

ECG Excellence

CineECG instructions for use

Code:	ECG-Sales-Doc21
Version:	4.1
Created by:	\${Authors}
Approved by:	\${Reviewers}
Date of publication:	\${Published_date}
Status:	Confidential

ECG Excellence BV
Weijland 38
2415BC, Nieuwerbrug aan den Rijn
The Netherlands
info@ecg-excellence.com
www.ecg-excellence.com



CineECG Services INSTRUCTIONS FOR USE

Last update: March 14 2024

Content

1. Intended use CineECG Services	2
2. Medical Device.....	2
3. Manufacturer.....	3
4. Software version	3
5. CE.....	3
6. Precaution	3
7. Requirements	3
8. Location.....	4
9. CineECG report	4
10. Performance	6
11. In case of.....	6
12. Security	6
13. Further information	6
Appendix: Detailed CineECG report description.....	8

1. Intended use CineECG Services

CineECG Services is software which requires 12-lead ECG data for input and delivers a report containing multiple views of the ECG data as output. CineECG Services processes 12-lead ECG data by relating 12 lead ECG data to the heart anatomy to derive electrical pathway. Both pathways and ECG waveform values are compared with a normal distribution of normal classified ECGs. With the purpose of assisting a licensed health care practitioner in making an assessment for adult persons if the heart ventricular ECG is within a normal range.

CineECG is not intended to monitor vital signs.

2. Medical Device

CineECG Services is a medical device in CE-MDR risk class IIa.





3. Manufacturer

CineECG services has been developed and is produced and delivered by
ECG Excellence BV
Weijland 38
2415BC Nieuwerbrug aan den Rijn
The Netherlands

4. Software version

The current software version of CineECG 2.0.0.67, research only
If you want to communicate regarding CineECG to the manufacturer or other parties please mention this software version number.

CineECG Services is only made available through a cloud based solution. There is only one single version of CineECG active in the market.

Local versions of CineECG can be made available to support research programs & projects. Please contact the manufacturer if you are interested. Research applications of CineECG are outside the scope of the CE-MDR certification and can only be used for research purposes.

5. CE



CineECG services is audited by BSI Group and pending for CE certification. CineECG is not yet CE certified.

6. Precaution

CineECG services provides additional views on 12-lead ECG data. The licensed physician must be trained in reading and interpreting 12 lead ECG standard output. A full diagnosis of the condition of a person should always consider additional characteristics of the person which are not part of the ECG data, such as (but not limited to) medical history, other physical characteristics, genetic information.
The user should not rely on the lack of a suspected finding to rule out other follow-up procedures.

7. Requirements



CineECG Services requires 12-lead resting ECG data presented in a JSON format. 60 seconds length ECG recording optional but CineECG is primed for 10 seconds ECG recording.

The ECG signal quality needs to be sufficient to derive a median beat from the data received in the CineECG system. If the quality of the signal is insufficient in two or more leads the system will only generate a first page (see below). The person or organisation responsible for recording the ECG data is also responsible for the data quality. This includes correctness of leads positioning, conduction quality of electrodes used in the process.

The (physical) gender of the patient must be provided with the JSON formatted data in order to deliver gender personalized outcome.

CineECG does not recognize so-called lead switches.

A licensed and trained medical professional is needed to assess the ECG output in order to recognize lead switches.

8. Location

CineECG services delivers a PDF report based on provided 12 lead ECG data of a person. The report is provided as soon as possible and sent to the user of the service by means of the cloud based solution or by file transfer. There is no requirement regarding the location of the receiver of the CineECG services report.

9. CineECG report

The CineECG report contains 5 pages of which 4 pages contain data which relates to the 12 lead ECG data of a specific person. The final page contains generic information regarding CineECG and provides an explanation on the content of the 4 preceding pages.

Page 1 provides standard 12 lead ECG output (12 lead graphs and a rhythm strip). The page contains data regarding the patient (name, ID, birth date and gender), the recording date/time and a report number.

Page 1 also shows standard 12 lead ECG rhythm parameter values (heart beat, PR, QRS, RR, NN, QT, QTc).

On page 1 percentage bars indicate the level of conformity between the recorded ECG and the bandwidth of a normal distribution of CineECG electrical pathways (PathECG) and ECG amplitudes (WaveECG) derived from the analysis of +6000 classified normal ECGs.

There are percentage bars in each category (PathECG and

WaveECG) for the QRS, ST, T-wave and P-wave.

