CARDIOLINE

ECGWebApp

General Information

Product Name	ECGWebApp
Generic Name	ECGWebApp
Product Code	81019560
Manufacturer	Cardioline Spa Registered Office and Production: Via Linz, 151 38121 Trento Italy
Description of Device	ECGWebApp by Cardioline is an innovative and cutting-edge web application for reporting and archiving all ECG methods. Accredited users have access via any Internet browser (Microsoft Edge, Chrome, Firefox), without the need for special software on their PC. ECGWebApp can receive and store in its ECG database ECGs acquired and transmitted from Cardioline devices but is also compatible with third party devices (see compatible devices). ECGWebApp is a very flexible and powerful tool, highly scalable, that can rely on a wide Internet infrastructure as well as a local network (intranet). ECGWebApp is perfectly adaptable to any scenario, from complex e-health networks, to hospital archives, to private medical practices. Namely, ECGWebApp is able to manage resting ECG, ECG Holter, ABPM Holter and stress ECG tests: ▪ **Resting ECG tests**: Resting tests are entirely managed online. Indeed, ECGWebApp receives the test, saves the test in SCP format on its own database and lets you review it using an online ECG viewer, with which the trace can be fully analysed. The reviewed test is then saved on the database in SCP format. This way users can access tests and review them simply by opening the browser on their computer, without having to locally install additional applications. ▪ **ECG Holter tests** are managed as PDFs generated by the Cubeholter WS software. Their reporting is possible by adding a page with the conclusions to the final pdf report. ▪ **ABPM Holter and stress ECG tests**: ABPM Holter and stress ECG tests are managed as PDFs, generated by the Cardioline Cube Suite software. Reviewing is possible by adding a page with the conclusions to the final PDF report. The ECGWebApp database consists of: ▪ Tests archive - resting ECG (in SCP format), ECG Holter (in PDF format), Stress ECG tests (in PDF format), and ABPM Holter (in PDF format). ▪ Patient archive – to which the tests are associated. ▪ User archive – who can access the ECGWebApp and perform various operations based on the permissions associated to them (for example, reviewing tests, managing patient demographics, etc.). ▪ Unit archive – clinics, hospitals and healthcare facilities that have sent tests, corresponding to the Department ID associated with the test. ▪ Device archive – list of devices that have sent tests to ECGWebApp.

It is possible to connect to ECGWebApp using a standard internet browser (Microsoft Edge, Chrome, Firefox), in order to gain access to the saved tests, as well as to the master data of patients, users and units.
The available options and functions (e.g. maximum number of sending devices, type of method enabled for reviewing, integration with other IT systems, etc.) depend on the specific configuration that was purchased and are saved in the provided hardware protection key, without which the software cannot be used.
If ECGWebApp has a Digital Signature option, it is possible to digitally sign the final test report.

Technical Specifications

Minimum Requirements for the Server

Operating System	SERVER Systems Windows 2016 Server Windows 2012 Server DESKTOP Systems Windows 10 64 bit Windows 8.1 64 bit
Processor	Intel (or compatible) 2 core at least 2GHz
RAM	8 GB (minimum) for Windows Server 4 GB (minimum) for Windows Desktop
Hard Disk	To be checked with Cardioline, based on the configuration purchased
Network interface	At least one network interface
Additional applications	Microsoft SQL Server 2008/2012/2016 (any edition, if the GDPR option is not provided – see GDPR section) Microsoft Internet Information Services (IIS) Microsoft .NET Framework 4.5.2 (64 bit)

Minimum Requirements for Work Stations

Browser	Chrome ver. 81 Firefox ver. 75 Edge ver. 81
Screen	10” or more resolution 1366x768 or higher

Minimum Requirements for the signature Virtual Machine

Processor	Intel (or compatible) 2 core, at least 2GHz
RAM	8 GB
Hard Disk	40 GB
Network interface	At least one network interface
Additional applications	VMWare virtualisation system (VMWare Workstation PRO or superior systems)

