



AMPS LLC
Analyzing Medical Parameters for Solutions

Technical Document
AMPS-TD-RD-SM-Electra_320 v01

TITLE

Electra_320 System Manual

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1. Hardware/Software Overview

Minimal hardware requirements

- 32bit (x86) or 64bit (x64) 2Ghz Processor
- 4 Gigabytes (GB) of RAM, 8 GB or higher is recommended
- 100 megabytes (MB) of available hard disk space

Minimal display requirements

- Screen resolution of 1080p (Full HD, 1920x1080); resolution of 1440p (WQHD, 2560x1440) or higher is recommended

Operating System required (one of the following):

- Windows 7
- Windows 8.1
- Windows 10
- Windows Server 2008 R2
- Windows Server 2012 R2
- Windows Server 2016

2. Logical Security

No security features are required for this application.

3. Application Interfaces or API

The system can be used as standalone or as a command-line application.

Refer to the User Manual for details on standalone usage.

Here follows the list of command-line flags that can be visualized by typing "CER-S.exe -?" in the command prompt.

3.1. Command-line options

- "h" ["--hide"] : hide program Graphical interface
- "--saveSession" : Automatically Save Session file
- Input options
 - "-i" ["--input"] : Path to input Continuous ECG Recording file
 - "-d" ["--demographics"] : Path to INI file containing demographics values to be added.
- Lead Modifier options
 - "--hideLeadFail" : Hide Lead Fail segments
 - "--remove4Leads" : Remove leads III, aVR, aVL, aVF
 - "--remove3Leads" : Remove leads aVR, aVL, aVF
 - "--reconstructLimbLeads" : Reconstruct limb leads
 - "--reconstructCxLeads" : Reconstruct CL, CR, CF leads
- Timepoints input options (aECG Generator module)
 - "--tpInputFile" : Path to Timepoint windows file
 - "--tpFormat" : Timepoint windows file format

- Allowed timepoint values are:
- 0: absolute date/time, time in the first column (format HH:MM:SS), date in the second column (format dd/mm/yyyy), separated by ";"
 - 1: relative time, single column (format +/-HH:MM:SS), the additional parameter "Dosing time" is needed
- "--tpDosingTime" : Value of dosing time (reference time) related to relative timepoints. Allowed format is yyyyymmddHHMMSS
 - "--tpWindowSize" : Length in seconds of timepoint window. Default value is zero
 - "--obsWindowSize" : Length in seconds of observation window. Default value is zero
 - "--removeAnnotOutTPW" : Remove annotations outside TimePoint Windows
 - "--removeAnnotOutTPWandObsWnd" : Remove annotations outside TimePoint Windows and Observation Window
- Analysis Windows options (aECG Generator module)
 - "--AnalysisWindowsPath" : Path to input folder containing annotated ECG analysis windows, in aECG FDA HL7 XML v.1 format (multiple values allowed for this flag)
 - "--recurseAW" : recurse in the Analysis Windows folder. Default is FALSE
 - Protocol Events input options (aECG Generator module)
 - "--peInputFile" : Path to Protocol Events file.
 - "--peFormat" : Protocol Events file format.

Allowed time values are:

 - 0: absolute date/time, time in the first column (format HH:MM:SS), date in the second column (format dd/mm/yyyy), separated by ";"
 - 1: relative time, single column (format +/-HH:MM:SS), the additional parameter "Dosing time" is needed
 - "--peDosingTime" : Value of dosing time (reference time) related to relative protocol events. Allowed format is yyyyymmddHHMMSS
 - FDA HL7 Holter Output options (aECG Generator module)
 - "--outputFDAHL7Folder" : Path to output folder for continuous ECG record files in aECG FDA HL7 XML v. 2 format.
 - "--outputFDAHL7suffix" : Suffix to add to output filename

The folder must not contain a file with the same filename as the concatenation of the input record filename and the suffix, otherwise the file will not be outputted.
 - Beat Detection options (Beat Detector module)
 - "--analyzeBeat" : Run Beat Detection Analysis
 - "--BeatSetting" : Path to Beat Detection Setting INI file to be used (if not set, the default options will be used)
 - Multiday Detection options (Long Analysis module)
 - "--analyzeBeatLong" : Run Multiday Detection Analysis
 - "--BeatSettingLong" : Path to Multiday Detection Setting INI file to be used (if not set, the default options will be used)
 - Rhythm analysis options (Rhythm Analysis module)
 - "--analyzeRhythm" : Run Rhythm Analysis

- "--RhythmSetting" : Path to Rhythm Analysis Setting INI file (if not set, the default options will be used)
- Beats Measures options: (Beat Measure module)
 - "--runQT" : Run Beat Measures Analysis
 - "--QTSetting" : Path to Beat Measures Setting INI file (if not set, the default options will be used)
 - "--exportQTMeasures" : Path to output folder for Beat Measure CSV table
- Table options (Continuous ECG Viewer & Rhythm & Beat Editor modules)
 - "--exportTable" : Path to beats and rhythms Table file in CSV format
 - "--tableSettings" : Path to Table Setting INI file (if not set, the default options will be used)
- Templates generation options: (Template Generator module)
 - "--generateTemplates" : Run Templates Generation
 - "--BeatSetting" : Path to Templates Generator Setting INI file (is the one used for the beat detection)
- Trigger Jitter options: (Trigger Jitter module)
 - "--triggerJitter" : Run Trigger Jitter
 - "--TJSetting" : Path to Trigger Jitter Setting INI file. (If not set, default settings will be used)
- HRV analysis options: (HRV module)
 - "--exportHRV" : Path to HRV output CSV file
- Report options: (Report module)
 - "--printReport" : Print report to the provided PDF file path
 - "--ReportSetting" : Path to Report Setting INI file (mandatory)
- Output options:
 - "-o" [--output] : Full path to output record file
 - "-y" [--outputType] : Output record type, refer to section 3.1.1 for details
 - "--outputSamplingRate" : Output sampling rate [50 - 1000 Hz], default being the same sampling rate as the input recording
 - "--outputResolution" : Output amplitude resolution [40 - 1000 count/mV], default being the same amplitude resolution as the input recording
 - "--fltFilter" : Enable filtering of ECG when saving
 - "--fltLowPass" : Set Low Pass Butterworth cutoff frequency [10 - 200 Hz], default being 40 Hz
 - "--fltHighPass" : Set High Pass cutoff frequency [0.01 - 5 Hz], default being 0.01 Hz
 - "--fltNotch1" : Set first notch filter cutoff frequency [25 - 100 Hz], default being 60 Hz
 - "--fltNotch2" : Set second notch filter cutoff frequency [25 - 100 Hz], default being 50 Hz
 - "--fltSequence" : Sequence of filter application, LP, HP, Notch1 and Notch2 respectively, default being "1000" (LP only). E.g. "2130": HP, LP, Notch1

