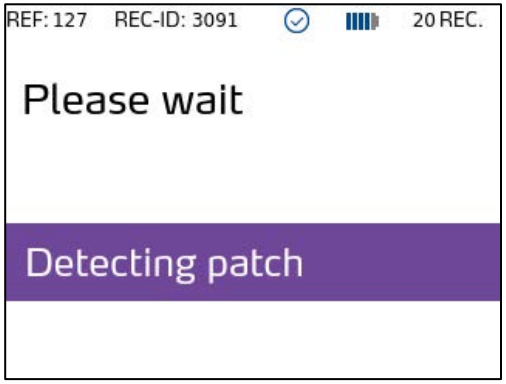
Mount a new patch as described above (section 8.5) or as described on the back of the patch pouch.
Inspect if sensor head is correctly seated in the coupling ring.

When patch is attached to sensor, press DONE.
The patch production data are checked by the sensor (REF:127).

Avoid placing the assembled sensor and patch on a metal-table during patch checking since this can interfere with the sensor reading the patch information.

Always detect patch before patch is applied to patient.





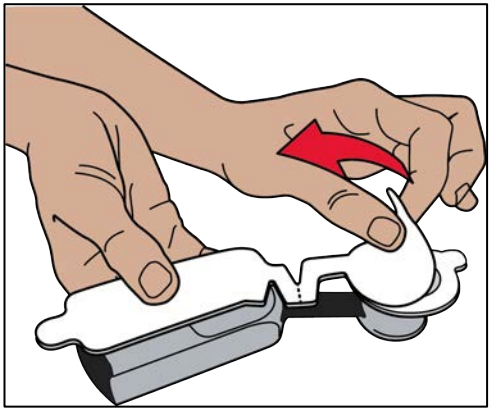
When the patch information has been verified and recognised a confirmation is given (REF:111).

Proceed to place sensor on IC4-L.

First remove the release liner marked *"1"* on the patch.
The part under the sensor microphone is taken of separately, divided from the remaining release liner by a pre-made cut.

Keep the remaining release liner part in place until sensor is placed at IC4-L.

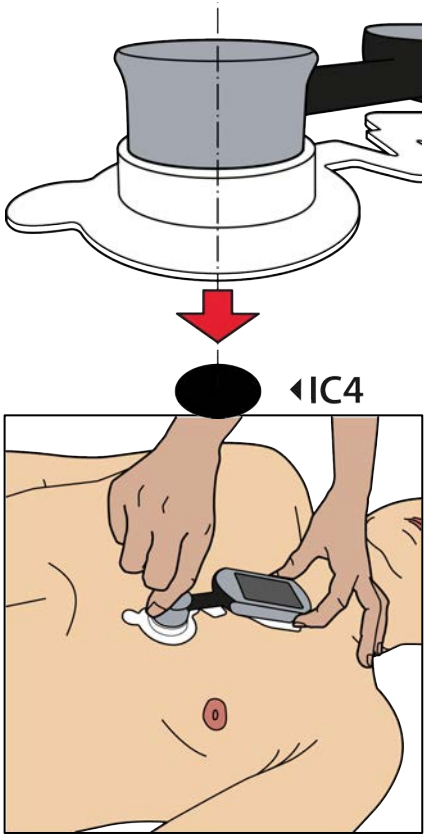
⚠ Do not attempt to re-use a CADScor®Patch. The patch is single use only for hygienic reasons, to prevent possible cross contamination/infection between patients.



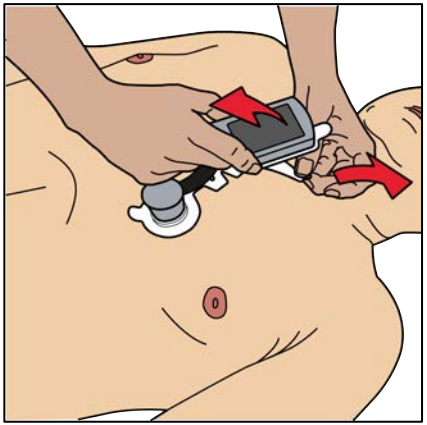
Now, place the sensor head at the pre-marked IC4-L position, orienting the sensor body towards the patient head on the sternum.

Do not apply strong pressure to the sensor head when applying patch on the patient.

Ensure proper adherence of sensor head to chest by pressing on coupling ring around the sensor head.

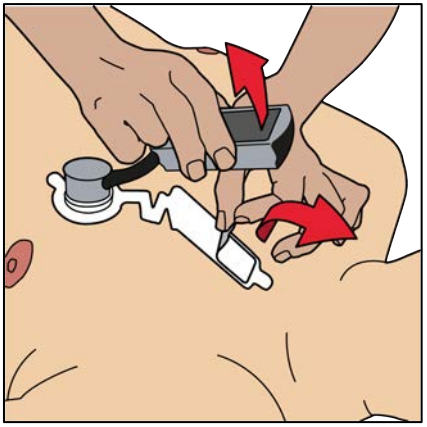


Then, Peel-off release liner marked *"2"* on the patch and anchor the long part of the patch onto the chest.



Finally, remove release liner marked "*3*" on the patch and fix the sensor body to the top adhesive on the patch.

Do not pull the sensor to fix it on the patch, but let the sensor follow the curvature of the patient chest.

