

CineECG instructions for use

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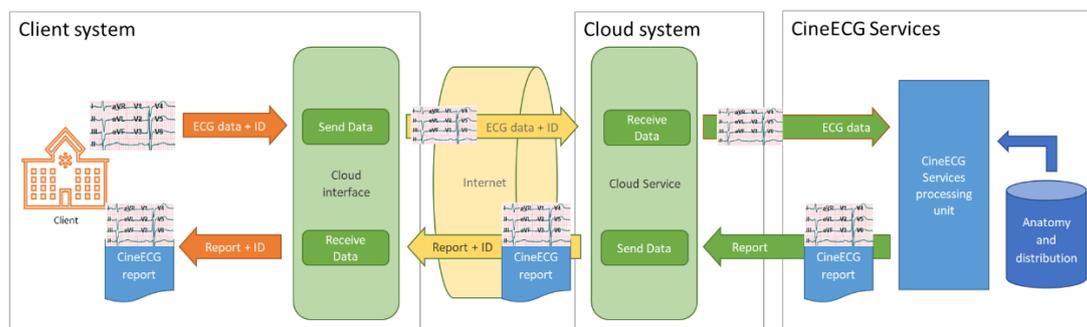
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1 Intended use CineECG Services

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 to 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.

2 General description

CineECG Services is a stand-alone application which has no user interface. CineECG Services should be used in combination with CineECG Connector (UDI: 08720299883420).



CineECG Connector has a client and a cloud/server application (see figure above).

- 1) **Client system sends ECG data:**
 - a. Converts the major industry standard ECG formats (e.g. DICOM waveforms) to the file format for CineECG services.
 - b. Sends this data through a defined protocol to the server side of the CineECG Connector
- 2) **Cloud system receives** the ECG data and send it to CineECG Services which creates a pdf report for the given ECG file.
- 3) **Cloud system sends** CineECG report
- 4) **Client system receives** CineECG report

Via a defined interface (will be supplied by the manufacturer during integration) digital 12 lead resting ECG data will be supplied to CineECG Services. The CineECG Services algorithm will automatically create a report from the received ECG file. CineECG Services is offered to end users through the interaction with the direct commercial partners of the manufacturer (a Business to Business market model) such as 'remote ECG interpretation service providers'.



3 Medical Device

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



4 CE / UDI

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



Basic-UDI: 1178800CineE-01MD
UDI-DI : (01)8720299883413(8012)200170



5 Manufacturer

CineECG services has been developed, produced and delivered by:

ECG Excellence BV
Weijland 38
2415BC
Nieuwerbrug aan den Rijn
The Netherlands



6 Labelling information



CineECG Services
Version 2.0.0.170
Release November 2025



(01)8720299883413(8012)200170



ECG Excellence BV



Weijland 38
2415BC
Nieuwerbrug aan den Rijn
The Netherlands

7 Precautions



The user of CineECG must be a licensed physician, trained in reading and interpreting 12 lead ECG standard output. CineECG does support by classifying the ECG, but does not make the decision for a physician.



CineECG compares ECG's with a database with adult ECG's. Therefore, CineECG should not be used for patients under 18 years old.



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.



The user should not rely on the lack of a suspected finding to rule out other follow-up procedures. 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.



CineECG does only classify ECG waveforms from a median beat. This means it only analyses the most frequent presented waveform beat and thereby does not analyse deviating beats (for instance: PVC's)



If no median beat can be created, only the first page is provided and no waveform analysis is done. This might happen when noisy data is presented to CineECG or with missing leads.

8 Contra indications and residual risks

The use of CineECG Services is not recommended for the analysis of stress test ECG recordings and Holter recordings. CineECG Services is not for use in life-supporting or sustaining systems or ECG monitor and Alarm devices.

8.1 Residual risks

- **Verification of the results is required:** CineECG delivers an outstanding performance in distinction between normal or abnormal QRST activation but there is always the possibility of both false negatives or false positive outcomes. As stated in the intended use CineECG Services has 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. Not in making the overall assessment.
- **Electrode misplacement / lead switches:** CineECG Services does not detect lead switches or misplaced electrodes (i.e. electrodes are not positioned according to the standard 12 lead resting ECG positions, this includes the Mason-Likar lead system), as it cannot automatically correct these lead switches. It is assumed that the intended user is able to detect misplaced electrodes or lead switches. **Mistake in patient gender:** When the gender is incorrectly given the comparison to normal can be wrong. This is however relatively easy to identify, as the gender is also given on the report

9 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. To contact the manufacturer, email to info@cineecg.com.