On Page 1 an exclamation mark is shown if the level of conformity with normal requires further attention by the medical professional using CineECG. Next to the exclamation mark two circular dots (not filled means normal) indicate if the attention should be focused on the Ventricular activation, Atria activation or both.

If CineECG cannot derive a median beat only page 1 and page 5 will be made available for the user. There will be no exclamation mark visible.

If CineECG cannot determine a median P-wave only pages 1-3 and 5 will be made available for the user. If an exclamation mark is shown this only relates to the ventricle analysis.

On the top of page 1 information is provided regarding the patient (Name, ID, gender, age) if this information is included in the received ECG data file. The report also shows the date/time the ECG data was recorded when this information is included in the received ECG data file.

Page 2: Report of heart performance in the ventricles. Page 2 shows median beat for all leads (left side column). Page 2 also shows 2 dimensional graphs of both median beat, amplitudes compared to mean normal (in case of no deviations these lines are flat) and mean activation path through ventricular chambers (2 graphs both comparing recorded data against normal). First PathECG graph shows electrical pathway in 3 heart axis in a field identified by orange lines representing the normal bandwidth. Second graph shows deviations against mean normal (in case of no deviations these lines are flat).

In the right side column the percentage bars for QRS, ST and T-wave are shown again.

Page 3: Report of heart performance in the ventricles. Page shows two 2 dimensional graphs of mean activation flow (CineECG) through the ventricles. Colors indicate: i) amplitude against normal superposed on the PathECG vector in the top row (traffic light colors) and ii) PathECG trajectory in the ventricles related to the torso anatomy. In all views the mean normal trajectory is shown as a white line.

Page 4: Report of heart performance in the atria. Page 4 shows median beat for all leads but with focus on the P wave (left side column). The signals are ordered according the Cabrera system. Page 4 also shows PathECG in both heart axis in a field identified by orange lines representing the normal bandwidth. The 2 dimensional visualization shows the PathECG trajectory in atria related to the torso anatomy. In the 2 dimensional view the normal trajectory is shown as a white line. In the right side top column the P-wave percentage bars for both PathECG and WaveECG are shown.

Page 5: provides information regarding the page content, the intended use of CineECG, more details regarding the heart models used and provides CE MDR required label information. This page is always made available to the users when CineECG generates a report.

More detailed information on the CineECG in the appendix.

10. Performance

CineECG has been validated to make a distinction between normal and abnormal 12-lead ECG performance. If the patient gender is provided in the submitted data CineECG will run a comparison of the recorded data against a gender selected normal distribution of normal healthy ECGs processed in the CineECG methodology.

The CineECG performance results are the following

Gender	QRS			P wave		
	AUC	Sensitivity	Specificity	AUC	Sensitivity	Specificity
Male	87.2	78.2	81.3	65.7	58.9	64.3
Female	87.4	78.6	81.4	66.7	62.0	61.6
Unknown	86.8	77.6	80.7	66.2	58.1	65.6

11. In case of...

In case any serious incident occurs in relation to the device this should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

12. Security

CineECG is available as a cloud based solution only. The manufacturer ensures all measure are taken to avoid, limit and detect unauthorized access to the software.

13. Further information

You can find more information on CineECG and tutorials regarding the use of CineECG on <https://www.cineecg.com>
To contact the manufacture: info@cineecg.com.



Appendix: Detailed CineECG report description

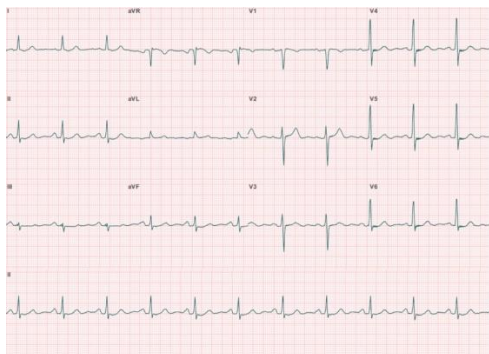
Page 1

Patient name:	Henk	Patient ID:	88_2022.12.21_11.41.37_6125
Date of birth:	september 8, 1935	Gender:	Male

The report shows the patient information as contained in the received ECG data set. The gender indication is used to select a normal distribution category which is used in the CineECG analysis process. Within the selection process three categories are used: Male, Female or Unknown corresponding with the gender indication in the data provided in the ECG data set.

