DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

DZHK-SOP-C-03

12-lead surface electrocardiography at rest (basic ECG)

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Modification notice: Long-term ECG
IT Fact-sheet

This SOP is a translation from the original German SOP and valid without signatures. Printouts are not updated!

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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Full form
aVF	augmented Vector Foot: left foot Þ left arm + right arm (vertical to I)
aVL	augmented Vector Left: left arm Þ right arm + left foot (vertical to II)
aVR	augmented Vector Right: right arm Þ left arm + left foot (vertical to III)
DDD	see point 1.5, cardiac pacemakers
eCRF	electronic Case Report Form
ECG	electrocardiogram
ICS	intercostal space
LAH	left anterior hemiblock
LPH	left posterior hemiblock
LBBB	left bundle branch block
RBBB	right bundle branch block
SDNN	standard deviation of all NN intervals of the global index of heart rate variability
SVES	supraventricular extrasystoles
VES	ventricular extrasystoles
VT	ventricular tachycardia
VVI	see point 1.5, cardiac pacemakers
WG	working group

1.2 OBJECTIVE

On the one hand, the aim of the electrocardiographic examination is to document cardiological diseases such as ischemic heart disease (e.g. previous myocardial infarction) or arrhythmias (e.g. extrasystoles, atrial fibrillation). On the other hand, heart rate variability (HRV) can be studied as an indicator of sympathovagal balance and/or autonomic dysfunction in cases of reduced HRV.

1.3 TARGET GROUP

In principle, it is desirable to have a 12-lead resting ECG (hereafter basic ECG) recording for all subjects included in DZHK-studies available, including repeated ECG recordings, if necessary. Performance and frequency of ECG registration depends on the respective study protocol.

1.3.1 Inclusion Criteria

There are no general inclusion criteria (depending on the respective examination protocol).

1.3.2 Exclusion Criteria

In principle, a 12-lead ECG can be performed for each participating person. Except for potential irritation of the skin around the electrode adhesion sites, the examination itself does not involve any relevant risk.

1.4 APPLICATION AND TASKS

Electrocardiography is a standard cardiac diagnostic procedure. The differences in voltage that occur during cardiac action cause an electrical field in the organism. Changes in the electrical field can be recorded in the form of potential differences. These potential differences give rise to action currents which can be recorded on the body surface. As it is a relatively simple and non-invasive procedure, electrocardiography is widely used in medical practice and clinical routine.

Standard leads according to Einthoven (Leads I, II and III), extremity leads according to Goldberger (Leads aVR, aVL and aVF) and unipolar chest wall leads according to Wilson (Leads V1, V2, V3, V4, V5 and V6) are registered.

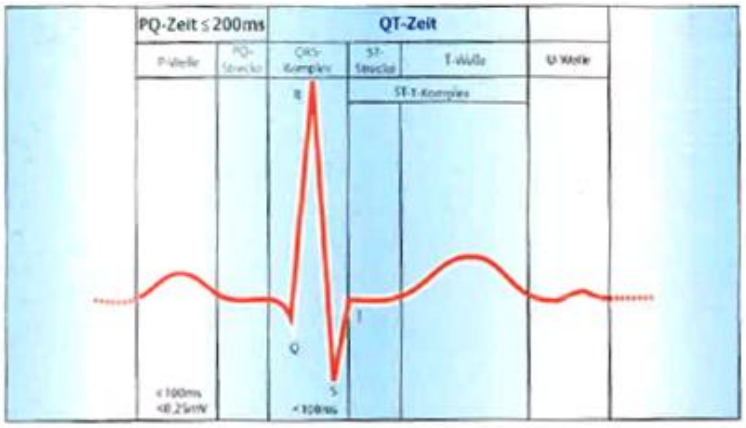


Figure 1: Components of the ECG waveform (Hamm, Willems 2007).

Automated ECG interpretation

All digitized ECGs should potentially be subjected to further processing and raw data extraction.

Results of the ECG examination

The results of the ECG recording are important both for the examined persons and for the study:

- The study examines the relationships between ECG changes and cardiovascular risk factors. In some cases, longitudinal questions involving repeated ECG recordings are also relevant. In those cases, changes in the ECG between baseline and follow-up examination and their possible causes are investigated.

1.5 Terms and Definitions

A brief description of all necessary terminology required to understand the SOP:

Cardiac pacemakers

Different types can be distinguished. For simplification, a uniform nomenclature exists. Here, pacemakers are designated by a three- to five-letter code.

- The first digit indicates the site of stimulation. Here, 'V' stands for ventricle (chamber), 'A' for atrium (atrial), and 'D' for both.
- The second digit indicates the site of signal recording. The abbreviation corresponds to the first digit.
- The third digit indicates the mode. Here, 'I' is for inhibited, meaning suppressed, 'T' is for triggered, meaning triggering, and 'D' is for both modes in atrium and ventricle.

1.6 Correlations to Other Examinations

Mandatory preliminary examination (SOP …):	-
Recommended preliminary examination (SOP …):	-

Preliminary examination to be excluded (SOP):	-
Interference with other parts of the examination:	Ensure a 10-minute rest period before recording the ECG. Thus, there is a relationship to the SOP of stress tests such as the 6-minute walk test (DZHK-SOP-C-04-6MWT).

Mandatory follow-up examination (SOP …):	-
Recommended follow-up examination (SOP …):	-
Follow-up examination to be excluded (SOP):	-

1.7 LEVEL OF QUALITY

This SOP corresponds to quality level 2-3, level 3 includes certification.

DZHK Quality Levels	
Implementation	
Level 1	The examination is performed in accordance with the guidelines of the scientific societies.
Level 2	The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements for ensuring the quality of the implementation and the examiners are defined in the SOP.
Level 3	The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

2 PREREQUISITE OF THE EXAMINATION

Electrocardiography is part of the examination program in observational and clinical studies of the DZHK. In corresponding participants, basic ECGs (10 seconds) should be digitally recorded with appropriate resting ECG systems (see below) and digitally exported. In addition, a rhythm strip can be recorded. The digitized ECG files must be stored in a long-term available and exportable way for later raw data extraction and coding.