10 Colour blindness

In case of colour blindness, the report might be easier to interpret when the PDF is converted to a grayscale version. The first page is completely understandable in black and white and comparable to all other currently available ECG prints. The subsequent pages are also easy to interpret, except for a few graphs.

If you are dealing with color blindness and have questions when checking a CineECG report, you can visit www.cineecg.com for more information.

11 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 provided ECG data CineECG will run a comparison of the recorded data against a gender selected normal distribution of normal healthy ECGs.

The CineECG performance results are shown in the table below.

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

12 Indications for use

CineECG services should be used in all situations when an ECG exam is performed or gathered by the intended users including routine examinations and preoperative testing.

13 Requirements

CineECG Services requires 12-lead resting ECG data presented in a JSON format. The recording time CineECG will accept is 10 - 60 seconds length, but Cine ECG is primed for 10 seconds ECG recording. Furthermore, the recorded data must contain signal data for all limb leads and at least 5 of the 6 precordial leads.

CineECG is meant to be used by a licensed physician, trained in reading and interpreting 12 lead ECG standard output. The additional CineECG information in the report should not require additional training for correct interpretation, other than provided in this instruction for use. In case the provided CineECG information is unclear, you can visit www.cineecg.com for more information and backgrounds on CineECG.

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.

14 Response time

CineECG services delivers a PDF report based on provided 12 lead ECG data of a person. The data will be analysed and send back within 5 minutes. In normal situations, the analysis will be done within 10 seconds. Depending on the internet connection, a user might expect to have a report back within 30 seconds.

15 Cyber security

CineECG is a standalone application which runs on a secured server. The application itself has no connection to the internet. Data will be transferred securely via authorized tools, e.g. CineECG Connector. For more information, please contact the manufacturer as described in the next chapter.

16 Further information

You can find more information on CineECG and tutorials regarding the use of CineECG on www.cineecg.com.

If you have any questions about CineECG and need more training for working with CineECG, please contact the manufacturer to book a session for personalized training.

To contact the manufacturer email to info@cineecg.com. When contacting the manufacturer, please refer to the used version of software by mentioning the UDI-DI code, which is described in chapter 5.