Archive specifications

Archive type	SQL Server
Archive capacity	At least 10GB available. Archive sizing depending on the quantity of data and the methods installed.
Compatible tests	▪ Resting ECG (saved in SCP format)

- ECG Holter (saved in PDF format)
- Stress ECG (saved in PDF format)
- ABPM Holter (saved in PDF format)

Compatible Cardioline devices

- Electrocardiographs:
  - ECG100+/S and ECG200+/S range
  - TouchECG
- ECG Holter devices (transmission of the final PDF report)
  - Cubeholter WS
  - WebUploader – test to be processed before transmission with Cubeholter WS to generate the PDF report
- ABPM Holter devices (transmission of the final PDF report):
  - Cubeabpm (part of Cube Suite)
  - WebUploader – test to be processed before transmission with Cubeabpm to generate the PDF report
- Stress ECG devices (transmission of the final PDF report)
  - Cubestress (part of Cube Suite)

Tests archive

Tests archive filters

- Paediatric Test
- Test status (to be reviewed, reviewed, signed)
- Test Type
- Time interval (Date of Acquisition or receipt)
- Sending unit
- Tests to be reviewed
- Advanced search on the Identification, Name, Surname, Date of Birth fields.

Tests list data

- Name and surname
- Patient identification
- Date of acquisition / Date of receipt (configurable)
- Unit
- Confirmed by
- Confirmed on
- Type of test / Paediatric test
- Assessment / emergency

Tests archive operations

- Display
- Reviewing and digital signature of the report (*with Digital Signature option*):
  - via resting ECG test display,
  - addition of the conclusions to the PDF report for the other tests,
- PDF exporting
- SCP Exporting for resting ECG tests
- Printing

Resting ECG viewer

Patient data

- Date and time of acquisition
- Unit
- State of the test
- Patient first and last name
- Patient's ID
- Gender
- Date of birth
- Age
- Height
- Weight
- SpO2 oxygen saturation

	▪ Blood pressure (Diastolic/Systolic)
Test data	▪ Working diagnosis ▪ Notes ▪ Medical history ▪ Medicines (max 3 words) ▪ Technician ▪ Accession number: reservation number
Overall measurements	▪ Heart rate ▪ P Duration ▪ PR Interval ▪ QRS Duration ▪ QT Interval ▪ QTc Bazett ▪ QTc Fridericia ▪ QTc Hodges ▪ Sokolow-Lyon index ▪ P QRS T Axis
Gain	5 – 10 – 20 mm/mV
Speed	5 – 10 – 25 – 50 mm/s
Formats displayed	3x4 – 3x4+1 – 3x4+3 – 6x2 – 12x1 – average complexes (AVG)
Muscle filters	25 – 40 – 150 Hz
Reviewing instruments	▪ Graphic measurement tools (callipers) ▪ Comparison between two resting ECG tests ▪ Measurement matrix per lead ▪ Automatic editable overall measurements
AVG view	▪ Rhythm lead (can be selected by the user) ▪ View of middle complexes in a 3x4 matrix ▪ View of overlapping middle complexes in a 2x1 matrix ▪ RR Gauge: measurement of the heart rate in the selected interval and duration and extent of the selected interval ▪ Markers of fiducial points (Pon, Poff, Qon and Toff): recalculation of overall measurements
Customisation of the final report	Configurable logo and fields of the report

PDF report display

Test data	▪ Name and surname ▪ Patient identification ▪ Age ▪ Gender ▪ Date of acquisition ▪ Reviewing Physician

Patient archive

Patient archive filter	Search with free text
Patient data	▪ Name and Surname ▪ Identification ▪ Date of birth ▪ Gender ▪ Race ▪ Address ▪ Nationality ▪ E-mail address