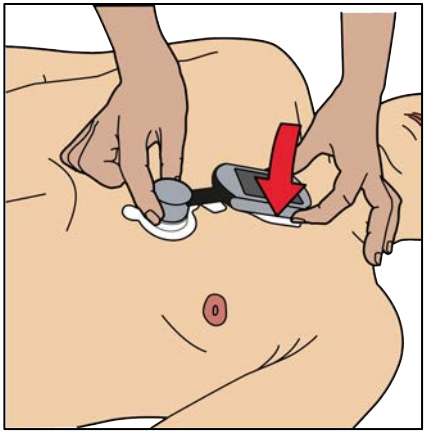


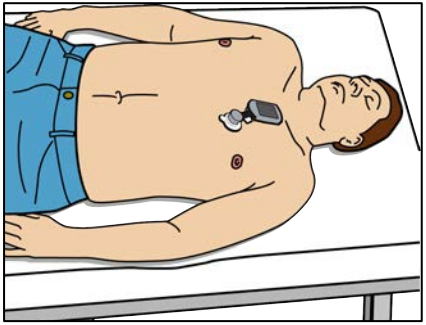
When sensor and patch assembly is securely positioned, press DONE to verify placement on IC4-L.
When the adhesive of the patch has been adhered to the patient, the Sensor and patch should not be moved.

Instruct patient to relax thorax by belly breathing and generally relaxing muscles: Relaxing while doing a CADScor® recording will increase the chances of a successful recording and subsequent CAD-scoring.

Find a suitable generally relaxing supine position, placing arms along the body and resting the head against the mattress.
Offer a pillow for increased comfort or elevated headrest.
Ask and ensure patient is comfortable and resting without significant muscle tonus.

Observe at least 5 minutes patient rest to ensure hemodynamic balance before doing CAD-scoring and blood pressure readings.





Three options will then become available (in REF:112):
START SOUND DEMO to demonstrate recording sounds to patient

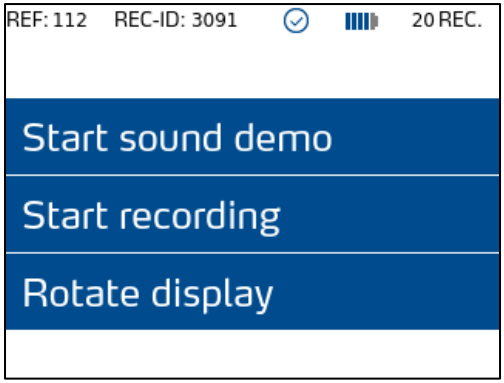
START RECORDING to initiate the actual recording, or

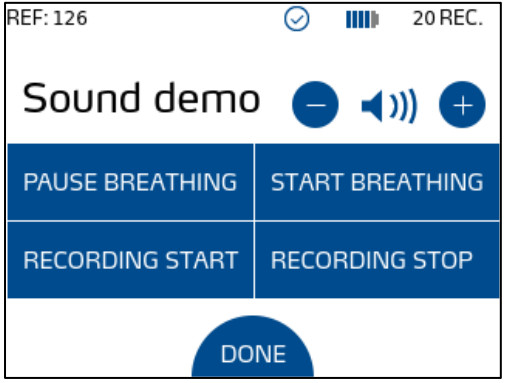
ROTATE DISPLAY to rotate the display by 180 degrees for better viewing comfort.

For the patient, it is important to become familiar with the sound instructions given during the recording phase.

Select START SOUND DEMO (REF:126), and demonstrate the PAUSE BREATHING (single beep), START BREATHING (double beep), RECORDING START (ascending tones) and RECORDING STOP sounds (descending tones).

Adjust speaker volume if needed.



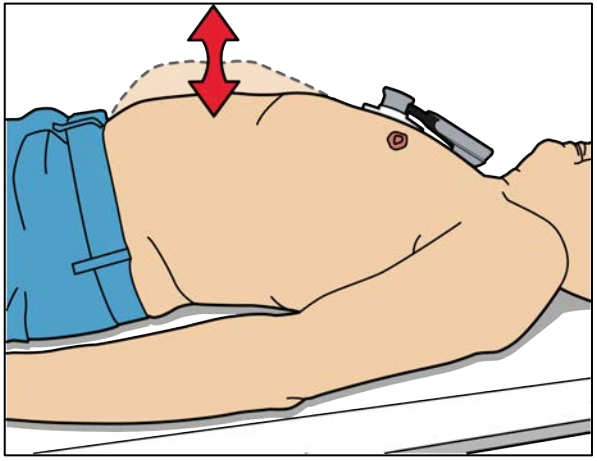


Press DONE to exit SOUND DEMO after patient has become familiar with the sounds.

Again, instruct patient to relax respiration and do belly breathing instead of thorax breathing.
Belly breathing will ensure better recording results.

Explain belly breathing to patient.
Show e.g. belly breathing by patient hand on belly, including inhalation, exhalation and natural breathing pause after exhalation.

Explain to the patient that he or she will be guided by the operator as well, to pause or start belly breathing intervals.



Instruct belly breathing

8.8 Recording phase, Start

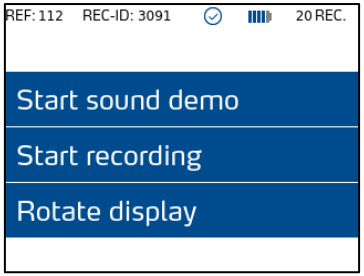
The CADScor®Sensor will evaluate current recording conditions during a Pre-recording, before continuing to the main heart sound recording.

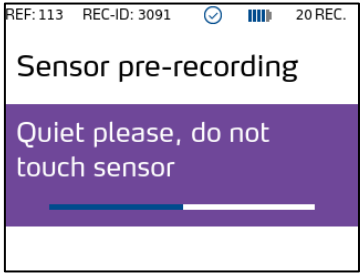
Press START RECORDING (REF:112) to begin recording process.

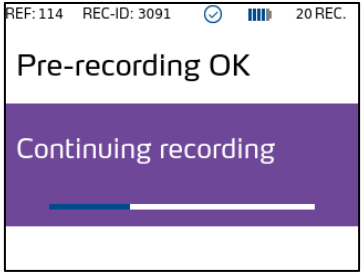
During Pre-recording, no talking should take place (REF:113).