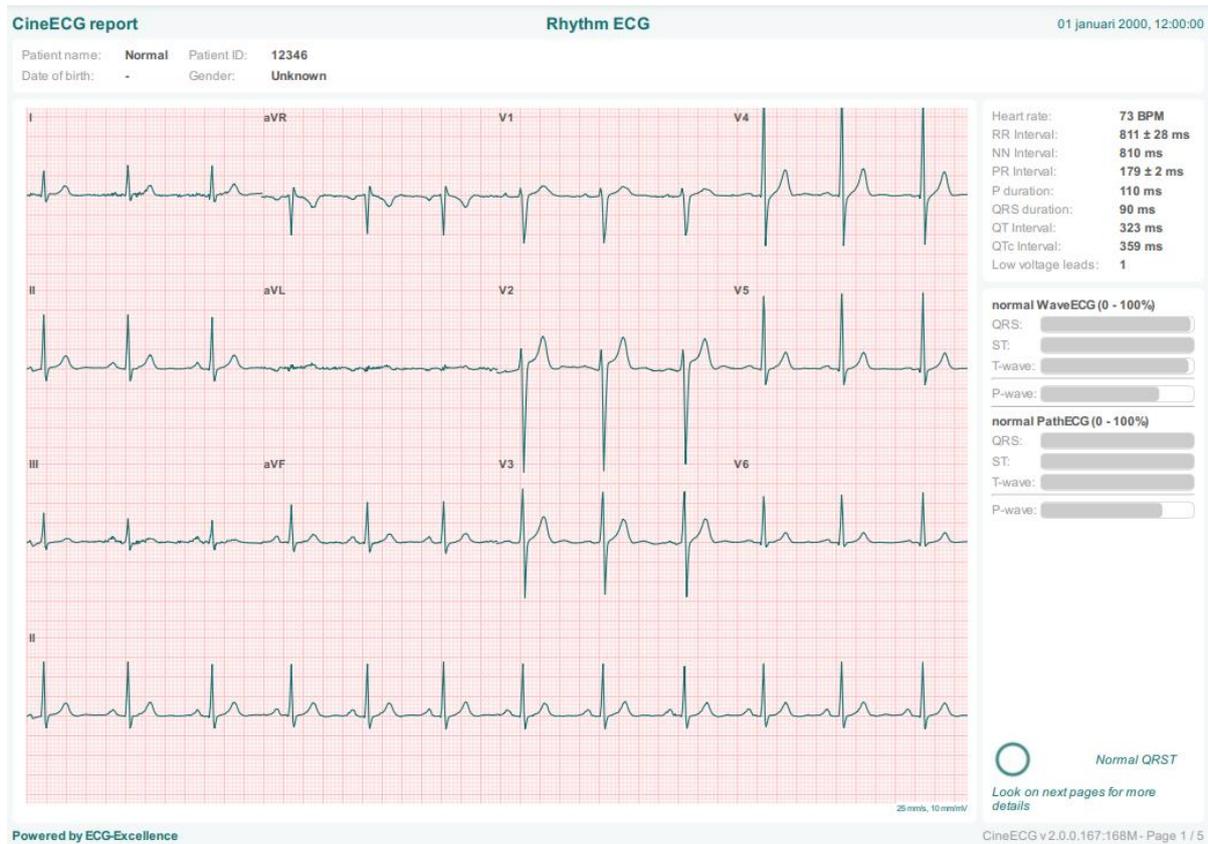
17 CineECG report

17.1 What to expect

CineECG will deliver a generated report after receiving a 12 lead ECG. Normally CineECG returns a 5 page report. However, there are situations conceivable in which only 4 or even 2 pages are returned. The table below explains when which page is generated. The last column explains which pages of this document contain the detailed explanation of the page in question.

Report Page:	Condition to generate	Displayed	Explained at section:
1	10 seconds ECG	Standard 12 lead ECG (4x3)	17.2
2	Median ventricular beat calculated	Normal/abnormal comparison and visualisation	17.3
3	Median ventricular beat calculated	CineECG wave pattern visualisation.	17.4
4	Median atrial and ventricular beat calculated	Normal/abnormal comparison and visualisation	17.5
5	10 seconds ECG	Intended use, precautions and labelling	17.6

17.2 Page 1 of the CineECG report



Page 1 provides a standard 12 lead ECG output (12 lead graphs and a rhythm strip).

The page shows the following items elements:

17.2.1 Patient information

In the Top left corner, patient information like the patient name, ID, birth date and gender.

17.2.2 Recording date

At the top Right corner, the recording date is provided. Please keep in mind that all dates in the report refer to the recording date, not to any date when CineECG has generated a report.

17.2.3 Version number and report number

In the bottom right corner, the used version of CineECG and page number is printed. At the bottom in the middle, a report number is printed.

17.2.4 Recorded ECG signals data

The main information at the first page is the recorded ECG signals grid. This is the standard 3 x 4 + 1 rhythm strip view of the provided ECG signals data.

For each lead a few beats are presented in line with the rhythm strip at the bottom of the grid, which shows the 10 second rhythm for lead II.

Standard paper speed on 25 mm/sec is used, and an amplitude scaling of 10 mm / mV.

17.2.5 ECG measurements

At the right side of the rhythm strip, the standard 12 lead ECG rhythm parameter values are presented. The presented values are :

- heart rate in beats per minute
- RR interval in milliseconds, the average interval between the R peaks, including the standard deviation of this value,
- NN interval in milliseconds, similar to RR interval but only for the beats used to create the median beat, so excluding the interval before and after a PVC for instance.
- PR interval in milliseconds, time between onset P-wave and onset QRS, including the standard deviation of this value,
- P duration in milliseconds
- QRS duration in milliseconds
- QT interval in milliseconds
- QTc interval in milliseconds, corrected QT interval using Bazett's formulae.
- Low voltage leads, the number of leads for which the minimum QRS amplitude is less than 0.5 mV

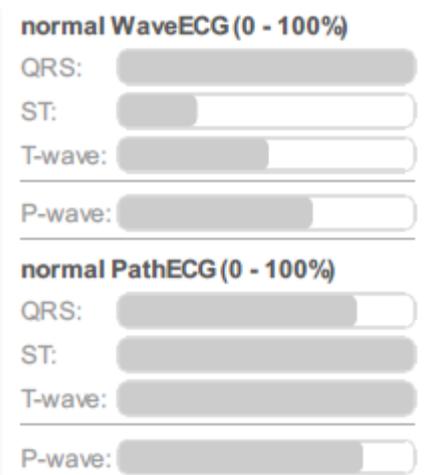
CineECG does not interpret these parameters. Guidance for 'normal' values may be the following table :

¹ Joseph Feher. 5.6 - The Electrocardiogram. Joseph Feher. *Quantitative Human Physiology (Second Edition)*. 2nd. 2012. 537-546. [\[Full Text\]](#).
Joseph Feher. 5.5 - The Cardiac Action Potential. Joseph Feher. *Quantitative Human Physiology (Second Edition) An Introduction*. 2nd. 2012. 528-536. [\[Full Text\]](#).