ECG registration quality

ECG registration is performed with high quality and standardization. This quality is also particularly dependent on the examiners who perform the ECG derivation. Central influences on the quality of the ECG registration and sources of error are explained below.

2.1 REQUIREMENTS FOR ROOMS/EQUIPMENT

PC with a monitor, keyboard, mouse, printer and printer paper

Examination couch that is at least 60 cm wide

2.2 EQUIPMENT/HARDWARE

Standard within the DZHK is:

CARDIOVIT AT-10 plus (Schiller Medizintechnik GmbH) (ECG software SEMA3 Office)

If necessary, other commercially available devices with digital recording capability, storage and DICOM format export. Alternative device solutions have to be coordinated and certified in advance with the DZHK office and the colleagues of the image data management (BDMS).

Electrode application system, adhesive electrodes (e.g. Blue Sensor Holter Electrode, type VL Ø 68mm), if a suction system cannot be used.

Software for post-processing

DZHK ECG postprocessor (V1.0) (source: DZHK Service4Studies website).

2.3 SPECIAL CLINICAL CONSUMABLES

Electrode spray

Disposable razor

2.4 DOCUMENTS REQUIRED

None.

2.5 INFORMATION REQUIRED

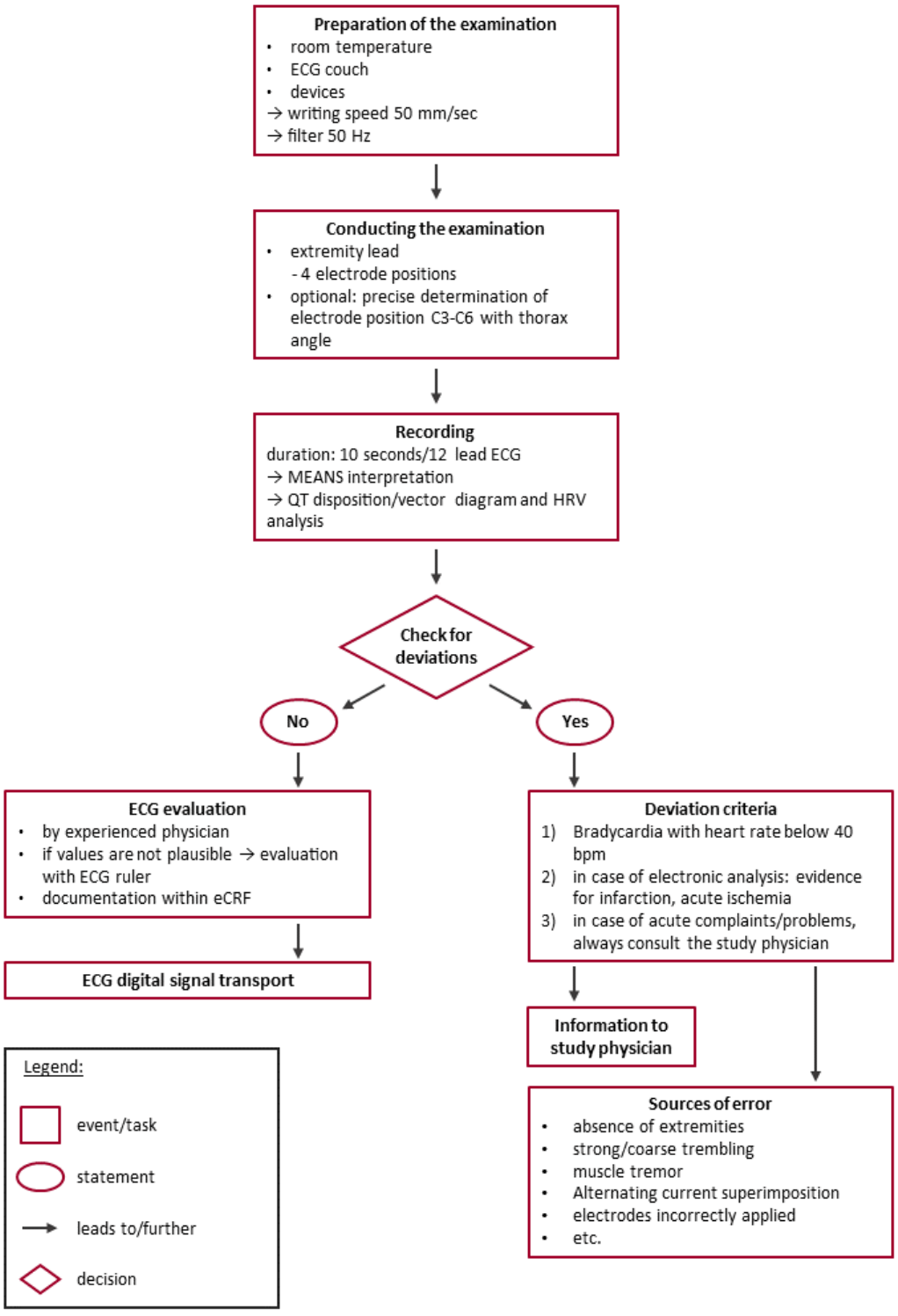
Subject ID (case number or DZHK pseudonym)

2.6 STAFF

The test can be performed by a study nurse after he/she has been instructed in the SOP. The person performing the test should have basic knowledge of ECG recording and analysis in order to be able to determine the quality of the recording and to identify gross deviations from the normal curve (e.g. ventricular flutter, tachycardia).

3 IMPLEMENTATION PROCESS/WORK PROCESS/WORK STEPS

3.1 PROCESS FLOW CHART



3.2 PREPARING FOR THE EXAMINATION

E.g. review of documents etc.

3.2.1 Preparing the work space

The room temperature should be comfortable; for ECG examinations it should be at least 22° C.