	▪ Telephone number
Patient management	▪ Edit ▪ Delete ▪ Re-associate tests
User archive	
User archive filters	Search with free text
User data	▪ User ▪ Name and Surname ▪ E-mail address
User authorisations	▪ Access to read tests and patient data ▪ Test access and reviewing ▪ Add a new test to the system ▪ Edit and delete tests and patient data ▪ System Management ▪ Access to patients list ▪ Digital signature
User management	▪ Edit ▪ Delete ▪ Deactivate ▪ Setting units that can be viewed by the user (to limit access to tests)
Unit archive	
Unit archive filters	Search with free text
Unit data	▪ Code ▪ Name ▪ Class
Unit management	▪ Edit ▪ Delete
Device archive	
Device archive filters	Search with free text
Unit data	▪ Serial number ▪ Device ID (optional) ▪ Unit (optional)
Unit management	▪ Delete ▪ List of users associated with the unit
Imported test formats	
SCP	For resting ECG
PDF	For all tests
XML	For resting ECG (Annotated ECG) - Annotated ECG module
DICOM	For resting ECG – DICOM option
Protocols for work lists	
DICOM	Patient list management for ECG and Holter – DICOM option
GDT	Patient list management for ECG – GDT option
HL7	Patient list management for ECG and Holter – HL7 option
Formats / test exporting formats	

SCP	For resting ECG
PDF	For all tests – PDF or custom PDF option
DICOM	Resting ECG test export – DICOM option
GDT	Resting ECG test export – GDT option
HL7	Resting ECG test export – HL7 option

Options

DICOM Option	The module allows a Worklist to be received with DICOM protocol (transferring the Worklist to Cardioline devices) and to send the test in DICOM format to an external PACS system (request DICOM Conformance Statements for further information).
Muse option	The module allows the user to export the test reviewed in ECGWebApp to a shared folder, converting it from SCP format to XMLGE format, which can be imported into a GE Muse system for archiving and/or reviewing.
Philips option	The module allows the test reviewed in ECGWebApp to be exported to a shared folder, converting it from SCP format to XMLPHILIPS format, which can be imported into a Philips system for archiving and/or reviewing.
GDT option	The module allows the user to import a Worklist in GDT format from external systems to ECGWebApp, transferring it to Cardioline electrocardiographs. It also allows the reviewed test to be exported from ECGWebApp to an external system in GDT or GDT+PDF format.
PDF Option	The module allows the reviewed test to be exported in PDF format from ECGWebApp to an external folder (shared folder). It is possible to customise the report (two pages, for resting ECG).
Custom PDF option	The module allows a custom report to be defined (two pages) for each unit, exporting the reviewed test from ECGWebApp to an external folder in PDF format (shared folder).
HL7 Option	The module allows a Worklist in HL7 format to be imported from external systems to ECGWebApp, transferring it to Cardioline electrocardiographs. It also enables the reviewed test to be exported in PDF or SCP format from ECGWebApp to an external system in HL7 protocol. The enabling module does not include customisations (request HL7 Conformance Statements for further details).
Mail Notification option	Upon receiving a test in ECGWebApp, the notification module allows an email – containing the link to connect directly to the reviewing page of the received test – to be forwarded to a preset recipient. It is possible to match the sending address to the unit and, depending on the type of test received (paediatric/adult), two separate e-mails can be set up.
Philips ECG Import ECG Option	The Philips ECG import module allows the user to import resting ECGWebApp ECGs in "Sierra XML" format produced by compatible Philips electrocardiographs, which can export the exams to a network folder. The import module operates in the background, without the need for user intervention, which will find the exams exported to ECGWebApp complete with biographical information, traces, measurements and automatic diagnosis if required. NOTE: The module does not allow the sending of working lists to the connected electrocardiographs. Required ECGWebApp software (with Import Philips option).
Mortara ECG Import Options	The Mortara ECG Import module allows the user to import resting ECGs in "Mortara XML" format into ECGWebApp. The module works in conjunction with EliLink software and allows ELI electrocardiographs equipped with a network interface (LAN or Wi-Fi) to send exams directly into ECGWebApp. The import module operates in the background, without the need for user intervention, which will find the exams exported to ECGWebApp complete with biographical information, traces, measurements and possible automatic diagnosis.