Thu May 25 2023, 21:31:34

The reports shows the data regarding the recording date/time for the ECG as contained within the received ECG data set.



Classic presentation of 4 * 3 12 lead ECG data + rhythm strip of lead II on bottom row. Standard paper speed on 25 mm/sec is used, and 10 mm / mV.

Heart rate:	71 BPM
RR Interval:	843 ± 9 ms
NN Interval:	843 ms
PR Interval:	166 ± 1 ms
P duration:	112 ms
QRS duration:	98 ms
QT Interval:	396 ms
QTc Interval:	431 ms
Low voltage leads:	2

Standard values derived from ECG data by CineECG application. NN interval is the mean interval between beats with the median morphology, thus excluding eventual PVC or disturbances. The QTc is derived using Bazett's formula. Low voltage leads gives the number of leads for which the QRS deflection is less than 0.5 mV in the limb and precordial leads. Two or less is a normal number for low voltage leads.

normal WaveECG (0 - 100%)



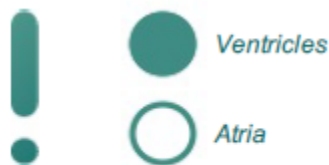
normal PathECG (0 - 100%)



normal WaveECG (0 - 100%)



normal PathECG (0 - 100%)



Look on next pages for more details

Percentage bars indicate the level of conformity between the recorded ECG data and the bandwidth of 'normal' classified ECG's which have been converted to both PathECG and WaveECG normal distributions.

The WaveECG is based on the median beat activation amplitudes.

The PathECG is based on the electrical pathway as derived by the CineECG algorithm

If no median P wave can be created from the ECG data the percentage bar for the P wave is only a thin outlined empty box.

If no median QRS wave can be determined from the ECG data all percentage bars are presented as thin outlined empty boxes.

An exclamation mark is shown when the level of conformity with the normal distribution is below a specific percentage.

The dots indicate if the deviation against normal is within the ventricles, the atria or both.

If all values are within normal range no exclamation mark is shown.

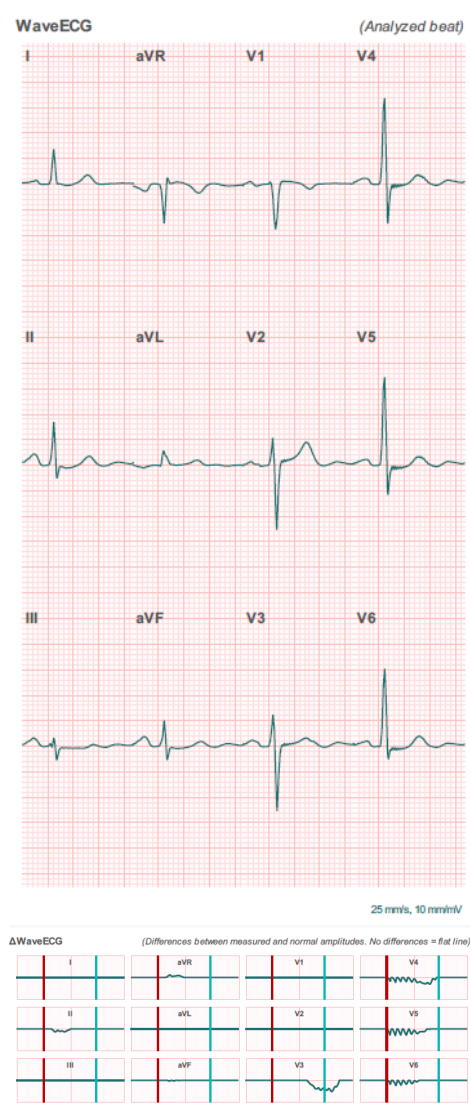
If CineECG cannot determine any median beat only page 1 and page 5 will be made available for the user. There will be no exclamation mark visible nor atrial or ventricular dots.

If CineECG cannot determine a median P-wave only pages 1-3 and 5 will be made available for the user. If an exclamation mark is shown this only relates to the ventricle analysis.