Arrangement of the ECG couch and the ECG acquisition system

- The ECG couch should be arranged in such a way that the cable routing between the ECG recorder/suction system and the PC is possible without any problems and without tripping. Make sure that the couch used for the ECG recording is wide enough (at least 60 cm).
- Power supply cables should be located as far away from the ECG couch and the electrode cables as possible.
- The ECG couch should not be set up directly beside power sockets (risk of alternating current interfering with the ECG signal during recording).

3.2.2 Preparing the equipment

1. All devices (PC/laptop, suction electrode system, printer) are switched on and must be ready for operation.
2. The acquisition device must be connected to the PC before the program is started.
3. The workstation is started.
4. The ECG couch is covered with fresh paper/sheet.
5. The electrodes must be in a hygienic state.
6. Paper speed should be set to 50 mm/sec, the filter should be set to 50 Hz. Deviations must be documented in the eCRF in the comments/notes section 1.4.
7. Other filter settings (muscle) are to be set depending on the device available.
8. The height of deflection should be set to 10 mm/mV.

3.2.3 Principles for preparing participants for the examination

The quality of the recorded electrocardiograms depends on the preparation of the participants and the application of the electrodes. The examination room should be at a comfortable temperature (at least 22°C), so that the electrocardiogram is not disturbed by muscle trembling due to freezing. The person's upper body must be undressed; if necessary, remove jewelry or wristwatch. Furthermore, the ankles must be accessible for electrode application (shoes and socks should be removed, if necessary). The person must be positioned comfortably and completely relaxed on a sufficiently wide examination couch. It is recommended to place an intermediate pad or knee roll under the knees to relieve the lower extremities.

If the ECG couch is against a wall, the person's arm should not come into contact with it. During the ECG recording the person's breathing should be as shallow as possible.

The participant should have been lain down resting for at least 10 minutes prior to the ECG recording and should not have straightened up his/her upper body. Furthermore, ensure that the atmosphere in the room is quiet and undisturbed. This is necessary to ensure standardized environmental conditions

and to exclude any factors which might affect the quality of the recording and parameters such as heart rate variability. Psychological stress and/or increased sympathetic tone, e.g. a full bladder, affect the measurement of ECG parameters such as HRV by shifting the balance between the autonomic and the sympathetic nervous system and should be avoided.

3.3 PERFORMING THE EXAMINATION

Technical procedure, ECG leads

Limb Extremity leads

First, a total of 4 electrodes are to be placed at the locations illustrated in figure 2. Place each electrode on the inside of the limbs.

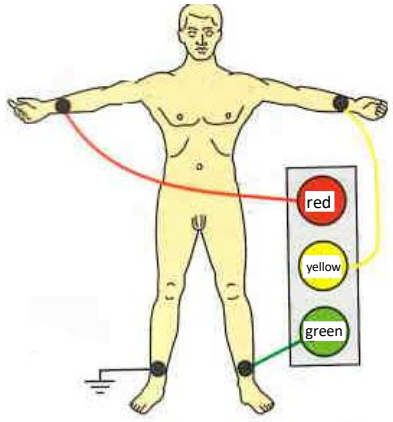


Figure 2: Tapping points for the extremity leads (Hamm, Willems 07).

Cable colors and lead placement sites according to Einthoven and Goldberger:

Sticker colors		**Limb lead sites**
either	**or**	
grey/red	red	R right arm
grey/yellow	yellow	L left arm
grey/green	green	F left leg
grey/black	black	N right leg, neutral

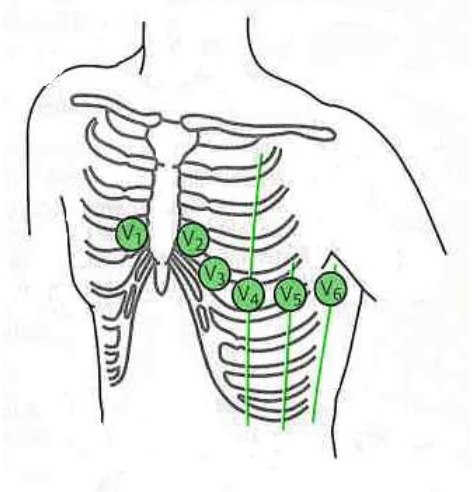


Figure 3: Tapping points for chest wall leads C1 – C6 (Hamm, Willems 07).

Electrode	Colour Code	Position of the Electrodes
C1	white/red	4th ICS, right sternal border
C2	white/yellow	4th ICS, left sternal border
C3	white/green	between C2 and C4
C4	white/brown	5th ICS, left, mid-clavicular line
C5	white/black	left, anterior axillary line
C6	white/purple	left, mid-axillary line, at the same level as C4

Precise determination of electrode positions C1-C6

Correct positioning of the chest wall leads is crucial for proper diagnostic evaluation of the ECG. Deviations of just a few centimeters on the surface of the thorax result in severe changes in the ECG waveform. Therefore, the so-called thoracic angle (DAL square) (see **Figure 4**) can be used to determine the exact electrode positions C1 – C6. The thoracic angle is used to mark the chest wall leads V3-V6. To do this, first set the anterior marker for the 5th intercostal space (E-point): Identify the 5th rib and the 5th intercostal space below V2, follow this position horizontally to the midsternal line and mark this point. This is the E-point. Next, identify the position for V6 by holding the thoracic angle horizontally against the torso with light pressure and marking V6 in the midaxillary line (straight down from the center of the axilla). If breast tissue overlies the V6 region, mark the position on the chest.

The distance between E and 0 on the thoracic angle is measured, e.g. 15.0, the distance between V6 on the middle axillary line and 0 is measured, e.g. 13.0, the difference is calculated, here in the example 2.0 with the longer distance in direction E, this can be read on the thoracic angle and shows the bisector for the position of V4. Depending on the shape of the thorax, the distance to V6 can also be greater, in which case the angle adjustment is shifted

in this direction. Then V3 (directly between V2 and V4) and V5 (directly between V4 and V6) can be marked on the horizontal line at the thorax angle. This will only be available in a small number of studies. Documentation in the eCRF is required.