Heart Rate (resting ECG):	Min 60 bpm and max 90 bpm
RR interval:	Min 670 ms and max 1000 ms
NN interval:	Same range as the RR interval
PR interval:	120 to 200 ms
QT interval:	Max 450 ms
QTc interval:	Max 450 ms
QRS duration:	Max 120 ms
P-wave duration:	Max 120 ms
Low voltage leads number	Maximum 2

17.2.6 Normal distribution

Below the ECG measurements, the presented ECG is compared with the normal distribution. The 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. A solid grey bar is corresponding to 100% within normal range, an empty (white) bar is corresponding to 0% within normal range. There are percentage bars for PathECG and WaveECG for each segment, i.e. QRS, ST, T-wave and P-wave.



17.2.7 Exclamation mark

Below the normal distribution, an exclamation mark can be visualized to indicate a potential deviating recorded ECG from normal ECG. The exclamation mark is shown if the combination of QRST activation/depolarization, so only ventricular segments, for PathECG and WaveECG are indicate as (partly) outside the normal range. If the ventricular values are within normal range no exclamation mark is shown. The combination of percentages at which this occurs have been optimized using a logistic regression model, consequently some of the percentages can be lower than 80% and still result in a normal classification without exclamation mark.

The exclamation mark does not appear when abnormal activations in the atria are found, due to low performance values (see chapter 12).

Next to the exclamation mark, a circular dot (not filled means within normal range) indicate if the ventricular activation and / or recovery (QRST segments) is outside the normal range.



Analysis classified as normal. Analysis classified as abnormal.



17.2.8 Unable to create CineECG pages due to received data quality

If CineECG cannot determine any median beat only page 1 and page 4 will be made available for the user. There will be no exclamation mark visible nor a ventricular dot.

If CineECG cannot determine a median P-wave only pages 1-2 and 4 will be made available for the user.

If no CineECG report can be produced due to poor data quality, the green text below is shown.

Unable to create CineECG pages due to received data quality

17.3 Page 2 of the CineECG report



Page 2 shows information of the electrical waveform and path in the ventricles. Page 2 is only made available when CineECG is able to derive a median beat from the recorded ECG data.

17.3.1 Normal distribution

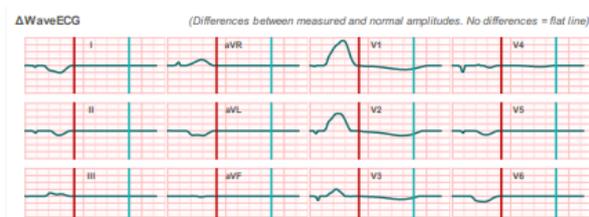
On this page, the normal distribution is shown in two graphs. The normal distribution describes a distribution bandwidth derived from 6000 normal ECG amplitudes (derived from the PBT-XL ECG database containing +23.000 classified ECGs).

If the gender of the person is known the CineECG application applies the distribution for the given gender, otherwise the generic/unknown gender is used.

17.3.2 Median beat view

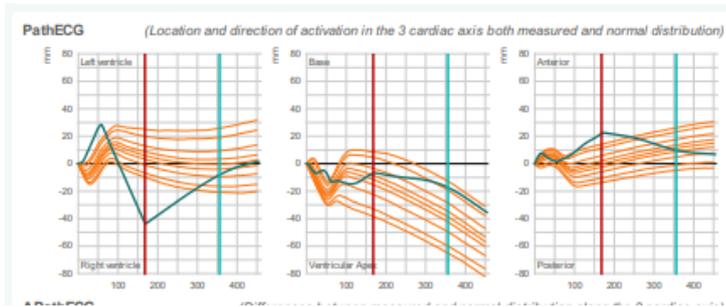
The median beat view displays a 3x4 view for all leads.

17.3.3 Delta Wave ECG



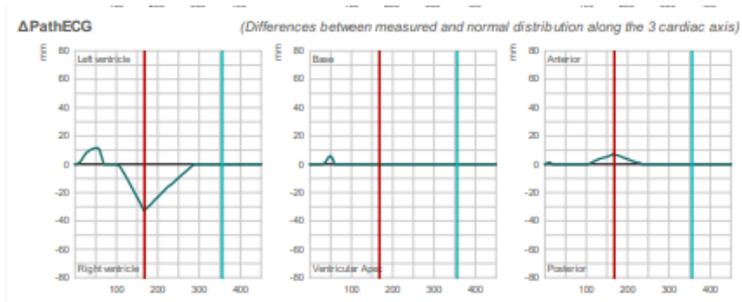
The first graph on the right side of the page provides the Delta Wave ECG. If the line in this graph is zero, the ECG is within normal range. If the line is deviating, the ECG waveform is (partly) outside the normal range. In this case the line value shows the direction (positive or negative) where the PathECG is abnormal.