- **CutOutput**
 - "--cutOutput" : Full path to output folder. Files will be generated as SgmentName1_GUID SegmentName2_GUID ...
 - "--cutSegment" : Segment to be cut (multiple values allowed). Format must be SegmentName:Datetimestart:Datetimeend. Datetimestart and Datetimeend must be in the format "YYYYMMDDhhmmss"
- **Plugins options**
 - "-p" ["--plugins"] : Path to folder/s (multiple values allowed) containing the plugins to load. Default is "\Plugins"
 - "-c" ["--recursePlugins"] : Recurse in the plugins folder. Deafulst is FALSE
 - "-t" ["--listPlugins"] : List loaded plugins
- **Help Options**
 - "--version" : Print version message
 - "-?" ["--help"] : Produce help message

3.1.1. Output record types

The list of available record types depends on the output plugins obtained in the current CER-S version:

- **ISHNE**
 - "ISHNE only waveforms": to export the Continuous ECG waveforms in ISHNE ".ecg" file
 - "ISHNE waveform and annotations": to export Continuous ECG waveforms and the beat annotations, in both textual ".txt" and binary ".ann" ISHNE formats
 - "ISHNE ANN annotations": to export only beat annotations, in binary ".ann" ISHNE format
 - "ISHNE TXT annotations": to export beat annotations, in textual ".txt" ISHNE format
- **MIT-WFDB**
 - "WFDB": to export header and waveforms in ".hea" and ".dat"
 - "WFDB Annotations": to export all annotations such as beat labels, rhythm annotations, noise regions in the ".atr" file
- **ACEA XML**
 - "AMPS Continuous ECG Annotation": to export all the analysis results, including beat labels, rhythm annotations, noise regions, template waveform, ECG annotations in AMPS ACEA XML format. Refer to section 3.5 for details on the structure of ACEA XML format.
- **AMPS Compressed format**
 - "AMPS Compress": to export Continuous ECG waveforms in AMPS compressed proprietary format, in ".ACecg" file

3.2. Command-line return codes

Code (string)	Code (int)	Meaning
ERC_NO_OPERATIONS	-3	No operation launched

ERC_UNHANDLED_EXCEPTION_WHILE_WORKING	-2	Unhandled error occurred while performing operations
ERC_UNABLE_TO_OPEN_HOLTER	-1	Invalid holter file/s. Unable to open and read it.
ERC_INVALID_COMMAND_LINE	0	Error present in the command line format
ERC_OK_WORK_EXECUTED	1	Requested operation/s has/have been performed. Check the command shell for details.

3.3. Command-line examples

3.3.1. aECG Generation

```
CER-S.exe -i "F:\Input\ABC.ecg" -h --tpInputFile="F:\tp.csv" --tpFormat=1 --tpWindowSize=300
--outputFDAHL7Folder="F:\Out" --AnalysisWindowsPath="F:\AWs" --tpDosingTime="20020124080000"
```

Generation of continuous ECG recording in aECG FDA HL7 XML v.2, starting from the "ABC.ecg" ISHNE record. The file "tp.csv" contains the timepoints in relative time format, dosing time is 08:00:00, 23 Jan 2002, and the window size is set to 5 minutes. The Analysis Windows are in the "AWs" folder and the output is to be saved in the "Out" folder. CER-S graphical interface will not be displayed.

```
CER-S.exe -i "F:\Input\AB.ecg" -h --tpInputFile="F:\tpA.csv" --tpFormat=0 --tpWindowSize=180
--outputFDAHL7Folder="F:\Out" --AnalysisWindowsPath="F:\AWs" --remove4Leads
--outputFDAHL7suffix="XYZ" --peInputFile="F:\Events.csv" --peFormat=0
```

Generation of continuous ECG recording in aECG FDA HL7 XML v.2, starting from the "AB.ecg" ISHNE record and reducing it to 9 leads: III, aVR, aVL and aVF will be removed. The file "tpA.csv" contains the timepoints in absolute time format and the window size is set to 3 minutes. The file "Events.csv" contains the events list in absolute time format. The Analysis Windows are in the "AWs" folder and the output is to be saved in the "Out" folder, adding the "XYZ" suffix to all files. CER-S graphical interface will not be displayed.

3.3.2. Continuous ECG display with Continuous ECG Viewer or Rhythm & Beat Editor

```
CER-S.exe -i "F:\Input\ABC.ecg"
```

This will start CER- with graphical display with the ABC.ecg ISHNE record loaded. If both Rhythm & Beat Editor and Continuous ECG Viewer, CER-S will be loaded with the last panel displayed.

```
CER-S.exe -i "F:\Input\X.xml"
```

This will start CER-S with graphical display with the "X.xml" aECG FDA HL7 XML v.2 record loaded.