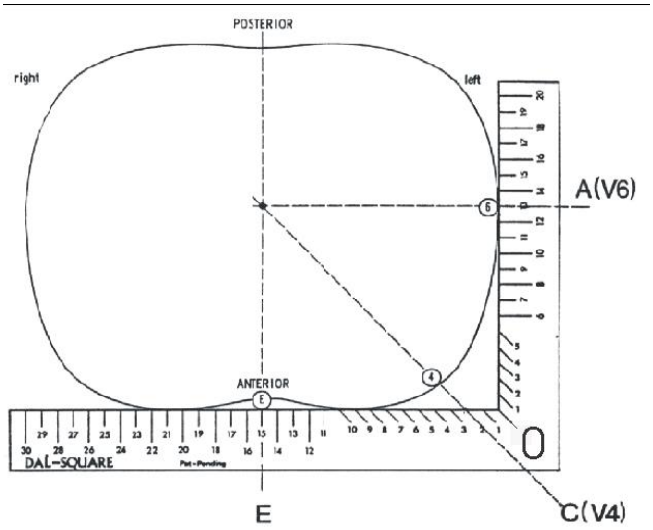


Figure 4: Thoracic angle.

The electrode positions can be marked with a grease pencil before placing the electrodes on the thorax of the person lying on his back before applying the electrodes. Proceed as follows:

(1) Palpate the first intercostal space at the left sternal border with the middle finger of the right hand.
(2) With successive palpation of the following intercostal spaces, count up to the 4th intercostal space.
(3) Place the C2 electrode on the left sternal border of the 4th intercostal space.
(4) Place the C1 electrode on the right sternal border of the 4th intercostal space.
(5) Thoracic angle:
    a. Without thoracic angle: Place electrodes C5 and C6 as shown in the illustration using visual judgement.
    b. With thoracic angle: see above.

For women with large breasts, the electrodes should be placed on the skin under the breast. The ECG system is connected to a PC or laptop. The recording of the ECGs is menu-controlled via a preset program on the computer screen. Record a 12-lead ECG strip for a period of 10 seconds, if possible, with an additional rhythm strip (the length of the strip is up to the physician). In case of insufficient ECG quality, check the condition of the system and the participant (see chapter Technical problems, suboptimal recording quality section) and, after optimizing the conditions, record the ECG again. If the poor recording quality persists, the study physician will be informed. For evaluation of the ECG, analysis software, which includes

diagnostic MEANS interpretation, QT dispersion analysis, vectorcardiogram and heart rate variability, is available (see point 1.4. above). The MEANS software implemented in the systems is based on a development of the Department of Medical Informatics at Erasmus University Rotterdam.

Information for participants

For participating individuals, an additional copy of the 12-lead ECG printout can be made upon request, study specific. Do not communicate any information about the current computer findings yourself without a specific report.

3.4 FOLLOW-UP AND RECORDING THE DATA

3.4.1 ECG evaluation by a physician experienced in ECG interpretation

Generally, the data registered electronically by the ECG system are transferred to the eCRF. In case of clinically implausible values, a manual re-evaluation should be performed using a standard ECG ruler and these values should be entered into the eCRF. If the ECG quality is not sufficient to collect of study-specific ECG parameters, this will be documented in the eCRF. Any peculiarities of the ECG considered to be relevant can be recorded in the comments field. A systematic evaluation is possible to a limited extent.

Check paper speed and filters prior to ECG analysis. Deviations should be documented in the eCRF.

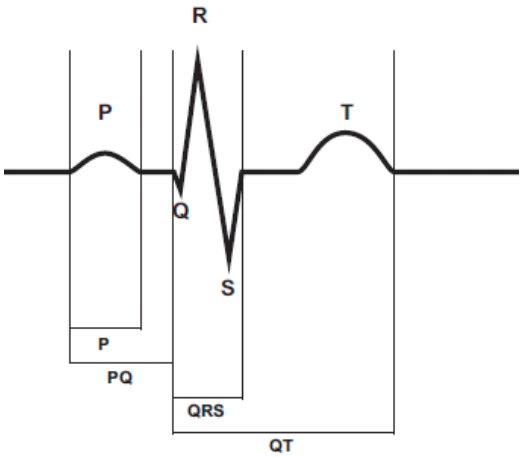


Figure 5: Representation of the intervals required for ECG evaluation.

Guidance on measurement and definition of terms in the eCRF.

Basic ECG

Date of examination (dd.mm.yyyy)

ECG recording quality insufficient

Use of DAL-Square

Comment

Possibility of general comment on ECG

Heart rate (number/minute)

Rhythm

Please specify (free text)

Pacemaker stimulation

Atrial excitation by pacemaker

Ventricular excitation by pacemaker

Other

Please specify (free text)

PQ time

Start: P leaves the isoelectric line. End: start of the Q-wave. In the absence of a Q-wave, the measurement ends at the beginning of the R-score.

Measurement in lead II, otherwise in lead with optimal display.

QRS duration

Start: Q leaves the isoelectric line. End: S meets the isoelectric line. In the absence of a Q wave, measurement begins at the R wave upstroke.

Measured in lead II, otherwise in lead with optimal display.

QT time

Begin: Q leaves the isoelectric line. End: T meets the isoelectric line.

Measured in lead II, otherwise in lead with optimal display. QT time is the measured, not the corrected, QT time.

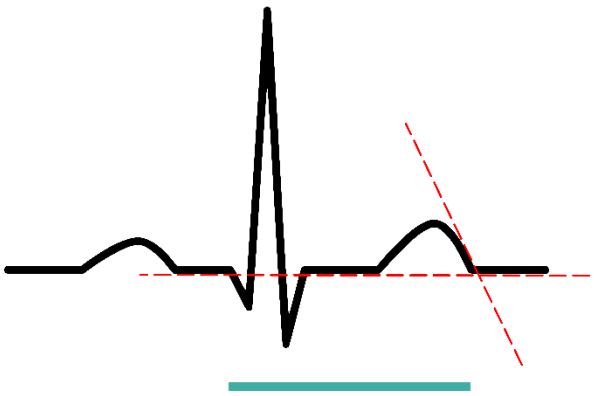


Figure 6: Schematic representation of the tangent method. Illustration with kind permission of Marian Stiehler (https://de.short-qt-syndrome.info/qtc-calculator-self/).

