

CER-S v. 4.6.z

Basic UDI: ++B972CERS437

Stand-alone software medical device intended to analyze, edit, review and report digital continuous ECG recordings.

Installation Procedure

To install the software simply double-click the primary (LEFT) mouse button on the ".exe" file (installer). Following defaults settings, CER-S software will be installed together with all the required libraries and modules.

After the installation of the software is completed, the application can be launched by double-clicking the **CER-S.exe** program file.

The program file is typically installed in the "C:\Program Files (x86)\AMPS\CER-S" folder.

The user can also launch the software via the CER-S desktop icon, from the Start Menu or by command-line.

Information

Services

For technical support or to report issues (including complaints), please contact Cardio Calm using one of the following options:

- write an email to supporto@cardiocalm.com
- call Cardio Calm Support at +39 0308140128
- send a fax to Cardio Calm Support at +39 030 9650572
- write to Cardio Calm Support – Cardio Calm srl – Corso Martiri della Libertà, 40 – 25018 – Montichiari (BS), Italy

Label

Clicking the "Medical device label" button of the "About" menu of the application, the Medical Device Label will be displayed (Figure 1), listing:

- Name and version of the medical device (MD)
- The manufacturer
- The address of the manufacturer
- The CE mark and the certification body number
- The Reference number (REF)
- The Serial number (SN)
- The Unique Device Identification (UDI)
- The link to web page containing the software manuals (www.cardiocalm.com/manuals)

Instruction for use (IFU)

IFU are provided in electronic format. User must download and install any free PDF reader software (ex. Acrobat Reader) on the computer to visualize them. If necessary, it's possible to request the paper version free of charge at supporto@cardiocalm.com.

IFU are also available at www.cardiocalm.com/manuals/CER-S.

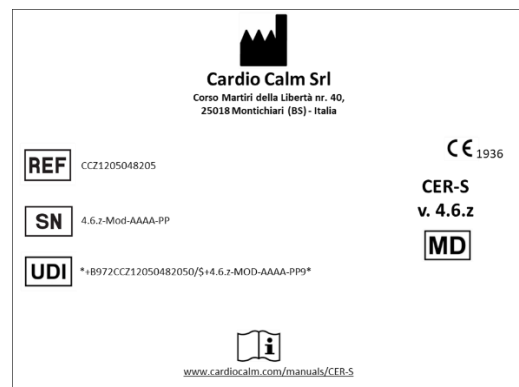


Figure 1: CER-S label