3.3.3. ECG Exportation in ISHNE format

```
CER-S.exe -h -i F:\Input\LekgNN\record.cl -o D:\OUT\AB.txt -y "ISHNE TXT annotations"
```

This will start CER-S without graphical display, loading the Getemed record *LekgNN* and saving only the beat annotations in the ISHNE TXT format, naming the file AB.txt.

```
CER-S.exe -h -i F:\Input\LekgNN\record.cl -o D:\OUT\AB.ecg -y "ISHNE only waveforms"
```

This will start CER-S without graphical display, loading the Getemed record *LekgNN* and saving only the ECG waveforms in ISHNE format, naming the file AB.ecg.

```
CER-S.exe -h -i F:\Input\LekgNN\record.cl -o D:\OUT\AB.ecg -y "ISHNE waveform and annotations"
--outputSamplingRate=1000 --outputResolution=350
```

This will start CER-S processing without graphical display, loading the Getemed record *LekgNN* and saving both waveforms and beat annotations in the ISHNE format. In addition the ISHNE waveforms file will be rescaled (to 350 count/mV) and re-sampled (to 1000 Hz) and also the annotations will be re-sampled. Three files will be generated: AB.ecg (ISHNE waveforms), AB.ann (ISHNE annotations in ANN binary format) and AB.txt (ISHNE annotations in TXT format).

```
CER-S.exe -h -i F:\Input\ABC.ecg -o D:\Out\ABC.ecg -y "ISHNE waveform and annotations"
--outputSamplingRate=500 --outputResolution=350 --fltFilter --fltLowPass=50 --fltHighPass
--fltSequence=1203"
```

This will start CER-S processing without graphical display, loading the ISHNE record *ABC.ecg* and saving both waveforms and beat annotations in the ISHNE format, waveforms and annotations file will be rescaled (to 350 count/mV) and re-sampled (to 500 Hz). Last ECG waveforms will be filtered when saving, applying the low-pass filter, with cut-off frequency set to 50 Hz, the high-pass filter with default cut-off frequency (0.01 Hz) and the second notch filter with default cut-off frequency (50 Hz).

3.3.4. Beat Detection

```
CER-S.exe -i F:\Input\ECG01.ecg --analyzeBeat
```

This will start CER-S with graphical display, loading ECG01 record and performing the ECG Beat Detection/Beat classification.

```
CER-S.exe -i F:\Input\ECG01.ecg --analyzeBeat --BeatSetting="F:\Settings\AnalysisModuleOptions-Test1.ini"
--saveSession -o "F:\Out Folder\ECG01_ann.txt" -y "ISHNE TXT annotations" -h
```

This will start CER-S processing without graphical display, loading ECG01 record, performing the ECG Beat Detection and Beat classification using the Detection settings loaded from "AnalysisModuleOptions-Test1.ini" file. Then the session file will be saved in

the same folder as the loaded record and file "ECG01_ann.txt", containing the Beat annotation in TXT ISHNE format, will be exported in the folder "F:\Out Folder".

3.3.4.1. Beat Detection Settings

The beat detection settings file (.ini), loaded by "--BeatSetting" command line options, shall be structured as following:

[BeatDetection]

AutoMerge=1	enable/disable automerge of templates (0: disabled, 1:enabled, default:1)
ChnlMask=3 *	Beat detection channel mask (leads used for detection). Admitted values between 1 and 4'095, default value: 3 (channel 1 and channel 2)
ChnlMaskTemplates=3 *	Templates channel mask (leads used to generate templates), for a maximum of 8. Admitted values between 1 and 4'080, default: 3 (channel 1 and channel 2)
EndMinute=5760	End minute of the detection, admitted values between 1 and 5'760 (4 days), default 5'760
MinimumNoiseDistance=10000	Minimum distance between noise regions (the noise region having a distance lower than the given parameter will be merged). Default 5'000 millisecond.
NoiseDetectorSensitivity=2	Noise sensitivity level, admitted values 0: low sensitivity, 1: medium, 2: high sensitivity; default: 2.
StartMinute=0	Starting minute of the detection (default 0).

* Channel mask is decimal representation of the binary sequence which defines the selected leads (less significant bit represents channel 1).

Examples:

Bit sequence	Selected channels	Selected leads	Decimal representation
000000000001	1	I	1
000000000011	1 and 2	II, II	3
101000000010	2, 10 and 12	II, V4, V6	2562
010011000101	1, 3, 7, 8 and 11	I, III, V1, V2, V5	1221

3.3.5. Rhythm Analysis

```
CER-S.exe -i F:\Input\ABC1.ecg --analyzeRhythm --saveSession -o F:\Out\ABC1_acea.xml -y "AMPS Continuous ECG Annotation"
```

This will start CER-S with graphical display, loading ABC1.ecg record, loading Beat annotations from the TXT ISHNE file (or a session file if previously saved), performing Rhythm Analysis. Then the session file will be saved in the same folder as the loaded record and file "ABC1_acea.xml", containing Beat annotations, Rhythm annotations and Template information, will be exported in the folder "F:\Out".

```
CER-S.exe -i F:\Input\ABC1.ecg --analyzeBeat --BeatSetting="F:\Settings\AnalysisModuleOptions-Test1.ini"
--analyzeRhythm --RhythmSetting="F:\Settings\ArrhythmiaAnalysisModuleOptions-Test1.ini" --saveSession -o
F:\Out\ABC1_acea.xml -y "AMPS Continuous ECG Annotation" -h
```

This will start CER-S processing without graphical display, loading ABC1.ecg record, performing ECG Beat Detection/Beat classification using the Detection settings loaded from "AnalysisModuleOptions-Test1.ini" file and Rhythm Analysis using the Arrhythmia settings loaded from "ArrhythmiaAnalysisModuleOptions-Test1.ini" file.