If the T-wave does not intersect the isoelectric line, the tangent method can be used to determine the point of intersection with the isoelectric line as the end of the T-wave (see figure 6).

AV block

1st degree: PR time > 0.20 seconds

2nd degree: Includes type 1 (Wenckebach) and type 2 (Mobitz)

Type 1, Wenckebach: with each cycle, PR time prolongs until a QRS complex fails.

Type 2, Mobitz: intermittent failure of a QRS complex without prior increase in PQ time.

3rd degree: P waves appear independent of the QRS complexes, usually at a higher frequency than the ventricular escape rhythm.

Bundle branch block

Left bundle branch block: Prolongation QRS complex to final negativity motion in V5 or V6 or left pre chest wall leads to ≥0.06 sec.

Incomplete: QRS width ≤0.12 sec.

Complete: QRS width >0.12 sec.

Right bundle branch block:

Prolongation QRS complex final negativity motion in >30 sec.

Incomplete: RSB morphology with QRS complex ≤0.12 sec.

Complete: QRS complex >0.12 sec., wide, notched R-waves in V1-V2, S-waves in V5-V6

Hemiblock

Left anterior hemiblock: over-rotated left type in chest wall leads, deep S-wave in V5-V6, QRS is not widened.

Left posterior hemiblock: right type to over-rotated right type.

In cases of atrial fibrillation or irregular rhythm on the ECG, the intervals are measured three times in total, each time during a different cycle. The mean value is entered.

Discordant T-negativity

ST-segment pathological

Infarct typical (Measured at the J point in at least 2 adjacent leads ≥ 0.25 mV in men ≤ 40 years, ≥ 0.2 mV in men > 40 years, or ≥ 0.15 mV in women in leads v2-v3 or ≥ 0.1 in other leads in the absence of left bundle branch block).

Q waves as an indication of expired infarction

Long-term ECG

Date of examination (dd.mm.yyyy)

Recording duration (hh:mm)

Average heart rate (number/minute)

Minimum heart rate (number/minute)

Maximum heart rate (number/minute)

Number of VES

Number of SVES

VES: Ventricular extrasystoles during the recording period

SVES: Supraventricular extrasystoles during the recording period

Duration of the longest ventricular tachycardia (in seconds)

Frequency of longest ventricular tachycardia (number/minute)

Duration of the fastest ventricular tachycardia (in seconds)

Frequency of fastest ventricular tachycardia (number/minute)

SDNN (in ms)

Standard deviation of the NN intervals (to help RR intervals)

Pauses >3 seconds

Number of pauses >3 seconds

Duration of the longest pause >3 seconds

Time of the longest pause >3 seconds (hh:mm)

3.4.1 Digital storage and export

The ECG raw data are recorded in the standardized DICOM waveform format[1] in BDMS.

Unless the DZHK Schiller devices are used, a validated export process to this format must be ensured and confirmed by the DZHK.

The export of the data takes place for the Schiller devices at the SEMA server. If necessary, the support of your local IT representative is required for this. To do this, log into the Sema server and switch to the patient search (Figure 7). Call up the patient/case there. Select DICOM in the "Format" area. The patient ID and case number are automatically replaced during the upload, so that no extra anonymization is required for the upload to BDMS.

[1] Digital Imaging and Communications in Medicine (DICOM) Supplement 30: Waveform Interchange, DICOM Standards Committee, Working Group 1 - Cardiac and Vascular Information, NEMA 26 September 2000

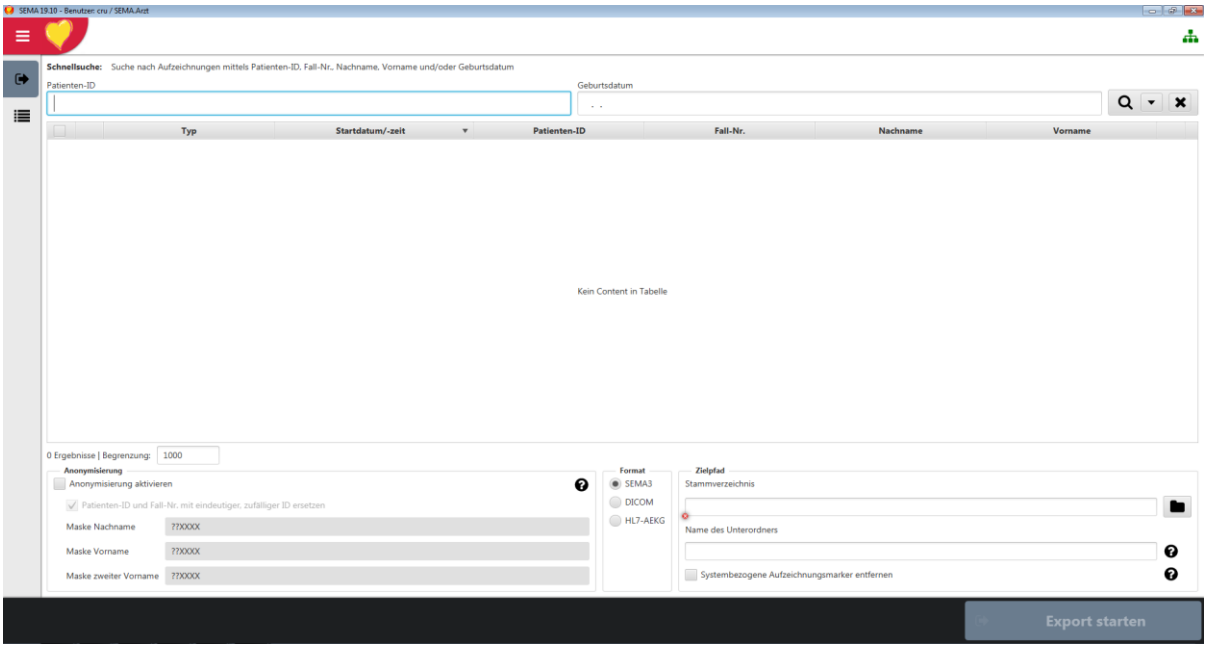


Figure 7: SEMA export menu: the upper part contains functions for patient selection. The lower part contains (from left to right) options for anonymization, data formats and storage locations/destination paths.