If external, internal and electrical noise conditions during Pre-recording are evaluated acceptable by the sensor, the sensor will proceed to heart sound recording automatically.

The Pre-recording and evaluation will take approximately one minute (REF:114).







8.9 Recording phase, Main recording

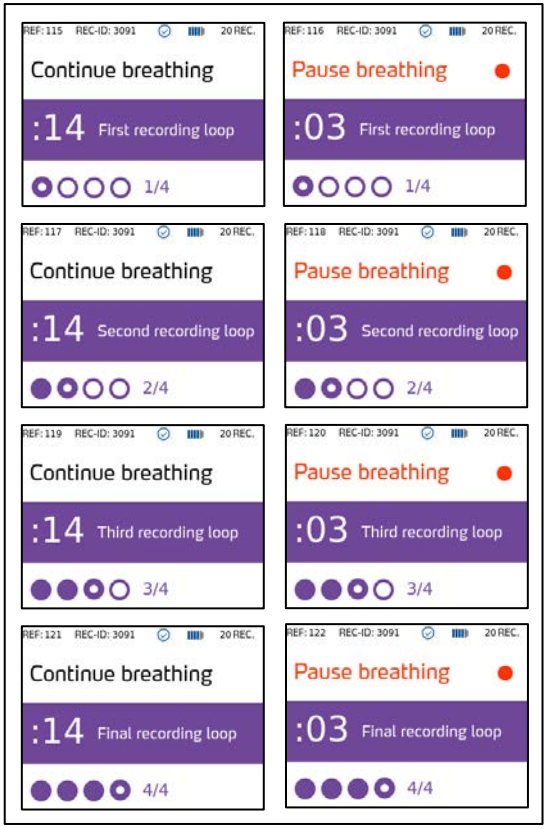
The Main recording has four recording loops of approximate 26 seconds each.

Each recording loop has two phases, 18 seconds of normal belly breathing and eight seconds of breathing pause.

During the Main recording, each recording phase will be indicated on the display in text as "Continue breathing" or "Pause breathing".

The time left in each phase of the loop is indicated by a count-down timer, from 18 to zero (breathing phase), or from eight to zero seconds (pause breathing).

The main heart sound recording phase will last approximately two minutes.



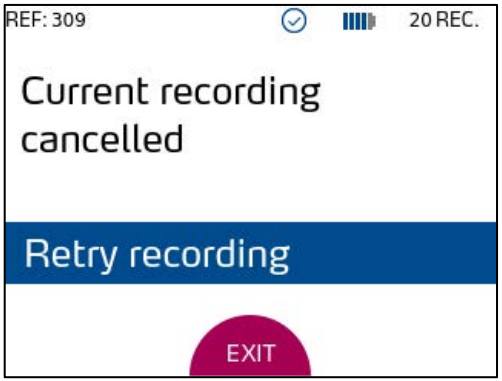
8.10 Recording phase, cancelling

The ongoing recording can be cancelled if conditions for recording heart sounds become unsuitable.

In case of increased external noise (like high traffic noise, helicopter landing, high sounding alarms) or internal noise (like patient coughing, stomach rumbling, increased hall-way talk), the actual recording can be retried without sacrificing a new patch.

To cancel the ongoing recording press the push button twice in quick succession. A triple beep warning will be heard.

A display message (REF:309) will appear asking if cancel is only concerning the current recording or will be to exit recording altogether. Exiting recording will invalidate the patch used.

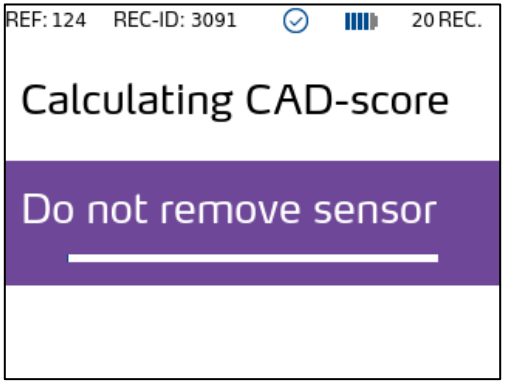


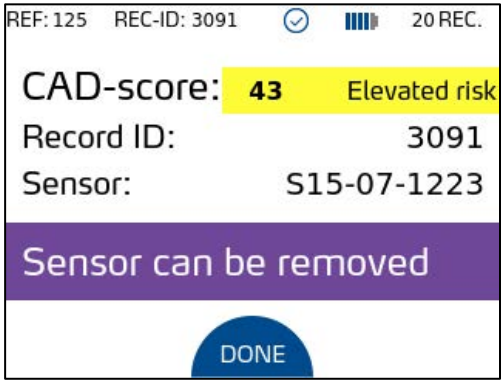
8.11 Recording phase, CAD-scoring

After the heart sound recording has ended the sound-file will be evaluated for errors like excessive noise, and a CAD-score is calculated (REF:124).
The sensor/patch should not be removed from the patient at this moment, in case of a new recording has to be made due to recording errors.

The calculation time is approximately 1-2 minutes. The CAD-score will be shown on the display in a colored bar indicating the patient risk group, with the corresponding Record-ID. Note the CAD-score result and Record-ID in the patient's medical file.

The sensor and patch can now be gently removed by pulling patch ear (REF:125). The sensor is released by pulling the string of the coupling ring in the direction of the arrow.