Then the session file will be saved in the same folder as the loaded record and file "ABC1_acea.xml", containing Beat annotations, Rhythm annotations and Template information, will be exported in the folder "F:\Out".

3.3.5.1. Rhythm Analysis Settings

The rhythm analysis settings file (.ini), loaded by "--RhythmSetting" command line options, shall be structured as following:

[RhythmAnalysis]

BradyDuration=10000	Minimum length of data in milliseconds to annotate the rhythm as "Bradycardia". Admitted values between 1'000 and 50'000, default: 10'000.
BradyThreshold=45	Upper threshold in bpm to annotate the rhythm as "Bradycardia". Admitted values from 1 to 90, default: 45.
DetectSBeats=1	Enable/disable S beat detection (0: disabled, 1: enabled, default:1)
FindAfibs=1	Enable/disable atrial fibrillation detection (0: disabled, 1: enabled, default:1)
FindRhythms=1	Enable/disable rhythm detection (0: disabled, 1: enabled, default:1)
PauseThreshold=2500	Pause threshold in milliseconds. Allowed values are between 1'000 and 20'000 ms, 2'500 being the default.
PrematureIndex=75	Prematurity index in percentage. Admitted values between 10 and 90, default: 75%.
ProlongedRRInterval=200	Prolonged RR threshold in percentage, admitted values between 10 and 1'000, default 200%.
RRpWindowSize=8	Number of beats used to compute the RRp. Admitted values are 4, 8, 12 and 16 (default: 8)
SupraVentricularTachyThreshold=150	Minimum threshold in bpm to annotate the rhythm as "Supraventricular Tachycardia". Admitted values from 1 to 500, default: 150.
TachyDuration=5000	Minimum length of data in milliseconds to annotate the rhythm as "Tachycardia". Admitted values between 1'000 and 50'000, default: 5'000.
VentricularTachyThreshold=150	Minimum threshold in bpm to annotate the rhythm as "Ventricular Tachycardia". Admitted values from 1 to 500, default: 150.
AfibDuration=30	Minimum length of Atrial fibrillation events, in second. Detected events shorter than the threshold will be ignored. Admitted values from 0 to 3'600 (1 hour), default: 0.

3.3.6. Beat Measures Analysis

```
CER-S.exe -i F:\Input\ABC1.ecg --runQT --saveSession
```

This will start CER-S with graphical display, loading ABC1.ecg record, loading Beat annotations from the TXT ISHNE file (or a session file if previously saved), performing Beats Measures Analysis on the whole Holter. Then the session file will be saved in the same folder as the loaded record.

```
CER-S.exe -i F:\Input\ABC1.ecg --analyzeBeat --BeatSetting="F:\Settings\AnalysisModuleOptions-Test1.ini"
--runQT --saveSession --QTSetting="F:\Settings\BeatToBeatModuleOptions-Test1.ini"
--exportQTMeasures="F:\Outout\ABC1_BeatMeasure.csv" -h
```

This will start CER-S processing without graphical display, loading ABC1.ecg record, performing ECG Beat Detection/Beat classification using the Detection settings loaded from "AnalysisModuleOptions-Test1.ini" file.

Beat Measures Analysis is performed using the Measures settings loaded from "BeatToBeatModuleOptions -Test1.ini" file.

Then the session file will be saved in the same folder as the loaded record and the results of Beat Measures analysis will be outputted in the CSV file "ABC1_BeatMeasure.csv".

3.3.6.1. Beat Measures Settings

The beat measures settings file (.ini), loaded by "--QTSetting" command line options, shall be structured as following:

[QTAnalysisOptions]

ChnlMask=3 *	Beat measures' channel mask (leads to be analyzed). Admitted values between 1 and 4'095, default value: 3 (channel 1 and channel 2).
AnalyzeFamilies=1	Parameter for internal usage. Only admitted value and default: 1.
TimeBinDimension=30	Families' time-bin dimension in seconds. Admitted values from 5 to 300, default being 30.
AnalyzeST=1	Enable/disable ST segment analysis (0: disabled, 1: enabled, default:1)
StartSTEPWindow=80	ST elevation start point after the Qon in milliseconds. Admitted values from 0 to 300, default being 20.
NrOfElevationPoints=1	Number of elevation points. Admitted values from 1 to 20, default being 1.
ElevationPointsInterval=10	Distance in milliseconds between the elevation points. Admitted values from 1 to 20, default being 10.

* Refer to section 3.3.4.1 for details and examples related to "ChnlMask" parameter.

It is possible to set up to 3 periods of analysis, if no period is given, the analysis will be performed on the entire recording.

[Period1]

Start= YYYY-MM-DD hh.mm.ss	Period1 start time. If the time is earlier than the beginning of the recording, the analysis will be performed starting from the beginning of the Continuous ECG.
End= YYYY-MM-DD hh.mm.ss	Period1 end time. If the time is after the end of the recording, the analysis will be performed to the end of the recording.

[Period2]

Start= ...
End= ...

[Period3]

...

3.3.7. Long Analysis - Multiday detection

```
CER-S.exe -i F:\Input\LongRecordABC.ecg --analyzeBeatLong
```

This will start CER-S with graphical display, loading LongRecordABC record and performing the Multiday detection analysis.

```
CER-S.exe -i F:\Input\LongRecordABC.ecg --analyzeBeatLong --saveSession
```

This will start CER-S with graphical display, loading LongRecordABC.ecg record, performing Multiday detection analysis using the default settings and saving the session file in the same folder as the loaded record.

```
CER-S.exe -h -i F:\Input\ABC1.ecg --analyzeBeatLong
--BeatSettingLong="F:\Settings\LongAnalysisModuleOptions-Test1.ini" --saveSession
```

This will start CER-S processing without graphical display, loading ABC1.ecg record, performing Multiday detection analysis using the Multiday detection analysis settings loaded from "LongAnalysisModuleOptions-Test1.ini" file and saving the session file in the same folder as the loaded recording.