Unable to create CineECG pages due to received data quality

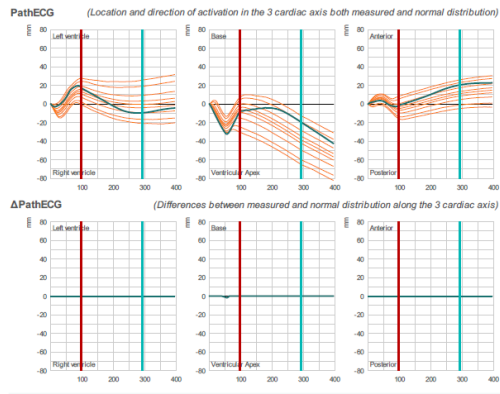
If no CineECG report can be produced due to poor data quality this text is shown

Page 2



The derived median beat is shown on the left side of the page at standard paper speed on 25 mm/sec is used, and 10 mm / mV.

The delta wave map shows the comparison of the median QT beat amplitudes with the mean of the normal distribution of 6000 normal ECG amplitudes (derived from the PBT-XL ECG database containing +23.000 classified ECGs). If the gender of the person is known the CineECG application applies a different distribution per gender. Only when a deviation is recognized the map shows an amplitude. If a recorded values is within normal the line remains horizontal. The vertical red line indicates the end of the QRS, the cyan line the peak of the T-wave. The



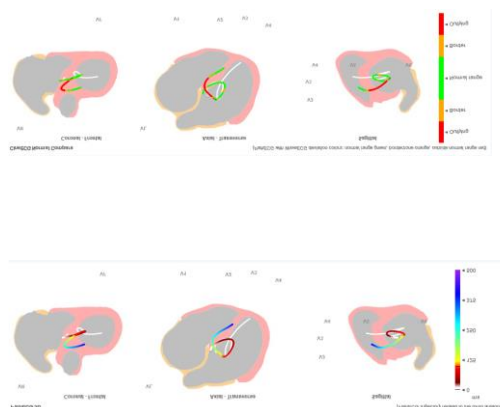
The PathECG is presented in two views: a 3 axis view in 3 graphs each showing a different axis and combining the recorded value and the bandwidth of the normal distribution (orange lines) during the ventricular activation and recovery process. If for instance the recorded value moves to the bottom of the first graph this indicates the activation moves to the right side of the heart. The vertical red line indicates the end of the QRS, the cyan line the peak of the T-wave

The delta map view shows the result of the comparison between the recorded value and the normal distribution. Recorded values within the normal bandwidth result in a horizontal line

Percentage bars of the PathECG and WaveECG are copies of page 1

Page 2 is not made available when CineECG is not able to deriving a median beat from the recorded ECG data.

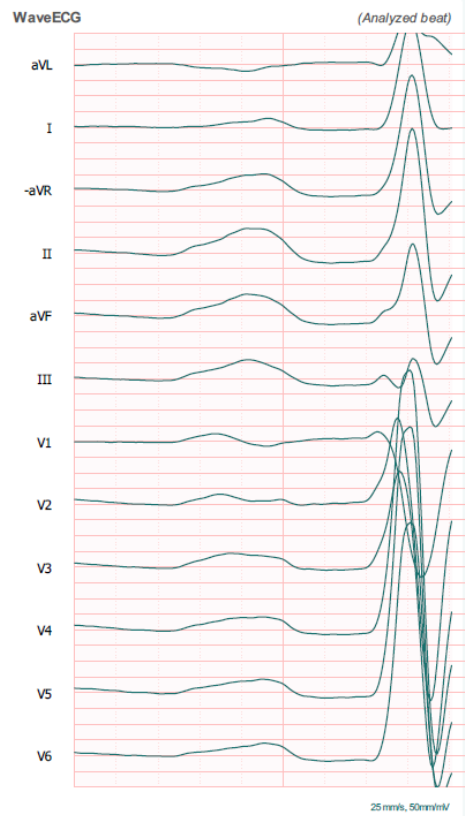
Page 3



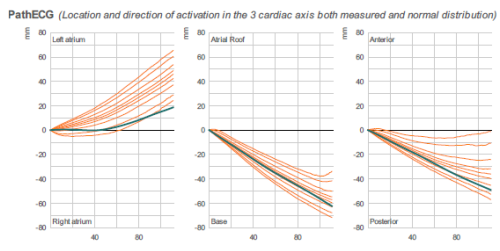
The ventricles PathECG is shown in 3 heart views and in each view the mean normal PathECG is presented as a white line.

The color of the other line indicates the level of conformity with normal of the WaveECG during the activation cycle. The ventricles PathECG is also shown in its relationship with the heart anatomy and the momentum in the activation and recovery process in the ventricles. The colors represent the time in the QRST sequence, with red the QRS, yellow – green the ST segment and blue the T-wave.