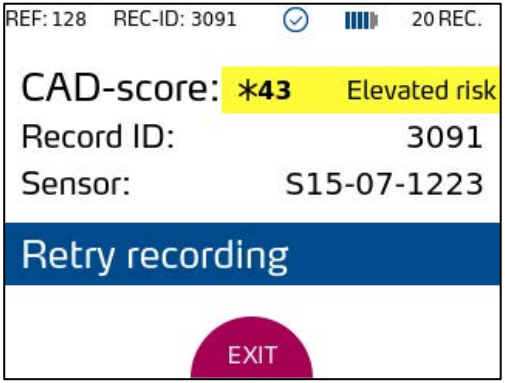


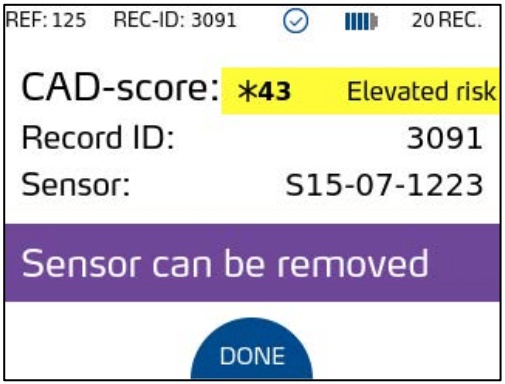


8.12 Short diastole CAD-score

In a few cases a standard CAD-score cannot be calculated based on a minimum diastolic period length, however an estimated CAD-score will be shown. The short diastole CAD-score is indicated by an asterisk (*) in front of the CAD-score.

When a short diastole-based CAD-score is presented, a possibility to redo the recording is offered. Try to relax (lower the heart rate) the patient further before attempting a new recording. A maximum of four recording attempts are allowed per patch. It is not recommended to pursue recording after four attempts on the same patient.
A short diastole-based CAD-score is not as precise as the standard CAD-score, which is why prompting for a new recording is encouraged (REF:128).





8.13 QR-code for printing, archiving and sending a CADScor patient report

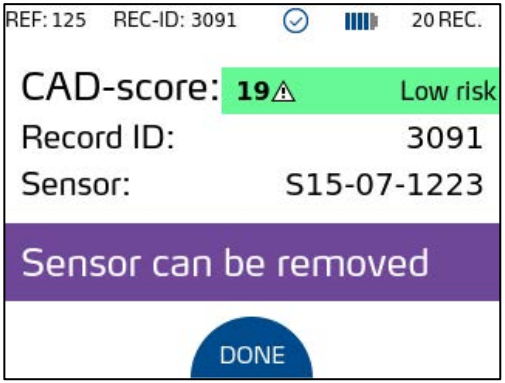
A functionality of the CADScor®System is the integration of a QR-code for printing, archiving and sending a patient report from a previous CAD-scoring, using a mobile device like a smart phone, or a QR code scanner set up for the purpose.

Currently, mobile devices running iOS system, at least version 13, with a camera can be used. The CADScor app can be downloaded from the Apple App Store and should be installed/configured prior to use.

On the result screen of the CADScor®Sensor, press the CAD-score result and the screen will convert to a QR-code. Point the activated CADScor App in “Scan Report” mode to transfer the data to the mobile device.
The QR-code functionality can be disabled/enabled by your local sales agent.

8.14 CAD-score in the 30-39 year age group

⚠ The CAD-scores from patients in the 30-39-year group are currently outside the intended patient population. A warning triangle indicates the higher uncertainty of their CAD-score.



8.15 Possible CADScor®System messages during or after recording

The CADScor®Sensor will during a pre-recording, prior to the heart sound recording sequence, determine if ambient conditions are fulfilled.
If recording conditions are fulfilled the heart sound recording will continue.

In case of unsuitable recording conditions or other errors, a display message will be shown indicating the cause of error. Depending on error or message type the CADScor®Sensor may prompt for an additional recording or aborting recording altogether.

In case of failure to obtain a CAD-score result, other patient evaluations should be pursued.

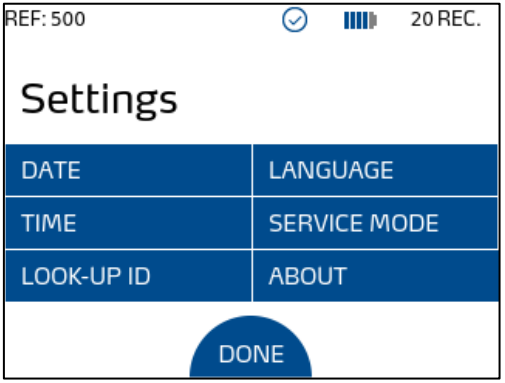
A comprehensive list of errors and messages is listed in the troubleshooting section 11.

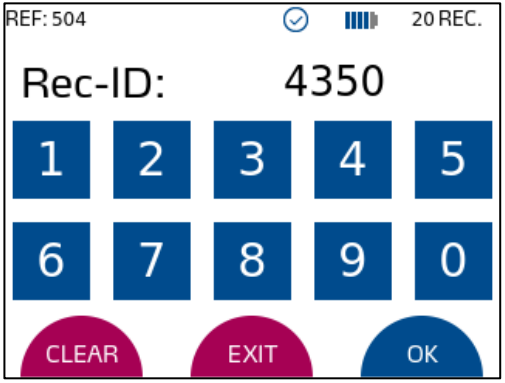
8.16 Recalling a previous recording result

From the Settings display (REF:500) it is possible to select a LOOK-UP ID function to recall data from a previous recording session if the Record-ID (REC-ID) is known. Only REC-IDs with a resulting CAD-score can be found.
Within the LOOK-UP ID display (REF:504) enter the four-digit REC-ID number and press the OK button to continue.

Notice that the REC-ID is relating to the specific CADScor®Sensor that performed the recording and the subsequent CAD-score calculation.
REC-IDs from cancelled recordings cannot be looked up.

Also notice that the REC-ID counter will reset to 1000 after REC-ID 9999.
Previous recording REC-ID data will thus be overwritten with new data having the same REC-ID number.