3.3.7.1. Long Analysis Settings

[BeatDetection]

ChnlMask=3 *	Beat detection channel mask (leads used for detection). Admitted values between 1 and 4'095, default value: 3 (channel 1 and channel 2)
EndMinute=86400	End minute of the detection, admitted values between 1 and 86'400 (60 days), default 86'400
MinimumNoiseDistance=10000	Minimum distance between noise regions (the noise region having a distance lower than the given parameter will be merged). Default 5'000 millisecond.
NoiseDetectorSensitivity=2	Noise sensitivity level, admitted values 0: low sensitivity, 1: medium, 2: high sensitivity; default: 2.
StartMinute=0	Starting minute of the detection (default 0).

[RhythmAnalysis]

FindAfibs=1	Enable/disable atrial fibrillation detection (0: disabled, 1: enabled, default:1)
FindRhythms=1	Enable/disable rhythm detection (0: disabled, 1: enabled, default:1)
PauseThreshold=2500	Pause threshold in milliseconds. Allowed values are between 1'000 and 20'000 ms, 2'500 being the default.
TachyDuration=5000	Minimum length of data in milliseconds to annotate the rhythm as "Tachycardia". Admitted values between 1'000 and 50'000, default: 5'000.
VentricularTachyThreshold=150	Minimum threshold in bpm to annotate the rhythm as "Ventricular

AfibDuration=30

Tachycardia". Admitted values from 1 to 500, default: 150.

Minimum length of Atrial fibrillation events, in second. Detected events shorter than the threshold will be ignored. Admitted values from 0 to 3'600 (1 hour), default: 0.

* Refer to section 3.3.4.1 for details and examples related to "ChnlMask" parameter.

3.3.8. PDF Report generation

```
CER-S.exe -h -i F:\Input\RecordXY.ecg --printReport="D:\outputReport\ReportRecordXY.pdf"
--ReportSetting="F:\Settings\ReportModuleOptions-Test1.ini"
```

This will start CER-S without graphical display, loading RecordXY record, restoring the analysis previously performed stored in the ACEA session file, and generate the PDF report "ReportRecordXY.pdf" in "D:\outputReport" folder with report settings loaded from "ReportModuleOptions-Test1.ini" file.

Report settings ini file must be passed to CER-S software in order to generate the Report PDF file.

3.3.8.1. PDF Report settings

[Options]

showRRAvrPlot=1	Include the RR average plot (1), allowed values 0, 1.
showExtrema=1	Show extrema of each averaged window in the RR average plot (1), allowed values 0, 1.
showDev=1	Show Standard Deviation of each averaged window in the RR average plot (1), allowed values 0, 1.
showRhythmsPlot=1	Include the Rhythms plot (1), allowed values 0, 1.
showAllRhythms=0	Show all rhythms (1) or only the existing ones (0) in the Rhythms plot, allowed values 0, 1.
RRWindow=10	Window size in minutes for average RR computation, allowed values between 1 and 60.
InitialDirectory=D:/del/tt	Parameter for internal usage in case of stand-alone usage.
AfibList=1	Report all Atrial Fibrillation episodes in Rhythms list.
PauseList=1	Report all Pause episodes in Rhythms list.
VTList=1	Report all episodes of Ventricular Tachycardia in Rhythms list.
SVTList=1	Report all episodes of Supraventricular Tachycardia in Rhythms list.
VRunList=0	Report all Supraventricular Runs in Rhythms list.
SRunList=0	Report all Ventricular Runs in Rhythms list.
Beats and Rhythm Table=1	Hide (0) or include (1) the summary Table.
Selected strip=1	Include manually selected ECG strips (1).
Automatic strip=1	Include automatically selected ECG strips (1).
Templates waveforms (N)=1	Include ECG waveforms of type-N templates (1).
Templates waveforms (V)=1	Include ECG waveforms of type-V templates (1).
Templates waveforms (X)=0	Include ECG waveforms of type-X templates (1).
Templates waveforms (S)=0	Include ECG waveforms of type-S templates (1).

FullDisclosure=1

Include ECG recording full disclosure. Allowed values 0-3. 0: no full disclosure, 1: "1 lead (lead II, 1h per page)", 1: "2 leads (II, V2 - 30 min per page)", 1: "3 lead (II, V2, V5 - 20 min per page)".

[Params]

CenterID=Center for Clinical Research ABCD

Text of center ID to be place as Page header in each page of the Report

Language=0

Language for PDF Report. Allowed values 0-2. 0: English, 1: French, 2: Italian.

3.4. Software settings

All CER-S configuration files are stored in "AMPS/CER-S" subfolder from the User profile folder, typically C:\Users\LoggedUser\AMPS\CER-S.

Here display configuration files can be found and in particular the six .ini configuration files for:

- aECG XML v.2 Generation: "aECGModule.ini" file
- ECG Beat Detection: "AnalysisModuleOptions.ini" file
- Rhythm Analysis: "ArrhythmiaAnalysisModuleOptions.ini" file
- Beat Measures Analysis: "BeatToBeatModuleOptions.ini" file
- Multiday Detection Analysis: "LongAnalysisModuleOptions.ini" file
- Report: "ReportModule.ini" file

aECG XML v.2 Generation configuration is deeply described in section 3.20.2 of the User Manual.

To create customized "AnalysisModuleOptions.ini", "ArrhythmiaAnalysisModuleOptions.ini" and "BeatToBeatModuleOptions.ini", "LongAnalysisModuleOptions.ini" and "ReportModule.ini" files, ini files can be edited directly or the standalone dedicated options dialog shall be used, which will update the .ini file.