The steps in detail:

1. log in to the SEMA server
2. open patient search
3. select patient
4. set format to DICOM
5. select target path on your PC (e.g. C:\temp)
6. specify the name of the subfolder (e.g. SemaExport001)

You should find files (e.g. C:\temp\SemaExport001) with the name sema-XXXXXXXXXXX.dcm in the directory. These files can but do not have to be annotated in the following step for better assignment with the DZHK-EKG postprocessor in order to assign them to the correct study participant for upload. By means of the DZHK ECG post-processor (see study preparation page-BDMS), file contents (e.g. study participant name/ID) can also be annotated to the file name from the DICOM format to

facilitate data assignment. For alternative ECG device solutions, the tool supports other common formats and converts it to the DZHK target format.

To do this, proceed in the following steps:

1. export the data from the ECG device to the input directory (in_Data - **Figure 8**, top right).

   Note: If necessary, rename the file name so that it consists only of letters and numbers and hyphens and underscores. (e.g. sema-221312332.dcm).
2. start the conversion/annotation process with the script run.bat (**Figure 8** – marked with A).
3. transfer of the annotated data (surname_first_name_date_time_original_filename.dcm) from the directory (ex_DICOM_sorted - **Figure 8**, bottom right) to the BDMS (DZHK-SOP-P02).
4. emptying the input directory (in_Data - **Figure 8** top right)
5. deletion of the export directories via the deletion script Reset.bat (**Figure 8** - mark B)

Important: UNC paths (like \dataserver.MusterCenter.de\FolderXY) are not supported, please run the batch file Run and Reset from a drive folder (like C:\FolderXY).

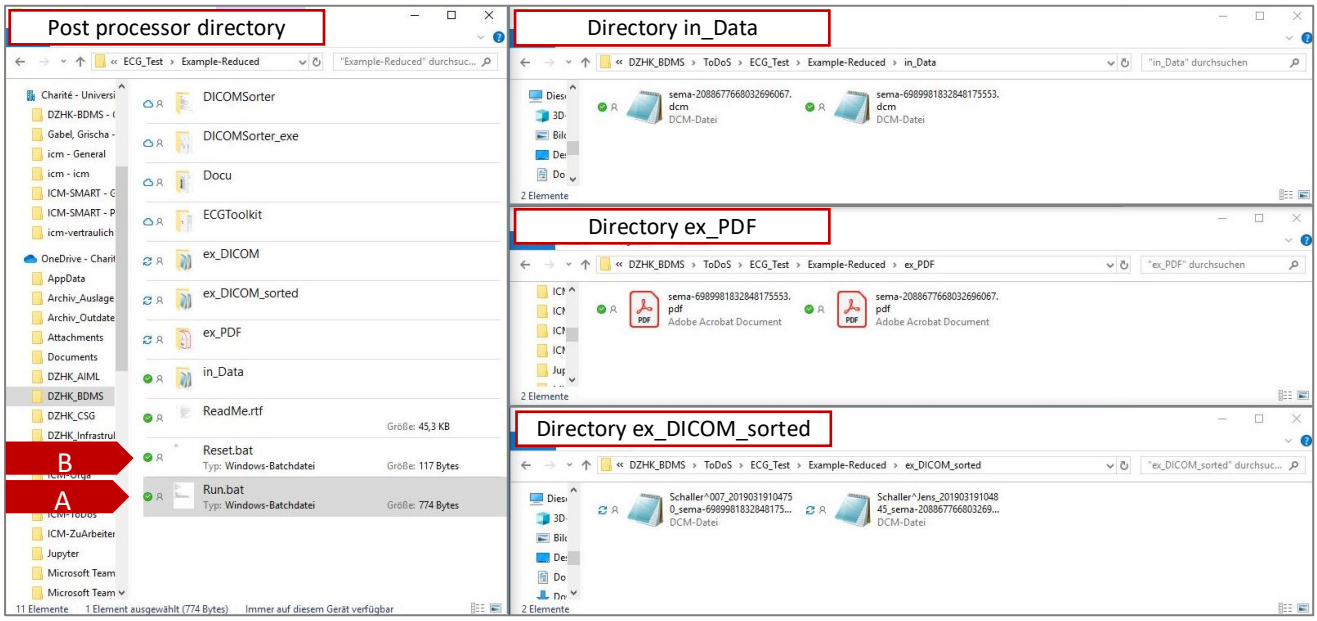


Figure 8: Directory structure of the DZHK ECG postprocessor. Start script A to start the conversion process and script B to delete the files in all export directories (ex_XXXXXXX). The data to be converted are copied to the Input directory in_Data before the start. After the conversion process, PDF files (D-ex_PDF directory) are generated to display the curves and associated DICOM files (D-ex_DICOM directory) are generated with prefixed annotations (structure: {LastName^FirstName}_{RecordingDateTime}_{originalFilename}.dcm).

3.5 DEALING WITH DEVIATIONS

Deviations should be documented in the comments/notes.

Criteria when an ECG must be shown to the study physician

(1) bradycardia with a heart rate below 40 bpm
(2) in case of electronic analysis: evidence of infarction, acute ischemia
(3) in case of acute symptoms/problems, always consult the study physician

Missing limbs, shortened limbs

If limbs are missing or shortened, the electrodes for the limb leads should be symmetrically placed closer to the trunk.