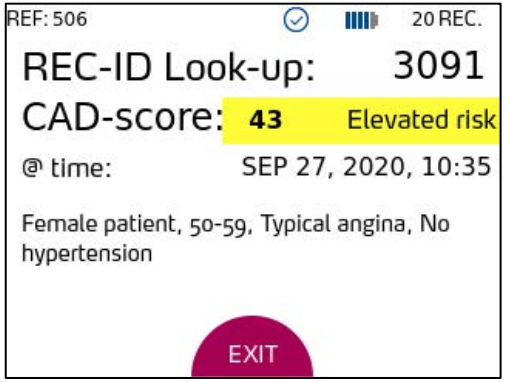
Check in the LOOK-UP data that the LOOK-UP REC-ID recording date corresponds to the anticipated date for the recording that is being identified.
The other patients' parameters (e.g. gender and age-group), can also be used for establishing the relevance of the Look-up data to the patient (REF:506).

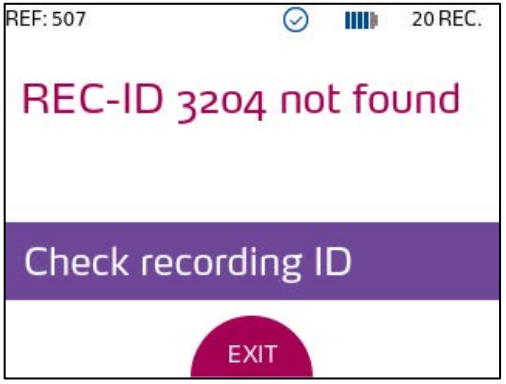
If the REC-ID is not found (REF:507), check if the entered REC-ID number or sensor number is correct.

If the LOOK-UP function is used on a different sensor than the original recording sensor, the LOOK-UP can display data relating to another patient, from a different recording session.

If the CADScor device is used in a blinded clinical investigation, the CAD-score will not be shown in the LOOK-UP display.

Press EXIT to return to settings menu.





8.17 After the recording

Clean the sensor using 70% ethanol wipes after use.

The sensor will automatically turn itself off.

Place the sensor in the Docking station for charging and automatic qualification until next recording session.

Do not use running tap- or splashing water to clean the sensor.

If the sensor has become accidentally wet, wipe it dry and leave to dry out for minimum 24 hours.

Do not attempt to dry in oven or using dry blower.

⚠ Do not expose the CADScor®System to liquids (water, oils, detergents or similar) or dust, since this may damage the CADScor®System permanently.

⚠ The CADScor®System cannot be heat- or radiation sterilized, or machine washed/cleaned, since this may damage the CADScor®System permanently.

9 Sound guidance used in the interface

During operation of the CADScor®System sounds are indicating the various events.

Some sounds are related to the timing of breathing/pause breathing intervals in the recording sequence and other sounds to confirm actions or as a warning of intended action.

Tone	Indication
Three tones in ascending frequency	Recording sequence start.
Single tone	Initiation of breathing pause.
Double tone	Ending of breathing pause.
Three tones in descending frequency	Recording sequence ended.
2x double tone	Completion of CAD-score calculation.
Single beep	Forced qualification initiated after 4+ seconds push button activation.
Double beep	Forced reset after 8+ seconds push button activation. Will turn sensor off, and require qualification after restart.
Triple beep	Warning after double-click in recording sequence to abort recording.

10 Maintenance

There are no user serviceable parts within the CADScor®System.

Maintenance is limited to cleaning the external surfaces of the sensor and the Docking station.

Only use 70% ethanol wipes for cleaning, do not use running tap water, splashing water or waterjets, or oils, detergents or similar substances.

The CADScor®System cannot be machine washed or autoclaved nor heat or radiation sterilized.

⚠ Do not expose the CADScor®System to liquids (water, oils, detergents or similar) or dust, since this may damage the CADScor®System permanently.

⚠ The CADScor®System cannot be heat- or radiation sterilized, or machine washed/cleaned, since this may damage the CADScor®System permanently.

⚠ Do not modify the CADScor®System or use or repair a defect CADScor®System, due to risk of malfunctioning. The CADScor®System must only be serviced by qualified Acarix personnel.

10.1 Disposal

Patch
The patch can be disposed of in ordinary waste.

Sensor and Docking station
The CADScor®System, when reaching its end of life, must be collected and recycled separately from other waste according to national requirements. Please contact your local Acarix distributor for instructions.

Acarix and its distributors within the European Union and associated states have taken the necessary steps to comply with the directive, 2012/19/EU on waste electrical and electronic equipment (WEEE)

Waste electrical and Electronic Equipment environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health.

11 Troubleshooting guide

Error message	Display reference	Possible cause	Correction action
#1 The CAD-score has a *-symbol in front of it.	REF:102, REF:103, REF:125, REF:128, REF:506	The diastolic periods in the recorded acoustic patient file are shorter than optimal for precise CAD-score calculation, due to higher heart rate. See section 8.12.	Try to relax patient to lower heart rate below 80-90 bpm and retry recording. Heart rates above 80-90 may result in error message “Irregular heart beat” see #9 (REF:209; REF:210).
#2 The CAD-score has a warning symbol behind it. ⚠	REF:102, REF:103, REF:125, REF:128, REF:506	If a CAD-score is calculated from a patient below 40 years (outside intended patient group), the CAD-score is presented with a warning symbol.	Establish if the entered patient information was correct. Be aware that the patient group below 40 years of age is outside current intended population group, and therefore conclude cautiously.
#3 Sensor restarted due to battery supply error or Low battery power	REF:306 REF:308	Defect in battery. The sensor battery power level is too low. The sensor battery has been deep discharged. See also #20.	Place the sensor in the Docking station for charging >15 REC. Set system for recharging, may take 1-2 days for recharging after deep discharge. Contact local distributor/Acarix for available options if problem persisting.