17.3.4 2d Path ECG



On the right side, the second graph describes the calculated Path ECG in 2D. By displaying 3 graphs, the PathECG through the heart can be inspected. The dark green line represents the calculated PathECG of the analyzed ECG. The distribution of the normal database is shown in orange. The percentage normal PathECG can be verified in this view, i.e. the part where the PathECG is within the orange surface. The vertical red line indicates the end of the QRS, the cyan line the peak of the T-wave.

17.3.5 2D PathECG delta map



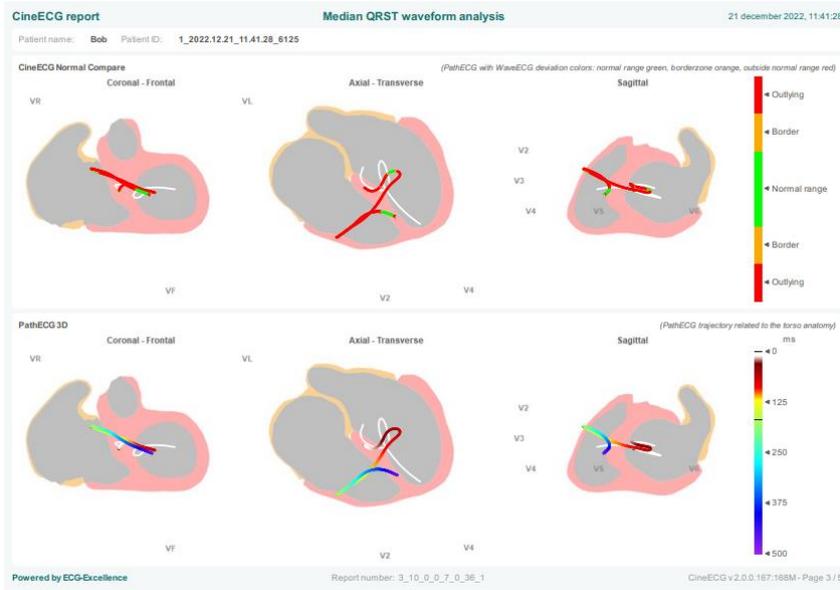
This graph shows the PathECG per cardiac axis outside the normal range, every sample within the normal range is set to zero. If the line is deviating, the PathECG is outside the normal range. In this case the line value shows the direction (positive or negative) the waveform is abnormal.

17.3.6 Percentage bar



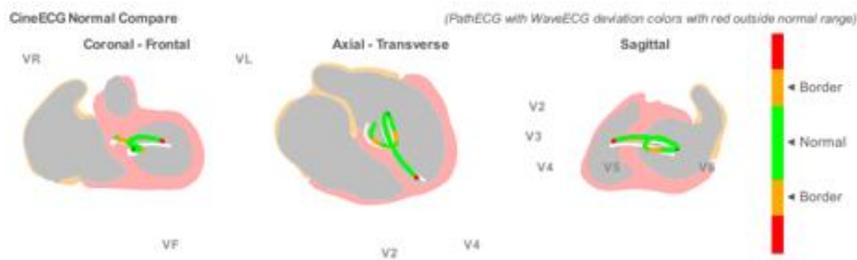
On the far right side of the second page, the percentage bars are presented for the ventricles. These are the same bars as shown on page 1. The description of those bars can be found in chapter 1.1.6.

17.4 Page 3 of the CineECG report

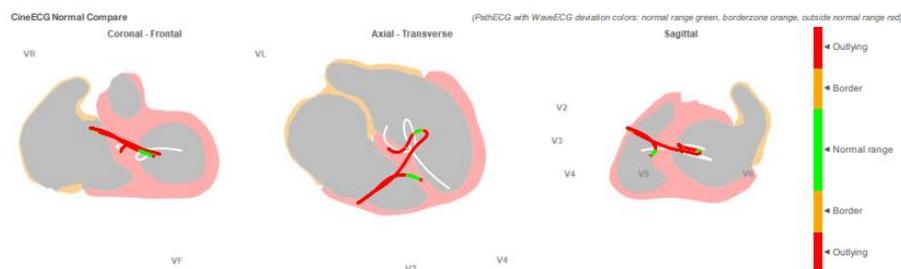


At page 3 of the report, a visual presentation of the CineECG waveform is presented in two graphs. When a median beat of the QRST segment is calculated, page 3 is shown.