Here the reference to the User Manual relates sections: Detection Options (section 3.20.1.1), Analysis Options (section 3.20.2.1) and Beat Measures Options (section 3.21.1). Multiday Analysis Options (section 3.20.3.1)

3.5. Structure of ACEA XML format

The first line is the declaration of the XML:

```
<?xml version="1.0" encoding="utf-8"?>
```

The format is structured on the following way:

<code><acea version=" " fileCreator=" "></code>	acea tag, containing <i>version</i> and <i>fileCreator</i> . - <i>Version</i> : specifies the version of the ACEA /e.g. "ACEA 1.2" - <i>fileCreator</i> : specifies the platform used to create the acea file
<code><Section id=" " name=" " itemCount=" "></code>	Section definition, containing ID, name and itemCount. Id: section ID Name: section name itemCount: specifies the number of item of the section
<code></Section></code>	End of a section
<code></acea></code>	End of the document.

There can be one or more section, at last one for each type, the available section type are:

- Record Information
- Beats
- Rhythm annotations
- Noise annotations

- Templates
- Beats in noise annotations
- Time Points information

Record information section

<Section id="16" name="Record information" itemsCount="">	Section definition, containing ID, name and itemCount. Id: 16 Name: Record Information itemCount: specifies the number of information items
<Info id=" " name=" " value=" " />	Information item: <ul style="list-style-type: none"> - Id : code of the information - Name: name of the information - Value: value of the information The list of available information items is described in sec. 0
</Section>	End of record information section

Information items

The available information items are:

Id	Name	value
25	Sampling Rate	[Hz]
26	Amplitude Resolution [count/mV]	[count/mV]
27	"Date/Time of recording	YYYYMMDDhhmmss.fff*
28	Samples per Lead	Number of samples per lead [units]
29	Leads	Number of leads [units]
30	PatientId	Subject ID [text]
31	Software Name	[text]
32	Software Manufacturer	[text]

* YYYY: year, MM: month, DD: day, hh: hour, mm: minutes, ss: seconds, fff: milliseconds

Beats section

<Section id="11" name="Beats" itemsCount="">	Section definition, containing ID, name and itemCount. Id: 11 Name: Beats itemCount: specifies the number of beat items
<Beat id=" " name=" " pos=" " />	Beat item: <ul style="list-style-type: none"> - <u>id</u> : code of beat type - <u>name</u>: Beat Label (ref to 0 for available labels) - <u>pos</u>: position in samples from the beginning of the holter
<Info id=" " name=" " value=" " />	Beat information items (this can be not present) The list of available information items is described in sec. 0
</Beat>	End of beat item
</Section>	End of beat section

Beat Name

The available beats are:

Id	Name	Meaning
101	N	Normal
102	V	Ventricular Beat
103	S	Supraventricular Beat
104	C	Calibration Pulse
105	B	Bundle Branch Block
106	P	Pacemaker
107	E	Ventricular Escape
108	F	Fusion Beat
100	U	Unknown Beat
109	X	Artefact *

* X is not a beat

Beat Information items

The available information items are:

Id	Name	value
21	Template Id	Id of the belonging template
22	RR	RR value [ms]
23	RRp	RRp (RR mean) value [ms]

Rhythm annotations section

<Section id="12" name="Rhythm annotations" itemCount="">	Section definition, containing ID, name and itemCount. Id: 12 Name: Rhythm annotations itemCount: specifies the number of rhythm items
<Rhythm id="" name="" start="" end="" />	Rhythm item: <ul style="list-style-type: none"> - id: code of the rhythm annotation - name: Rhythm Name - start: annotation's start sample - end: annotation's end sample Ref to 0 for available rhythms' Id an names
<Info id="20" name="" value="" />	Rhythm information items (this can be not present) The list of available information items is described in sec. 0
</Rhythm>	End of rhythm item
</Section>	End of rhythm section

Rhythm Annotations

The available beat names are:

Id	Name
200	Atrial Fibrillation
201	Bradycardia
202	Pause
203	Prolonged RR Interval
204	Supraventricular Tachycardia
205	Isolated Supraventricular Beat
206	Supraventricular Couplet
207	Supraventricular Run
208	Supraventricular Bigeminy
209	Supraventricular Trigeminy
210	Atrial Flutter
211	Ventricular Tachycardia
212	Isolated Ventricular Beat
213	Ventricular Couplet
214	Ventricular Run
215	Ventricular Bigeminy
216	Ventricular Trigeminy
217	ST Depression
218	ST Elevation
219	Atrial Tachycardia
220	First-degree AVB
221	Type1 second-degree AVB
222	Type1 second-degree AVB
223	Third-degree AVB
228	Unknown
229	Ventricular Fibrillation
330	Ventricular Flutter
331	Torsade de Pointes

Rhythm Information items

The available information items are:

Name	value
first RR	RR value of the first RR of the rhythm annotation [ms]
# of Beats	Number of beats belonging to the rhythm annotation
shortest RR	Shortest RR of the rhythm annotation [ms]
longest RR	longest RR of the rhythm annotation [ms]
average RR	RR average of the rhythm annotation [ms]

Noise annotations section

<Section id="13" name="Noise annotations" itemsCount="">	Section definition, containing ID, name and itemCount. Id: 13 Name: Noise annotations itemCount: specifies the number of noise items
<Noise id="301" name="Noise Region" start=" " end=" " />	Noise item: <ul style="list-style-type: none"> - id : 301 - name: Noise Region - start: annotation's start sample - end: annotation's end sample
</Section>	End of rhythm section