Error message	Display reference	Possible cause	Correction action
#4 Qualification expired	REF:300	The previous qualification has expired.	Qualify the sensor in the Docking station.
#5 Qualification failed	REF:301	Incorrect Docking station.	Place sensor in home Docking station.
	REF:303	Leak between the sensor head and the Docking station sensor tester. Error in the Docking station. Error in the sensor.	Place the sensor head firmly into the sensor tester and observe that red indicator ring on the sensor head is not visible and retry qualification. Contact local distributor/Acarix if sensor will not qualify.
#6 Ambient noise too high	REF:203 REF:204	The acoustic noise level in the examination room was too high, above 65 dB SPL.	Close doors and windows to shield from acoustic noise coming from outside recording room. Keep silent during the recording. Turn off running nearby fans, radios or similar. Change examination room location. Other examples of noise: Construction/building machinery, road & rail traffic noise, emergency helicopter service and similar.

Error message	Display reference	Possible cause	Correction action
#7 Electrical noise too high	REF:205 REF:206	The electromagnetic field noise in the examination room was too high.	Unplug power (if any) to the examination bed. Turn off unused electronic equipment in the examination room. Turn off wireless electrical devices (e.g. cell phones). Change examination room location.
#8 Internal noise to high	REF:207 REF:208	Can be caused by intermittent stomach rumbling.	Typically stomach rumbling will occur in periods prior to eating as a consequence of air in the intestines. A minor meal prior to measurement may resolve frequent stomach rumble.
#9 Irregular heartbeat	REF:209 REF:210	Patient heart rate was too irregular or too high.	Try to relax patient to lower heart rate below 80-90 bpm and retry recording. Consider evaluating patient for arrhythmia. Patient may already be diagnosed having known arrhythmia.

Error message	Display reference	Possible cause	Correction action
#10 Heartbeat signal too low	REF:211 REF:212	The sensor head was not anchored correctly at the left IC4 position. The sensor head was incorrectly placed in coupling ring. Heart action weak.	Re-identify left IC4 space and use a new patch for positioning correctly at left IC4. Secure sensor appropriately in coupling ring using patch assembly tool. Abort if recording is not possible.
#11 The recording stopped after pre-recording.	REF:203 REF:205 REF:207 REF:209 REF:211	Ambient noise or electrical noise was too high. The heartbeat signal was too low. The heartbeat signal was irregular.	See all individual causes above, #6-10. Reduce ambient- and electrical noise. Guide the patient to relax to lower the heart rate, below 80-90 bpm.
#12 Inconsistent data analysis	REF:214 REF:215	Data collected outside normal algorithm pattern. Combination of heart related sounds not compatible with current algorithm.	Guide the patient to relax to lower the heart rate, below 80-90 bpm.

Error message	Display reference	Possible cause	Correction action
#13 The patch was not accepted; Patch is expired, or has been used previously, or Patch RFID reading was disturbed.	REF:200 REF:201 REF:202	The patch has past expiration date or was used previously. Maximum storage period is 48 months from production date.	Use a new non-expired or un-used patch. Reading a patch RFID on a metal-table (or close to metal) may interfere with proper patch reading. Do a retry patch RFID reading away from metal containing surfaces.
#14 Temperature or pressure out of range	REF:304 REF:313 REF:314	The temperature in the room has exceeded the operating conditions for the CADScor®System. The CADScor®System has been brought outside its height limitations.	Avoid exposing the CADScor®System to excessive heat, or direct sunlight. Observe maximum operating height 2500 meters above sea level.
#15 Algorithm interaction failed	REF:213 REF:218	A technical problem inside the CADScor®Sensor has occurred.	Retry recording. If persistent failure contact local distributor/Acarix service.

Error message	Display reference	Possible cause	Correction action
#16 Ambient microphone error	REF:216	The test signal received by the ambient microphone was lower than anticipated. Error was triggered by liquid exposure to sensor.	Take care not to cover sensor or ambient microphone during recording. Ensure CADScor®Sensor body is oriented along sternum towards chin. Allow sensor to dry >24 hours in Docking station. If persistent failure contact local distributor/Acarix service.
#17 Self-test failed	REF:315	A technical problem inside the CADScor®System has occurred.	Contact local distributor/Acarix service.
#18 Unexpected issue detected. Restart required.	REF:317	An internal error has occurred. Sensor needs to be restarted. The USB connection between Docking station and Sensor failed.	Place sensor in docking station and press “EXIT”. Wait for restart to finish. Inspect charging pins in Docking station for free up and down movement. Exercise pin gently to free up stuck pin. Clean charging pads on sensor using cotton swabs with 70% ethanol.

Error message	Display reference	Possible cause	Correction action
#19 REC-ID not found	REF:507	The patient REC-ID was not found on the Sensor.	Check that the REC-ID number was typed in correctly. Check that the Look-up function was performed on the Sensor that made the original recording. Check if the last REC-ID number on the Sensor display is lower than the Look-up REC-ID. If the Sensor REC-ID number is lower, the Look-up use-data text-file may have been overwritten by new data. The sensor may have been memory reset as part of service; Recording ID has been erased. Notice that REC-ID´s that have been cancelled do not appear in REC-ID log.

Error message	Display reference	Possible cause	Correction action
#20 The LED indicator on Docking station is off, or constant yellow when Sensor is docked.		The power adaptor has been turned off at mains. The power jack has been disconnected. Plug assembly not fully inserted into adaptor. The power adaptor is faulty, or electrical supply is missing. The Docking station contacts interface is not recognizing sensor.	Turn on power adaptor outlet. Apply power jack supply to the docking station. Establish full insertion of plug into power adaptor by pressing firmly. Replace power supply unit if suspected malfunctioning. Restore electrical supply. Try restart procedure (7.14). Contact local distributor/Acarix for available options if problem persists.
#21 The display is black.		The sensor is in off mode. The sensor battery is discharged. See also #3.	Press push button to switch on sensor. Charge the sensor battery in the Docking station. For deep discharged batteries recharging may take 1-2 days. It is recommended to always keep power on system, for ease of use and battery charging.
#22 Display cracked		The display is broken.	Contact local distributor/Acarix for available options.
#23 Sensor unresponsive		Software error.	Sensor needs restart. See section 7.14

12 CADScor®System requirements

Normal operating environment:
Temperature +10 to +40°C.
Relative humidity 20-80% non-condensing.
Below 2500 m above sea level.