17.4.1 3D CineECG Normal Compare



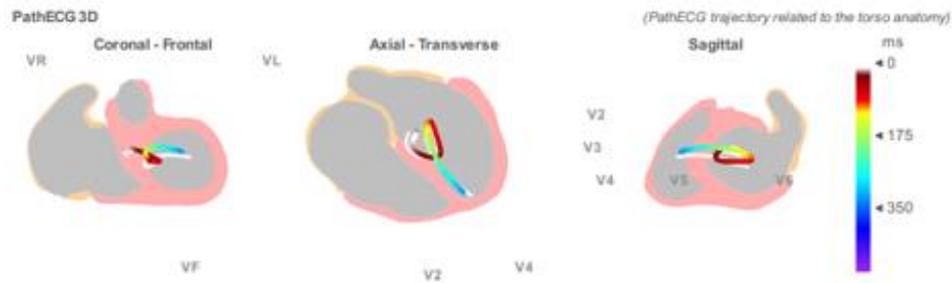
CineECG waveform presentation of a waveform classified as normal



CineECG Waveform classified as abnormal

The first graph, describes the 3D projection of the CineECG through a heart model. If the CineECG is within normal range, the line is projected in green. If the line is not within normal range, the color will be orange or red, where orange describes if it is a borderline situation (outer 10% range).

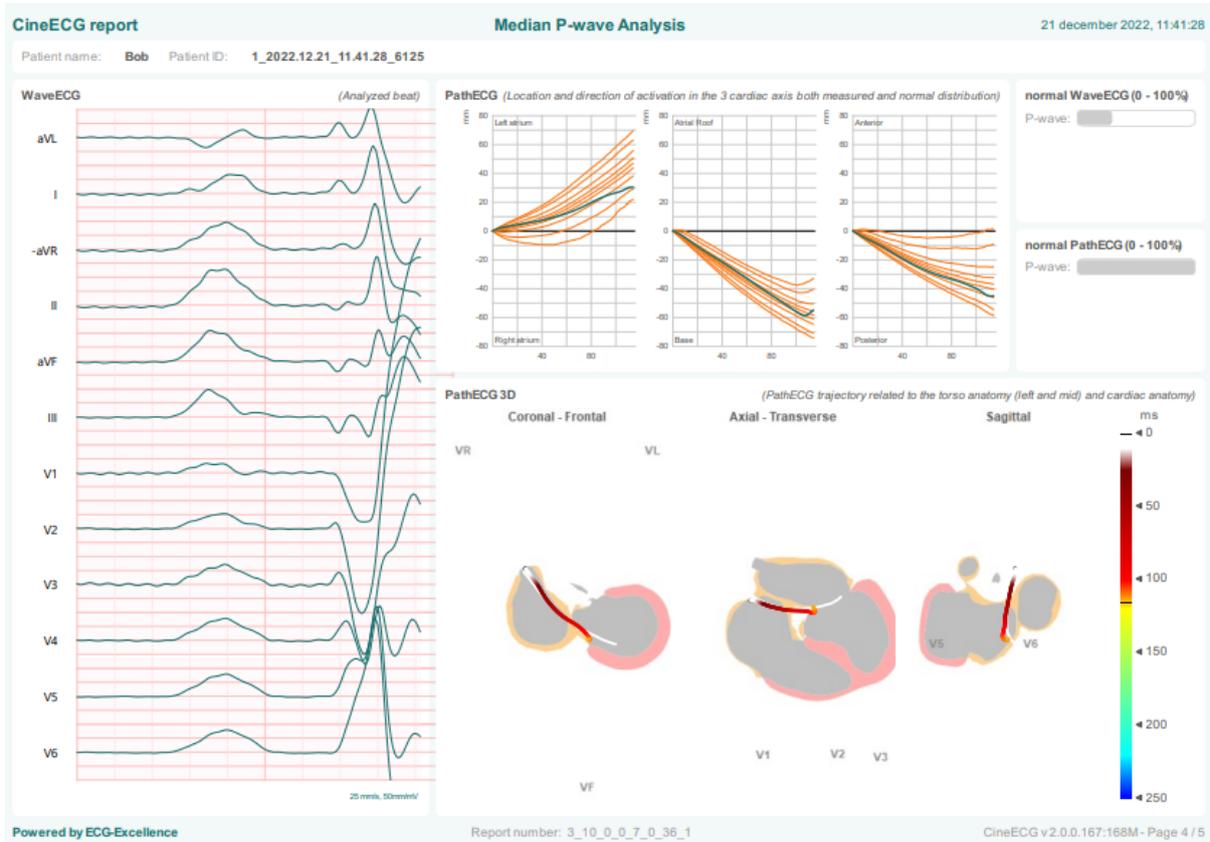
17.4.2 PathECG 3D



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 white/red the QRS, yellow – green the ST segment and blue the T-wave.