- ***Technical problems, suboptimal recording quality***
  - tremor
  - severe tremor due to coarse tremor of the left hand with electrode placement on the forearm → application of the limb electrodes close to the torso
  - coarse tremor of the ECG waveforms as a result of insufficient adhesion of the suction electrodes → elimination by reliable attachment of the electrodes
  - muscle tremor

- irregular oscillations of the recordings in trembling persons are due to muscle action currents → ensure that the person is not shivering due to cold or anxiety during the ECG recording, if necessary consider examination gown or thin blanket

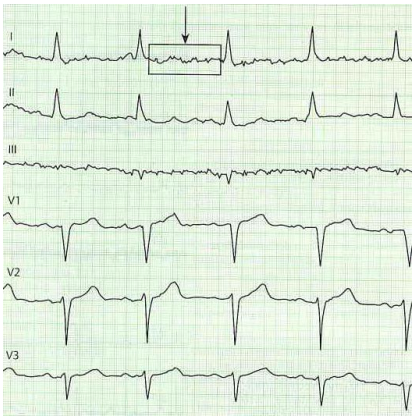


Figure 9: Muscle tremor in a patient with Parkinson's disease (Hamm, Willems 2007).

- ***Alternating current superimposition***

If the contact resistance between skin and electrodes is high, the electrocardiogram can be superimposed by alternating current artifacts. This interference is characterized by very regularly shaped small spikes corresponding to the alternating current frequency of 50 periods per second → Alternating current interference rarely persists after sufficient electrode spray is used. If necessary, the examination couch should be moved to a different position in the room.

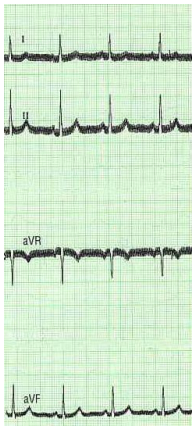


Figure 10: Alternating current interference (Hamm, Willems 2007).

- Abrupt jumps of the recording may be caused by defective contacts
- slow oscillations of the isoelectric line
- oscillations of the isoelectric may be caused by polarization of the electrodes through breathing motion or poor amplifier settings → adjustment of the amplifier

- ***Other sources of interference***
  - if breasts are particularly large, do not stick the electrodes underneath, but on top of the breast
  - make sure that the breasts are not displaced when measuring and marking with the thoracic angle, must be marked in a "natural lying position"
  - in case of dense hair growth "parting the hair" and increased suction is usually sufficient. If not, the hair must be shaved with consent of the participant
  - pay attention not only to the absolute interference level, but also ensure that the isoelectric line is not distorted in any of the 12 leads
  - critically observe whether one lead is worse than the others (alternating current or high interference level)
    - acute: Check the position of the electrode and re-attach it
    - in case of several ECGs succession: indicates defective electrodes → replace electrodes, cleaning bath
- alternating current interference in all leads: search for sources of electrical interference in the room (e.g. halogen lights, power supply units for laptop/PC, mobile phones), perhaps change the position of the examination couch in the room or use a different examination room, check grounding
- individual leads are not displayed and all electrodes are attached correctly/ not defective → check all connections between laptop/PC and the ECG device and suction system
- participant is absolutely unable to lie flat due to e.g. shortness of breath, dizziness or pain. In this case the ECG can also be performed even if the head is elevated to a sitting position
- very strong tremor, so that ECG can hardly be assessed → hold extremities during recording
- for persons who are extremely obese and for whom the examination couch is not wide enough → provide a chair to support the arms

In general

Special features are always noted in the commentary/notes

4 LITERATURE AND REFERENCES

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5 MODIFICATIONS

Modifications as compared to the previous version.

Section	Description of the modification as compared to the previous version
2.2	addition of the DZHK ECG tool to the devices/hardware
3.4.1	ECG evaluation: long-term → ECG
3.4.2	definition of the ECG data postprocessor and formats
7.3	FACT sheet DZHK ECG postprocessor

6 LIST OF CONTRIBUTORS

Name	Function	Contribution
PD Dr. Renate B. Schnabel	First author	Drafted the SOP
Dr. Clemens Scherer	Reviewer	Expert review
Dipl. Ing Jens Schaller	Author	ECG conversion
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Prof. Marcus Dörr	WG Data standardization	Scientific review
Prof. Frank Edelmann	WG Data standardization	Scientific review