Short term storage/transportation environment (up to 96 hours):
In packaging-box/shipper-box.
Maximum -30 to +70°C.
Maximum 93% RH condensing, at +40°C.
Minimum ambient pressure 59,7 kPa (4.267 m above sea level).
Normal storage environment:
Temperature +10 to +40°C.
Relative humidity 20-80% non-condensing.

Ingress Protection (IP) ratings:
CADScor®Sensor IP44
CADScor®Docking station IP22
Power adaptors IP20

Operating noise environment:
External noise level < 65dB SPL.
External electrical noise level < 65dB SPL.

System altitude correction
Up to 2500 m above sea level

System power source
Only the supplied power adaptor must be used, identified by a manufacturer name and type number:

XP-Power ACM06US05 (-XZ1505)

Rated input voltage: 100-240VAC, 50/60 Hz
Rated output voltage: 5VDC
Max. power: 6.0 W

⚠ Never use other power adaptor than supplied with the CADScor®System, due to risk of electrical shock.

12.1 System specification

Model: ACS-1401
Dimensions:
CADScor®Sensor: ASE-1401
75(W) x 160(L) x 26(H) mm
Approx. weight: 180 g

CADScor®Docking station: ADS-1401
193(W) x 109(D) x 53(H) mm
Approx. weight: 600 g

XP Power, Power adaptor: Excl. wire
42(W) x 70(D) x 69(H) mm
Approx. weight: 110 g (incl. wire, EU plug)

CADScor®Patch: ACP-1401
80(W) x 190(L) x 9(H) mm
Approx. weight: 10 g

RFID:
Frequency band: 13.56 MHz ISM band
Communication standard: ISO14443
Tx power: Magnetic field short range device with < 0 dB µA/m @10m
Modulation: ASK
Bandwidth: 14 kHz

⚠ Do not use the CADScor®System on patients with implanted electronics like ICD, Pacemakers, heart-pumps or closer than 50 cm to similar active electronic support equipment, due to risk of equipment failure from CADScor®System electromagnetic RFID impulse.

Date of manufacture:
The date of manufacture can be read from the serial [SN] numbers on the sensor or Docking station respectively, e.g: S14-02-0001 is manufactured Febr. 2014, and D14-04-0001 is manufactured April, 2014. The four last digits are lot numbers.

12.2 Packaging materials

System Box: 1x
Outside box made of recyclable corrugated cardboard. Internal fixtures made from recyclable folded corrugated cardboard.
Internal boxes made from recyclable cardboard.
User manual made of 80g/m^2 paper.
Separator tool made from stainless steel.
Total approx. weight, incl. CADScor®System and power adaptor: 1500 g

System Shipper-box: 1x
Outside box made of recyclable corrugated cardboard.
Approx. weight: 120 g

System Shipper-box: 6x
Outside box made of recyclable corrugated cardboard.
Approx. weight: 580 g

Patch box: 1x
Outside box made of recyclable cardboard.
Inside pouches made from Polyethylene and paper.
Assembly tool made from cardboard.
Total approx. weight, incl. patches: 240 g

Patch Shipper-box: 1x
Outside box made of recyclable corrugated cardboard.
Approx. weight: 100 g

Patch Shipper-box: 6x
Outside box made of recyclable corrugated cardboard.
Approx. weight: 580 g

13 Warranty

The CADScor®System is covered by a one (1) year warranty (subject to country regulations), replacing/correcting defective parts or system parts, or at least 1000 recordings in the warranty period.

Opening of the CADScor®Sensor or modifying the CADScor®System invalidates the warranty. The CADScor®Docking station can only be opened for wall mount installation. No serviceable parts inside.

The warranty does not cover any damages caused by improper operation.

This system comprises sensitive components and must be treated carefully to avoid strong vibrations or shock from dropping or handling.
Observe storage and operating conditions described in CADScor®System requirements, for temperature, altitude and humidity in section 12.

The manufacturer cannot be held liable for any damage caused by incorrect application or operation of CADScor®System.

The warranty does not extend to interpretation of results obtained using the CADScor®System or use of the system outside its intended use.

⚠ Do not modify the CADScor®System or use or repair a defect CADScor®System, due to risk of malfunctioning. The CADScor®System must only be serviced by qualified Acarix personnel (10).

⚠ Do not drop or exert excessive stress or force to the CADScor®System since this may damage the CADScor®System permanently.

14 Approvals and EMC information

The CADScor®System is a medical device class IIa, fulfilling the requirements in compliance with the Council Directive 93/42/EEC, Medical Device Directive (MDD).

The CADScor®System software is classified as safety class B, according to IEC/EN 62304, “Medical device software – Software life-cycle processes”

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CADScor sensor is compliant with the requirement for RF exposure in US with less than 50 mm separation distance between the user and/or bystander of the device.

CADScor sensor is only compliant if no changes or modifications are made to the device.