	NOTE: The module does not allow sending working lists to connected electrocardiographs. Required software ECGWebApp (with Import Mortara option) and Mortara EliLink v4
Physio-Control ECG import option	The Physio-Control ECG import module allows the user to import into the ECGWebApp ECG at rest in "HL7 to ECG" format (also known as FDA XML) produced by Physio-Control compatible monitors/defibrillators. The module converts and imports ECG files transferred to a network folder via the Physio-Control LIFENET system. The import module operates in the background, without the need for any intervention of the users, who will find the exams exported to ECGWebApp complete with biographical information, traces, measurements and possible automatic diagnosis. NOTE: The module does not allow sending work lists to connected devices. Required software ECGWebApp (with Import Physio option) and LIFENET System (with option to export 12-lead in HL7 format to ECG).
Digital Remote Signature Option	The module allows tests reviewed in ECGWebApp to be digitally signed by using the qualified electronic signature service, complying with Regulation (EU) 910/2014 (elDAS), supplied by Certification Authority Namirial SPA. The digital signature procedure is based on two-factor authentication: the user who has a digital certificate must enter the password assigned to them and an OTP code obtained by a suitable smartphone App, or by a physical token. The digital signature system requires installation of the Software SWS (SignWebServices) package on a virtual machine. The SWS server's task is to interface with the HSM (Hardware Security Module) system that is located at the data centre of the Certification Authority. SWS requires the customer to have a server infrastructure able to execute virtual machines. Alternatively, Cardioline can assist the customer in finding the server solution that is best suited to the volume of data to be managed.

Data security and protection

Transmission protocol	Configurable encrypted protocol (https)
Access	Access with authentication (user name and password) Possibility of authentication via Active Directory™
Logging (recording of errors)	▪ Timestamp ▪ Severity level info, debug, warn, error ▪ Class ▪ Message ▪ Error (if available)
Auditing	Audit trail saved in the database, for tests: ▪ Username ▪ IP address ▪ Resource ▪ Action ▪ Resource ID ▪ Timestamp ▪ Message ▪ Unit

***note:** for Cubeholter Web data protection and safety criteria (required with the Holter function), please refer to the Cardioline Cubeholter Web software data sheet.

Regulations and Safety

Classification according to MDD 93/42/EEC

Class	Class IIa
Rationale	Rule 10 annex IX Directive 93/42/EEC and its amendments
Notified Body	TUV (1936)

GDPR Compliance (General Data Protection Regulation)

Access control	Through the use of username and password to access the software. The system administrator can manage: ▪ password complexity ▪ password expiration ▪ inactive session timeout ▪ account lockout on number of failed login attempts
Data at rest protection	Through the use of the encryption system TDE (Transparent Data Encryption) by SQL Server Enterprise.
Audit trail	Through logging of the transactions on system objects (tests, patient data, etc.).
Patient data removal (right to be forgotten)	Option of deleting all the data concerning an individual patient.
Portability	Option of individually exporting all the tests of a patient to transfer them

Classification according to FDA

Classification	Exempt from approval

Classification according to IEC 62304 – Software

Class of risk	B

Performance (Resting 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)	1353629/R

Applicable Standards

EN ISO 15223-1	Medical devices - Symbols to be used for labels, labelling and information to be provided of the medical devices - Part 1: General requirements
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

Product codes

Available versions

81019560-05	ECGWebApp 1-5 (1-5 Devices and Unlimited users)
81019560-10	ECGWebApp 6-10 (6-10 Devices and Unlimited users)
81019560-20	ECGWebApp 11-20 (11-20 Devices and Unlimited users)
81019560-30	ECGWebApp 21-30 (21-30 Devices and Unlimited users)
81019560-WL	ECGWebApp Unlimited (Unlimited Devices and Users)
81019560-FL	ECGWebApp Full (Unlimited & ECGWebApp Options)