

## Important Safety Notice

**Product:** EC Sense 12-lead Exercise-ECG system

**Action:** Update of software for EC Sense with Exercise-ECG

**Recipient:** Technically responsible for the affected product

### Problem

We have observed that when an EC Sense 12-lead Exercise-ECG system (EC Sense with Exercise-ECG) is used in combination with ECG storage and archiving (EC Store), it has at a few occasions happened that a recorded Exercise-ECG is lost. The problem has occurred when using automatic storage of the initial rest-ECG in EC Sense with Exercise-ECG, at the same time as when the hospital network and/or the database server where EC Store is installed are performing poorly.

### Affected Product

All versions of EC Sense with Exercise-ECG, in combination with EC Store.

### Action

To resolve the problem, the software for EC Sense with Exercise-ECG must be updated. According to our files, there is at least one EC Sense with Exercise-ECG at your facility with software version older than 4.1 which means that one of the following alternatives must be performed:

Alternative I	Alternative II	Alternative III
Update EC Sense with Exercise-ECG software with a bug fix version 4.0.14 that fixes the problem.	Update EC Sense with Exercise-ECG software with a version 4.1.3 that in addition to fixing the problem, offers a range of new functions and advantages.	Sign a 3-year service agreement with free updates av EC Sense with Exercise-ECG (software version 4.1.3 included).
Free of charge	Cost: contact Cardiolex for an offer and a list of functions.	Cost: contact Cardiolex for an offer and a list of functions.

Regardless of the alternative chosen, the update shall be performed according to the action plan in appendix 1.

To avoid the problem from occurring in the period between now and until the update is performed, the automatic storage of rest-ECG must be deactivated on all the EC Sense with Exercise-ECG. If an initial rest-ECG is needed it must be stored manually.



Please send a copy of this notice to all other personnel to whom the information is relevant. This message has also been reported to the national competent authority of your country.

For further information, or any questions, contact Cardiolex using [support@cardiolex.se](mailto:support@cardiolex.se).

Best regards

Johanna Genberg  
CEO, Cardiolex Medical AB

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Head of Quality, Cardiolex Medical AB

## Appendix 1 – Action Plan

Action	Responsible
Confirm to Cardiolex that you have received this safety notice by replying to the email.	Customer
Deactivate automatic storage of rest-ECG on all the EC Sense with Exercise-ECG and inform/train all users to use manual storage of rest-ECG.	Customer
Notify Cardiolex using <a href="mailto:info@cardiolex.se">info@cardiolex.se</a> which of the above alternative that is chosen, along with the number of affected EC Sense with Exercise-ECG	Customer
Send an offer for the chosen alternative (except in the case the alternative free of charge was selected).	Cardiolex
Accept the offer (except in the case the alternative free of charge was selected).	Customer
Make available the selected software version for EC Sense with Exercise-ECG together with any license keys and an instruction on how to update.	Cardiolex
Download the selected software version for EC Sense with Exercise-ECG.	Customer
Update the software to the selected version (according to the instruction) on all the EC Sense with Exercise-ECG.	Customer
Activate automatic storage of rest-ECG on all the EC Sense with Exercise-ECG.	Customer
Send report of actions to Cardiolex (according to the instructions) after the update is complete.	Customer