CE-mark	Indicates compliance with the *Medical Device Directive* 93/42/EEC
IEC/EN 60601	In compliance with IEC/EN 60601-1
EMC-emission	The equipment complies with the emission requirements for Class B equipment in IEC/EN 60601-1-2
EMC-immunity	The equipment complies with the immunity requirements in IEC/EN 60601-1-2
FCC ID	2AYXI-ASE1401

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions		
The CADScor system ACS-1401 is intended for use in the electromagnetic environment specified below. The customer or the user of the CADScor system ACS-1401 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CADScor system ACS-1401 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The CADScor system ACS-1401 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity			
The CADScor system ACS-1401 is intended for use in the electromagnetic environment specified below. The customer or the user of the CADScor system ACS-1401 should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic Discharge, (ESD) IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A, no input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Table 2, continued: Guidance and manufacturer's declaration – electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% *U*T (100% dip in *U*T) for 0.5 cycle 0% *U*T (100% dip in *U*T) for 1 cycle 70 % *U*T (30 % dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 5 sec	0% *U*T (100% dip in *U*T) for 0.5 cycle 0% *U*T (100% dip in *U*T) for 1 cycle 70 % *U*T (30 % dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 2, continued: Guidance and manufacturer's declaration – electromagnetic immunity			
Conducted RF immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz. 80 % AM at 1 kHz 6 Vrms in ISM bands between 150 kHz and 80 MHz (see note)	3 Vrms 150 kHz to 80 MHz. 80 % AM at 1 kHz 6 Vrms in ISM bands between 150 kHz and 80 MHz (see note)	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CADScor system ACS-1401, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF immunity IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz Plus additional test levels according to the below table.	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz Plus, additional test levels according to the below table.	
NOTE: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.			

Table 3: Radiated Immunity Test Levels (Immunity to RF Wirelss Communication Equipment).

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

15 Acronyms & Definitions in text

Acronyms	Definitions
CAD	Coronary Artery Disease.
CSS	Chronic Coronary Syndrome
CADScor®System	Sensor, Docking station and Patch.
CADScor®Sensor	Acoustic recording sensor, part of the CADScor® System.
CADScor®Docking station	Docking station for charging and qualification of the sensor, part of the CADScor® system.
CADScor®Patch	Patch for anchoring the sensor onto the chest of the patient, part of the CADScor® System
Recording	Acoustic recording performed by the sensor.
IC4-L	Left fourth intercostal space.
Stenosis	Narrowing of the coronary arteries.
Coronary murmurs	Heart sounds that are produced as a result of turbulent blood flow that is sufficient to produce audible noise.
CAD-score	Calculated heart murmur score (of coronary murmurs) on the basis of the acoustic recording.
RFID-chip	Radio-frequency identification chip
Sensor qualification	A procedure to ensure sensor operational status.
External noise	The ambient noise surrounding the heart sensor.
Internal noise	The sounds arising from inside of human body (respiratory, muscle, bowel).
Electromagnetic noise	Non-acoustic noise generated by electromagnetic fields (EMC).

16 Licenses

The CADScor®System (r) makes use of several open source packages. Here is a list with package name, the name and version of the licenses used and, in some cases, other notes. Afterwards, the licenses will be written.

- alsa-lib, LGPL-2.1
- alsa-utils, GPL-2
- busybox, GPL-2
- dropbear, several licenses, see below
- freetype, GPL-2
- glib, LGPL-2.1
- i2c-tools, GPL-2
- jpeg, the jpeg library is work of the Independent JPEG Group.
- libpng, see http://www.libpng.org
- libsndfile, LGPL-2.1
- linux kernel, GPL-2
- memtester, GPL-2
- netbase, GPL-2
- pcre, BSD-3-Clause, see copyright holders below
- qt4-embedded, LGPL-2.1
- u-boot, GPL-2
- wireless-tools, GPL-2 and LGPL-2.1
- zlib, http://zlib.net

Some of the licenses grant the user full access to the source code for the specific package. To get this access, please contact Acarix at info@acarix.com.

dropbear
The majority of code is written by Matt Johnston, under the MIT license below. Portions of the client-mode work are (c) 2004 Mihnea Stoenescu, under the same license
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Portions copyright (c) 2004 Mihnea Stoenescu.
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=====
LibTomCrypt and LibTomMath are written by Tom St Denis, and are Public Domain.
=====
sshpty.c is taken from OpenSSH 3.5p1,
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"As far as I am concerned, the code I have written for this software can be used freely for any purpose. Any derived versions of this software must be clearly marked as such, and if the derived work is incompatible with the protocol description in the RFC file, it must be called by a name other than "ssh" or "Secure Shell". "
=====
loginrec.c, loginrec.h, atomicio.h, atomicio.c and strlcat() (included in util.c) are from OpenSSH 3.6.1p2, and are licensed under the 2 point BSD license (see below).
loginrec is written primarily by Andre Lucas, atomicio.c by Theo de Raadt.
strlcat() is (c) Todd C. Miller
=====
Import code in keyimport.c is modified from PuTTY's import.c, licensed as follows:
PuTTY is copyright 1997-2003 Simon Tatham.

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PCRE
PCRE is a library of functions to support regular expressions whose syntax and semantics are as close as possible to those of the Perl 5 language.

Release 8 of PCRE is distributed under the terms of the "BSD" licence, as specified below. The documentation for PCRE, supplied in the "doc" directory, is distributed under the same terms as the software itself.
The basic library functions are written in C and are freestanding. Also included in the distribution is a set of C++ wrapper functions, and a just-in-time compiler that can be used to optimize pattern matching. These are both optional features that can be omitted when the library is built.

THE BASIC LIBRARY FUNCTIONS
Written by: Philip Hazel
Email local part: ph10
Email domain: cam.ac.uk
University of Cambridge Computing Service, Cambridge, England.

PCRE JUST-IN-TIME COMPILATION SUPPORT
Written by: Zoltan Herczeg
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Emain domain: freemail.hu

STACK-LESS JUST-IN-TIME COMPILER
Written by: Zoltan Herczeg
Email local part: hzmester
Emain domain: freemail.hu

THE C++ WRAPPER FUNCTIONS
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