Templates section

<Section id="14" name="Templates" itemsCount="">	Section definition, containing ID, name and itemCount. Id: 14 Name: Templates itemCount: specifies the number of template items
<Template templateId=" " beatId=" " beatName=" " beatPos=" " beatsCount=" " sampleRate=" " resolution=" " />	Template item: <ul style="list-style-type: none"> - templateId : Id of the template - beatId: beat Id (template's type Id, Ref to 0) - beatName: beat label (template's type label, Ref to 0) - beatPos: position of the template's caliper (in samples from the beginning of the templates) - beatsCount: number of beats belonging to the templates - sampleRate: sampling rate of the template's waveform [Hz] - resolution: resolution of the templates waveform [count/mV]
<Samples lead=" " count=" " /> SAMPLE1 SAMPLE2 ... SAMPLEN </Samples>	Template's samples item (one for each lead): <ul style="list-style-type: none"> - lead: lead name - count: number of samples • SAMPLE1 SAMPLE2 ... SAMPLEN: sample values
</Template>	End of template item
</Section>	End of template section

Beats in noise annotation section

<Section id="15" name="Beats in noise annotation" itemsCount="">	Section definition, containing ID, name and itemCount. Id: 15 Name: Beats in noise itemCount: specifies the number of beat items
<Beat id=" " name=" " pos=" " />	Beat item: <ul style="list-style-type: none"> - id : code of beat type - name: Beat Label (ref to 0 for available labels) - pos: position in samples from the beginning of the holter
<Info id=" " name=" " value=" " />	Beat information items (this can be not present) The list of available information items is described in sec. 0
</Beat>	End of beat item
</Section>	End of beats under noise annotatin section

This section contains all the beats which are contained in a noise region.

Time Points information section

<Section id="17" name="Time Points information" itemsCount="">	Section definition, containing ID, name and itemCount. Id: 17 Name: Time Points information itemCount: specifies the number timepoints
< TimePointWindow TPWtime=" " dTPWduration=" " Id=" " VisitCode=" " ObsWndDuration=" " />	Timepoint item: <ul style="list-style-type: none"> - TPWtime: time point window date/time (e.g. 2010-Oct-22 07:15:52) - dTPWduration: duration in seconds of the time point window - Id: unique identification number - VisitCode: text describing the visit - ObsWndDuration: duration in seconds of the observation window
</Section>	End of Time Points information section

Protocol Events information section

<Section id="18" name="Protocol Events information" itemCount="">	Section definition, containing ID, name and itemCount. Id: 18 Name: Protocol Events information itemCount: specifies the number Protocol events
< ProtocolEvent time=" " label=" " Id=" " >	Event item: - <u>time</u> : date/time (e.g. 2010-Oct-22 07:15:52) of the protocol event - <u>label</u> : text label of the event - <u>Id</u> : unique identification number
</Section>	End of Protocol Events information section

Families section

<Section id="20" name="Families" itemCount="">	Section definition, containing ID, name and itemCount. Id: 20 Name: Families itemCount: specifies the number "families groups"
<FamiliesGroup groupName=" " familyType=" " binDimension="" periodStart="" periodEnd="">	Family group item: - <u>groupName</u> : name of the group - <u>familyType</u> : 0: Time-Bin family, 1: single beat (beat-to-beat analysis) - <u>binDimension</u> : length of the bin (in ms) in case of time-bin family - <u>periodStart</u> *: analysis period start sample - <u>periodEnd</u> *: analysis period end sample *If periodStart and periodEnd are "-1", the families group analysis regards the entire recording
<Family pos="" RRglobal="">	Family items of each Families Group. Family item: - <u>pos</u> : position in samples from the beginning of the record - <u>RRglobal</u> : value in "ms" of the RRglobal of the family (-9 means invalid value)
<Measure name="" value="" unit="" lead="">	Measure items of each Family. Measure Item: - <u>name</u> : measure's name - <u>value</u> : value of the measure - <u>unit</u> : measure's unit - <u>lead</u> : measure's channel
</Family>	End of family item
</ FamiliesGroup >	End of FamilyGroup item
</Section>	End of families section

Time domain Heart Rate Variability (HRV) information section

<Section id="99" name=" TimeDomainHRV" itemCount="">	Section definition, containing ID, name and itemCount. Id: 99 Name: Time Domain HRV itemCount: specifies the HRV parameters
<Info id="1" name="RRMean" value="1004.59 ms"/> <Info id="101" name="SDNN" value="181.36 ms"/> <Info id="102" name="RMSSD" value="153.48 ms"/> <Info id="103" name="PNN50" value="57.20 %"/>	HRV parameters: - Id 100 – RRMean in ms - Id 101 – SDNN in ms - Id 102 – RMSSD in ms - Id 103 – PNN50 in %
</Section>	End of Time Domain HRV section

