

# CARDIOLINE

## ECGEasyApp

### General Information

Product name	ECGEasyApp
Generic name	ECGEasyApp
Product code	81019594
Manufacturer	Cardioline Spa  Head Office and Production facility: Via Linz, 151 38121 Trento Italy  Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Description of Device	<p>ECGEasyApp is a self-installing Pc application dedicated to the management of tests conducted with Cardioline electrocardiograph. It can receive ECG tests, in SCP format (diagnostic format), via USB or connecting the electrocardiograph directly to the computer through the USB cable or connecting a USB pen drive where the tests were previously stored to the computer (for detailed instructions on how to store the ECG tests on a pen drive, see the user manual of the electrocardiographs).</p> <p>The tests are stored in SCP format on a local database, inside of which you may perform searches.</p> <p>The user may view the tests using a PDF viewer.</p> <p>The user can edit patient data and test data, including the conclusions associated with the test itself and, therefore, the automatic interpretation supplied by the electrocardiograph, if any. The user can also edit and customise the layout of the traces with specific commands (speed, amplitude, format, etc.). Commands regarding printing, saving PDF, sending e-mail, etc. are made available by the PDF viewer.</p>

### Technical Specifications

#### Minimum Requirements for the Computer

Operating System	Windows 10 32/64 bit Windows 8.1 32/64 bit (Italian) Windows 7 32/64bit (Italian)
Processor	Intel (or compatible) at least 2GHz
RAM	4 GB (minimum)
Monitor	10" or larger (at least 18.5" is recommended) Resolution 1366x768 or higher
Software pre-installed on computer	PDF file reader

#### Archive specifications

Archive type	SQL Compact Database
Archive capacity	10000 tests
Compatible tests	Resting ECG (SCP format)

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Compatible Cardioline devices      ECGxxxL range electrocardiographs or USB pen drive

## Tests archive

- |                          |  |
|--------------------------|--|
| Tests archive filters    | <ul style="list-style-type: none"><li>▪ Import data or test date</li><li>▪ Open text search by name/surname/patient ID</li></ul>   |
| Tests list data          | <ul style="list-style-type: none"><li>▪ Patient ID</li><li>▪ Surname and Name</li><li>▪ Year of birth/Age</li><li>▪ Patient gender</li><li>▪ Date the test was conducted</li><li>▪ Imported test data</li></ul>              |
| Tests archive operations | <ul style="list-style-type: none"><li>▪ Edit patient details</li><li>▪ Edit test data (test date, notes and conclusions)</li><li>▪ Test display: print test, save as PDF, send PDF via e-mail (through PDF viewer)</li></ul> |

## Test information

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|--------------|--|
| Patient data | <ul style="list-style-type: none"><li>▪ ID</li><li>▪ Name</li><li>▪ Surname</li><li>▪ Gender</li><li>▪ Date of birth</li><li>▪ Age and corresponding unit</li><li>▪ Race</li><li>▪ Pharmacological therapy</li></ul> |
| Test data    | <ul style="list-style-type: none"><li>▪ Test date</li><li>▪ Notes</li><li>▪ Conclusions</li></ul>  |

## Import

- |                  |   |
|------------------|---|
| Import functions | <ul style="list-style-type: none"><li>▪ Select single or multiple tests to import</li><li>▪ Possibility of automatically deleting the tests from the folder of origin</li></ul> |
|------------------|---|

## Settings

- |                   |   |
|-------------------|---|
| Program settings  | <ul style="list-style-type: none"><li>▪ Language (Italian - English - German - French)</li><li>▪ Name of department/clinic</li><li>▪ Send statistics and errors (to enable/disable sending of statistics and errors to Cardioline)</li></ul>  |
| PDF view settings | <ul style="list-style-type: none"><li>▪ Trace format: 12x1, 6x2, 3x4, 3x4+1, 3x4+3;</li><li>▪ Speed: 25, 50 mm/s;</li><li>▪ Amplitude: 5, 10, 20 mm/mV;</li><li>▪ Grid: complete, blank, partial;</li><li>▪ Grid colour: colour, black and white;</li><li>▪ Lead sequence: standard, Cabrera;</li><li>▪ Muscle filter: Off, 25, 40, 150 Hz.</li></ul> |

## Exported formats

PDF	Through PDF Viewer
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## Regulations and Safety

### Classification according to MDD 93/42/EEC

Class	Class I
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Rational Rule 1 annex IX Directive 93/42/EEC and its amendments

Notified Body TUV (1936)

## Classification according to IEC 62304 – Software

Class of risk A

## Performance (ECG viewer)

Standard EN 60601-2-25:2011

## Other classifications

GMDN 44098 Information system software, application program, cardiology

CND Z12059009 systems to analyse and manage ECG traces

RDM (Medical Device Catalogue) NA

## Applicable standards

EN 980 Symbols for use in the labelling of medical devices

EN 1041 Information supplied by the manufacturer of medical devices

EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971 Medical devices - Application of risk management to medical devices

EN 62304 Medical device software - Software life cycle processes

EN 62366 Medical devices - Application of usability engineering to medical devices