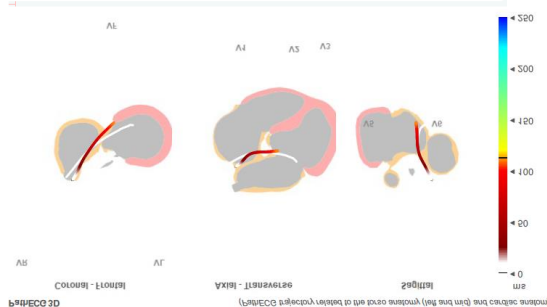
Page 3 is not made available when CineECG is not able to deriving a median beat from the recorded ECG data.



On page 4 again the median beat is shown but with the focus on the P wave segment. The signals are ordered according the Cabrera system. The horizontal lines are drawn at 50 mV/mm



The P wave PathECG is presented in the identical 3 graphs presentation as used on page 2 for the ventricles information. The recorded value is compared against the distribution of normal P waves Pathways



The P wave CineECG trajectory is also shown against a 3 heart model views. Again the normal P wave trajectory is presented as white line. The colors represent the time in the P-wave. A normal P-wave < 120 ms is within the red/orange color range.

Percentage bars on this page are copy of page 1

Page 4 is not made available when the median P wave cannot be derived from the recorded ECG data

Patient name: **Henk** Patient ID: **HE_2022.12.21_11.41.27_8126**

This version of CineECG is a research only beta version. CineECG is a brand of ECG Evaluation BV, The Netherlands. CineECG analysis is based on patented technology (Patents pending). CineECG shows a standard ECG lead in graphic and rhythm strip and subsequent further parameters. In the relation between normal standard CineECG pattern and the CineECG derived from 12 lead ECG data, it is the relation between normal ECG analysis and the modified lead ECG. CineECG uses creative developmental modeling and proprietary algorithms. CineECG results can be influenced by the quality of the patient recorded ECG data, influenced by ECG electrode, and time on the torso, the orientation and rotation of the torso, the quality of the ECG signal recording device, the quality of electrode for torso placement when recording CineECG device with our website www.CineECG.com. CineECG has been developed with the support of the European Commission, the Dutch Heart Foundation and Health Holland.

Explanation to main details:

Page 11 Standard visualization of 12-lead ECG recorded data and rhythm parameter. Added parameters are RR duration (normal to normal) and number of low voltage leads. The percentage bars in the right side column indicate the level of consistency of the recorded data with normal distributions of both electrical parameter and waveform derived from a standard standard ECG. When a percentage bar segment is empty (its border using no value could be detected). The explanation mark (only visible when abnormalities are expected) indicates a certain level of deviation between normal wave and the recorded wave. Fail to the explanation mark the indicator shows that an observation is required regarding the data, waveform or lead. This graph will always be generated.

Page 21 Report of heart performance in the ventricle. Page 2 shows median based for all leads (left side column). Page 3 also shows 2 dimensional graphs of both median based, unipolarities compared to normal (in case of unipolarities there are two axes) and mean activation path through ventricular chamber (2 graphs look comparing recorded data against normal). First graph shows structure pathway in 3 dimensions. Second graph shows deviations against normal (in case of no deviations there lines are flat). Percentage bars indicates the level of consistency with normal for both the amplitude based ECG and the CineECG.

Page 31 Report of heart performance in the atrium. Page shows 2 dimensional graphs of mean activation flow (CineECG) through the ventricles related to the torso anatomy. Color indicate (1) structure aspect normal to top on (right light color) and (2) CineECG aspect to the ventricle in relation to, as all show the normal trajectory is shown as a white line. When the graphics have accurate positions are shown for orientation.

Page 41 Report of heart performance in the torso. Page 4 shows median based for all leads but with the P wave highlighted and QZ condensed (left side column). Page 4 also shows PathECG in both 2D and 3D visualizations. The 2D graph shows the mean activation path through heart as an electrical pathway in 2 dimensions. The 3D visualization shows the PathECG in relation to the torso anatomy in this view the normal trajectory is shown as a white line. Percentage bar indicates the level of consistency with normal for both the amplitude based ECG and the CineECG. The graph underneath provides more detail on the visualization of normal activation.



The final page of the report contains the limitations in using CineECG, provides short introductions to the page content, shows the setup of the heart model views used in the report. The final page also provides information regarding the intended use of CineECG and provides a link to the label page on the cineecg.com website.