Example of ACEA XML File

```
<?xml version="1.0" encoding="utf-8"?>
<acea version="ACEA 1.1" fileCreator="AMPS Continuous ECG Annotation for PluginSystem v2.0.0">
  <Section id="16" name="Record information" itemCount="6">
    <Info id="25" name="Sampling Rate" value="180"/>
    <Info id="26" name="Amplitude Resolution [count/mV]" value="160"/>
    <Info id="27" name="Date/Time of recording" value="20101022071449.000"/>
    <Info id="28" name="Samples Per Lead" value="226800"/>
    <Info id="29" name="Leads" value="12"/>
    <Info id="30" name="PatientId" value="1044"/>
  </Section>
  <Section id="11" name="Beats" itemCount="1199">
    <Beat id="101" name="N" pos="168">
      <Info id="21" name="TemplatId" value="3"/>
    </Beat>
  </Section>
</acea>
```

```
</Beat>
<Beat id="101" name="N" pos="370">
    <Info id="21" name="TemplateId" value="4"/>
    <Info id="22" name="RR" value="1122 ms"/>
    <Info id="23" name="RRp" value="1060 ms"/>
</Beat>
<Beat id="101" name="N" pos="558">
    <Info id="21" name="TemplateId" value="3"/>
    <Info id="22" name="RR" value="1044 ms"/>
    <Info id="23" name="RRp" value="1059 ms"/>
</Beat>
<Beat id="102" name="V" pos="654">
    <Info id="21" name="TemplateId" value="12"/>
    <Info id="22" name="RR" value="504 ms"/>
    <Info id="23" name="RRp" value="1059 ms"/>
</Beat>
.....
</Section>
<Section id="12" name="Rhythm annotations" itemsCount="3">
    <Rhythm id="212" name="Isolated Ventricular Beat" start="135342" end="135432">
        <Info id="20" name="first RR" value="933"/>
    </Rhythm>
    <Rhythm id="212" name="Isolated Ventricular Beat" start="136220" end="136310">
        <Info id="20" name="first RR" value="722"/>
    </Rhythm>
    <Rhythm id="212" name="Isolated Ventricular Beat" start="160020" end="160110">
        <Info id="20" name="first RR" value="1011"/>
    </Rhythm>
</Section>
<Section id="13" name="Noise annotations" itemsCount="1">
    <Noise id="301" name="Noise region" start="1170" end="1358"/>
</Section>
<Section id="13" name="Noise annotations" itemsCount="1">
    <Noise id="301" name="Noise region" start="1170" end="1358"/>
</Section>
<Section id="14" name="Templates" itemsCount="10">
    <Template templateId="3" beatId="101" beatName="N" beatPos="72" beatsCount="884" sampleRate="180" resolution="160">
        <Samples lead="I" count="216">-7 ...7 -7 -7 -7 -7 -7 -7 -7 -7 -7 -7 </Samples>
        <Samples lead="II" count="216">-10 -11 -11 -11 -11 -11 ... -12 -11 -11 </Samples>
    </Template>
    <Template templateId="4" beatId="101" beatName="N" beatPos="72" beatsCount="306" sampleRate="180" resolution="160">
        <Samples lead="I" count="216">-5 -5 -6 -6 -6 ...6 </Samples>
        <Samples lead="II" count="216">-9 -9 -9 -10 ... -11 -11 -12 -11 -11 </Samples>
    </Template>
...
</Section>
<Section id="15" name="Beats in noise annotations" itemsCount="5">
    <Beat id="101" name="N" pos="2416704">
        <Info id="21" name="TemplateId" value="1"/>
        <Info id="22" name="RR" value="632 ms"/>
        <Info id="23" name="RRp" value="684 ms"/>
    </Beat>
    <Beat id="101" name="N" pos="2417020">
        <Info id="21" name="TemplateId" value="1"/>
        <Info id="22" name="RR" value="632 ms"/>
        <Info id="23" name="RRp" value="673 ms"/>
    </Beat>
</Section>
<Section id="17" name="Time Points information" itemsCount="2">
    <TimePointWindow TPWtime="2010-Dec-19 07:07:39" dTPWduration="300" Id="E5A672FB-10C2-4335-9A1D-70B683D1EBE5" VisitCode="" ObsWndDuration="0"/>
    <TimePointWindow TPWtime="2010-Dec-19 07:17:39" dTPWduration="206" Id="8887908E-8515-4215-BAAB-75093081A366" VisitCode="" ObsWndDuration="0"/>
</Section>
<Section id="20" name="Families" itemsCount="1">
    <FamiliesGroup groupName="Time bin" familyType="0" binDimension="30000" periodStart="-1" periodEnd="-1">
        <Family pos="0" RRglobal="1060">
            <Measure name="PR" value="169" unit=" ms" Lead="VM"/>
            <Measure name="QRS" value="94" unit=" ms" Lead="VM"/>
            <Measure name="QT" value="456" unit=" ms" Lead="VM"/>
            <Measure name="JT" value="362" unit=" ms" Lead="VM"/>
            <Measure name="QTp" value="351" unit=" ms" Lead="VM"/>
            <Measure name="TpTe" value="105" unit=" ms" Lead="VM"/>
            <Measure name="JTp" value="257" unit=" ms" Lead="VM"/>
            <Measure name="Pdur" value="117" unit=" ms" Lead="VM"/>
            <Measure name="Tamp" value="748" unit=" uV" Lead="VM"/>
            <Measure name="RR" value="1060" unit=" ms" Lead="VM"/>
            <Measure name="QTcB" value="443" unit=" ms" Lead="VM"/>
            <Measure name="QTcF" value="447" unit=" ms" Lead="VM"/>
            <Measure name="PR" value="172" unit=" ms" Lead="II"/>
            <Measure name="QRS" value="98" unit=" ms" Lead="II"/>
            ...
        </Family>
        <Family pos="30000" RRglobal="1001">
            <Measure name="PR" value="167" unit=" ms" Lead="VM"/>
            <Measure name="QRS" value="94" unit=" ms" Lead="VM"/>
            <Measure name="QT" value="452" unit=" ms" Lead="VM"/>
```

```
        </Family>
        ...
    </FamiliesGroup>
</Section>
<Section id="99" name="TimeDomainHRV" itemCount="4">
    <Info id="100" name="RRMean" value="1004.24 ms"/>
    <Info id="101" name="SDNN" value="181.19 ms"/>
    <Info id="102" name="RMSSD" value="154.5 ms"/>
    <Info id="103" name="PNN50" value="57.34 %"/>
</Section>
</acea>
```

4. Routine System Administration Tasks

None is required.

5. Troubleshooting

A logging facility is included. The log level may be adjusted via command line switches.

6. Backup Arrangements

None is required.

7. Support Provision

For any question or to report issues, please contact AMPS Support using one of the following options:

- write an email to support@amps-llc.com
- call AMPS Support at +1 646 658 3508 / +39 030 9650745
- send a fax to AMPS Support at +39 030 9650572
- write to AMPS Support - AMPS llc – Corso Martiri della Libertà, 40 – 25018 – Montichiari (BS) - Italy