The color of the white line shows the median normal of the PathECG of the QRST.

17.5 Page 4 of the CineECG report

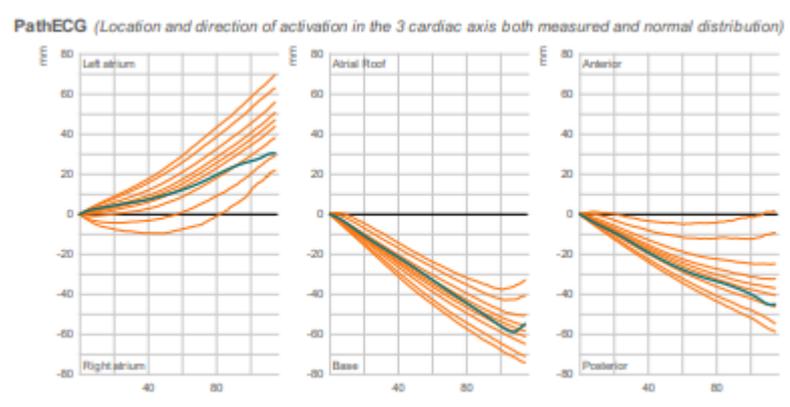


Page 4 shows information of the electrical waveform and path in the atria. Page 4 is not made available when CineECG is not able to derive a median P-wave from the recorded ECG data.

17.5.1 Median beat view

The median beat view displays a 1x12 view for all leads. In this view, the normal distribution per ECG lead is displayed in orange. The percentage normal WaveECG can be verified in this view, i.e. the part where the ECG signal is within the orange surface. The used paper speed is set to 25 mm/s, 50 mV/mm.

17.5.2 2D PathECG view

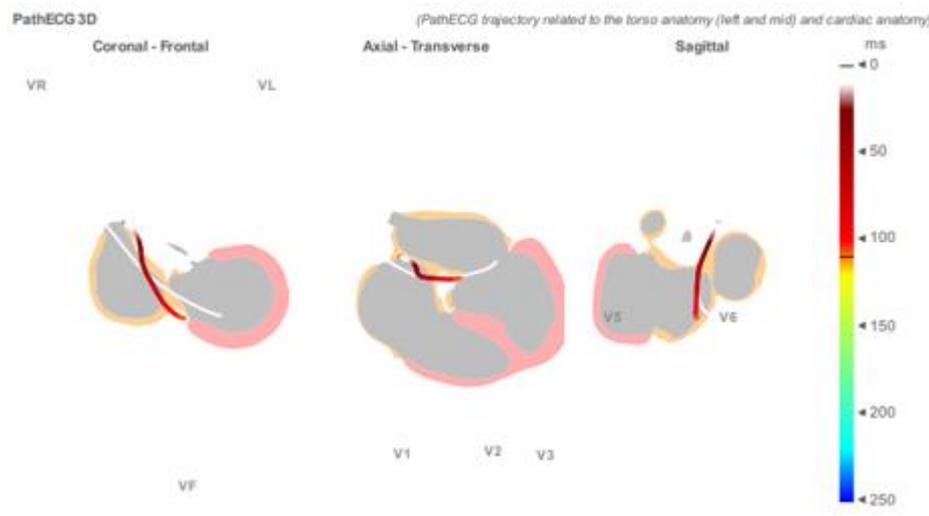


The P wave PathECG is presented in the identical 3 graphs presentation as used on page 2 for the ventricular information. The percentage normal PathECG can be verified in this view, i.e. the part where the PathECG is within the orange surface.

17.5.3 Percentage bar

On the far right side of the page, the percentage bars are presented for the atria. These are the same bars as shown on page 1. The description of those bars can be found in chapter 1.1.6.

17.5.4 PathECG 3D



The 2 dimensional visualization shows the PathECG trajectory in atria related to the heart anatomy. The color of the white line shows the median normal of the PathECG of the P-wave

The colors represent the time in the P-wave. A normal P-wave (< 120 ms) is within the red/orange color range.

17.6 Page 5 of the CineECG report

CineECG report
CineECG additional information
21 december 2022, 11:41:28

CineECG Services is a class IIA medical device according to the European CE-MDR. CineECG Services is not yet certified in any country.

Intended use:

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.

What to expect:

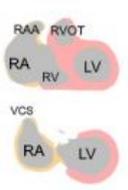
Page	Condition to generate	Contains
1	10 seconds ECG	Standard 12 lead ECG (4x3)
2	Median ventricular beat calculated	Normal/abnormal comparison and visualization
3	Median atrial and ventricular beat calculated	Normal / abnormal comparison and visualization
4	10 seconds ECG	Intended use, precautions and labeling

More information, including instructions for use, can be found at <https://cineecg.com/cineecg-services-label-information> or use the QR-code.

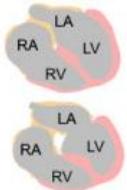
Precautions

- ⚠ The user of CineECG must be a licensed physician, trained in reading and interpreting 12 lead ECG standard output. CineECG does support by classifying the ECG, but does not make the decision for a physician.
- ⚠ CineECG compares ECG's with a database with adult ECG's. Therefore, CineECG should not be used for patients under 18 years old.
- ⚠ 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.
- ⚠ The user should not rely on the lack of a suspected finding to rule out other follow-up procedures. 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.
- ⚠ CineECG does only classify ECG waveforms from a median beat. This means it only analyses the most frequent presented waveform beat and thereby does not analyze single deviating beats (for instance: PVC's)
- ⚠ If no median beat can be created, only the first page is provided and no waveform analysis is done. This might happen with noisy data.
- ⚠ The light-gray text field at the top right of the first page can be used to provide user input related to the ECG. CineECG has no influence on its content.

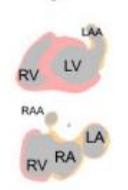
Coronal - Frontal



Axial - Transverse



Sagittal



Manufacturer:
ECG Excellence BV
Weijland 38
2415BC
Nieuwerbrug aan den Rijn
The Netherlands

UDI

MD



UDI-DI: 1178800 Cine E-01MD

Powered by ECG-Excellence
Report number: 3_10_0_0_7_0_36_1
CineECG v 2.0.0.167:168M - Page 5 / 5

Page 5 provides information regarding the page content, the intended use of CineECG and more details regarding the heart models used and CE MDR mandatory label information.

This page is always made available to the users when CineECG generates a pdf report.

17.6.1 Intended use

At the top of the last page, the intended use is described. The intended use describes the purpose for how to use the product and who are the intended users of the product.

17.6.2 What to expect

In the chapter “what to expect”, a 3 column wide table is made for an quick explanation of what is shown on which page. The last column describes the minimum conditions for publishing the described page.

17.6.3 Precautions

In the next section, the precautions for using CineECG are described. Those precautions are the same as described in chapter 8 of this document.

17.6.4 Manufacturer information

At the bottom of the report, above the report number, the address of the manufacturer is described.

17.6.5 Udi code

On the right side of the manufacturer information, the UDI-DI code of CineECG is described. UDI - DI stands for Unique Device Identification code – Device Identification. The UDI-DI code is describing the CineECG Algorithm, where the PDF report is the result of.

17.6.6 Medical Device label

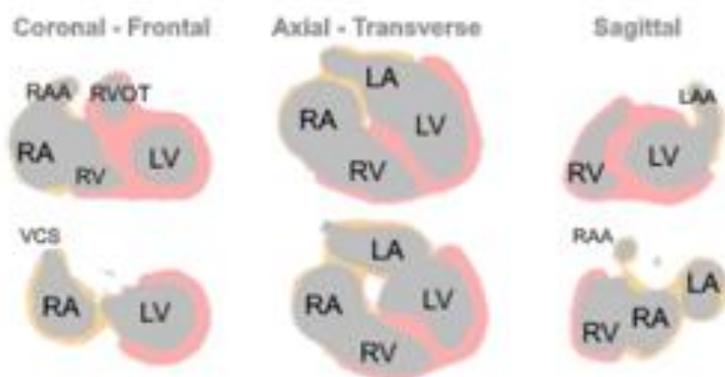
On the right side of the UDI-DI code, the label for describing the report as a Medical Device is shown. More over the Class of this product is described in chapter 4.

17.6.7 Instructions for use QR code

For easy access of the instruction for use and instruction video's, a QR code which refers to the website is included. When scanning this QR code, you will be guided to:

<https://cineecg.com/cineecg-services-label-information>

17.6.8 Description of the chambers within the used heart model of CineECG.



At the left bottom side of the report, the used heart model of page 2 and 3 is described. Because the CineECG activation pattern is described within those models, the description of which chamber is shown would make the interpretation of the activation pattern more difficult. Therefore, at the last page the different views with a description of the chambers are given. An overview of the abbreviations is described below:

RV	Right Ventricle
LV	Left Ventricle
RA	Right Atria
LA	Left Atria
RAA	Right Atrial Appendage
LAA	Left Atrial Appendage
RVOT	Right Ventricle Outflow Tract
VCS	Vena Cava Superior