Dr. Christoph Gertler	WG Data standardization	Scientific review
Prof. Stefan Kääb	WG Data standardization	Scientific review
Prof. Till Keller	WG Data standardization	Scientific review
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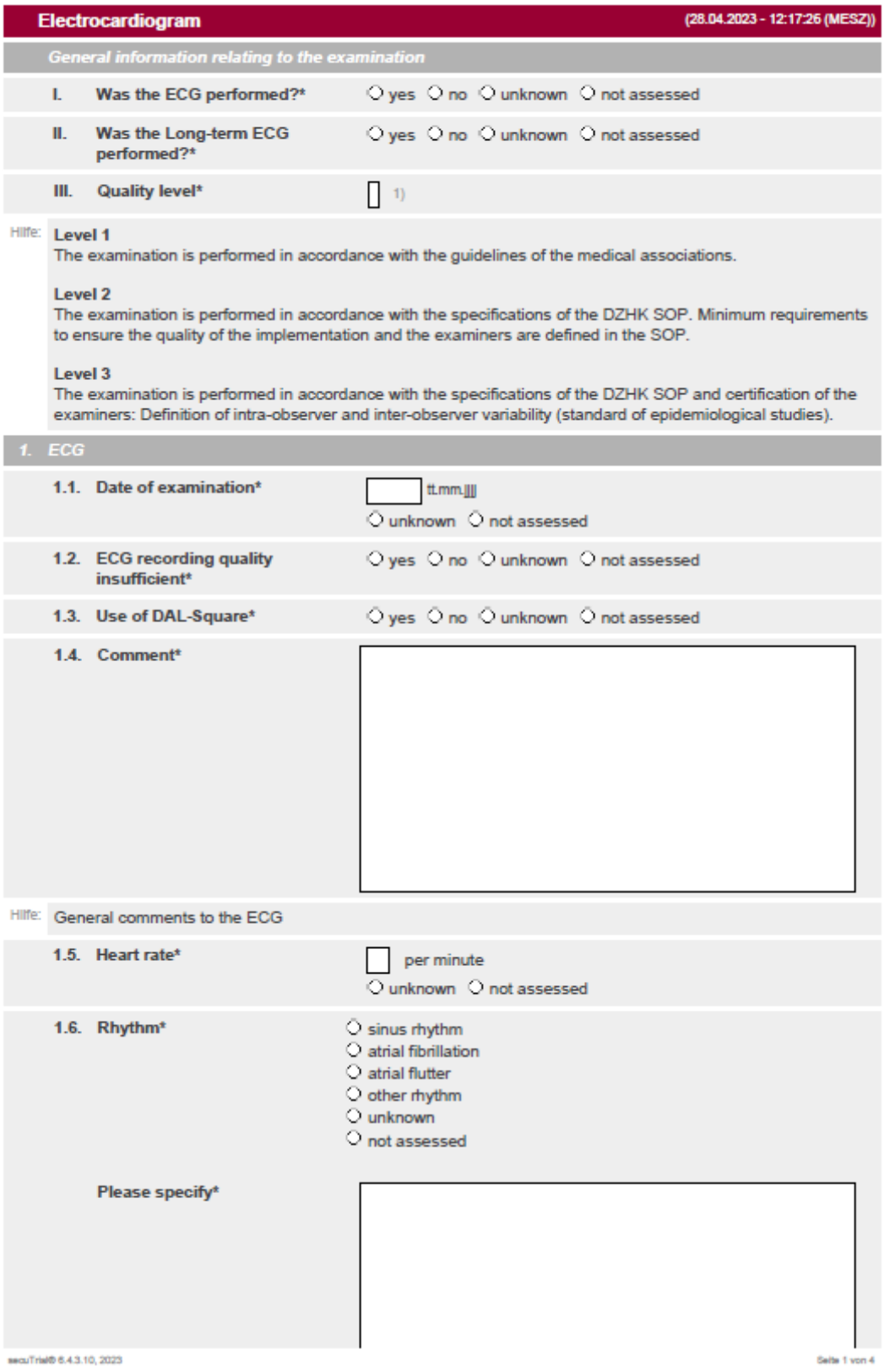
Dipl.-Inf. Sabine Hanß	WG Data standardization	IT implementation
Dr. Julia Hoffmann, Dr. Ilka Wilhelmi	WG Data standardization	Coordination

7 ANNEXES

7.1 LIST OF FIGURES

7.2 eCRF Module



Electrocardiogram (28.04.2023 - 12:17:26 (MESZ))

General information relating to the examination

I. **Was the ECG performed?*** ○ yes ○ no ○ unknown ○ not assessed

II. **Was the Long-term ECG performed?*** ○ yes ○ no ○ unknown ○ not assessed

III. **Quality level*** [ ] 1)

Hilfe: **Level 1**
The examination is performed in accordance with the guidelines of the medical associations.

Level 2
The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the examiners are defined in the SOP.

Level 3
The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

1. ECG

1.1. **Date of examination*** [ ] tt.mm.jjjj
○ unknown ○ not assessed

1.2. **ECG recording quality insufficient*** ○ yes ○ no ○ unknown ○ not assessed

1.3. **Use of DAL-Square*** ○ yes ○ no ○ unknown ○ not assessed

1.4. **Comment***

Hilfe: General comments to the ECG

1.5. **Heart rate*** [ ] per minute
○ unknown ○ not assessed

1.6. **Rhythm***
○ sinus rhythm
○ atrial fibrillation
○ atrial flutter
○ other rhythm
○ unknown
○ not assessed

Please specify*

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1.7.	**Pacemaker stimulation***	○ yes ○ no ○ unknown ○ not assessed
1.7.1.	**Atrial excitation following pacemaker stimulation***	○ yes ○ no ○ unknown ○ not assessed
1.7.2.	**Ventricular excitation following pacemaker stimulation***	○ yes ○ no ○ unknown ○ not assessed
1.7.3.	**Others***	○ yes ○ no ○ unknown ○ not assessed
1.7.4.	**Please specify***	

1.8.	**PQ time***	☐ ms ○ unknown ○ not assessed

Hilfe: Start: P leaves the isoelectric line. End: start of the Q-wave. In the absence of a Q-wave, the measurement ends at the beginning of the R-score. Measurement in lead II, otherwise in lead with optimal display.

1.9.	**QRS duration***	☐ ms ○ unknown ○ not assessed

Hilfe: Start: Q leaves the isoelectric line. End: S meets the isoelectric line. In the absence of a Q wave, measurement begins at the R wave upstroke. Measured in lead II, otherwise in lead with optimal display.

1.10.	**QT time***	☐ ms ○ unknown ○ not assessed

Hilfe: Begin: Q leaves the isoelectric line. End: T meets the isoelectric line. Measured in lead II, otherwise in lead with optimal display. QT time is the measured, not the corrected, QT time.

1.11.	**AV block***	○ yes ○ no ○ unknown ○ not assessed
1.11.1	**Degree***	○ I ○ II ○ III ○ unknown ○ not assessed

Hilfe: **1st degree**: PR time > 0.20 seconds

2nd degree: Includes type 1 (Wenckebach) and type 2 (Mobitz)
Type 1, Wenckebach: with each cycle, PR time prolongs until a QRS complex fails.
Type 2, Mobitz: intermittent failure of a QRS complex without prior increase in PQ time.

3rd degree: P waves appear independent of the QRS complexes, usually at a higher frequency than the ventricular escape rhythm.

1.12.	**Bundle branch block***	○ LBBB ○ RBBB ○ none ○ unknown ○ not assessed
	Please specify*	○ completed ○ incomplete ○ none ○ unknown ○ not assessed

Hilfe: **Left bundle branch block:**
Prolongation QRS complex to final negativity motion in V5 or V6 or left pre chest wall leads to ≥0.06 sec.
Incomplete: QRS width ≤0.12 sec.
Complete: QRS width >0.12 sec.

Right bundle branch block:
Prolongation QRS complex final negativity motion in >30 sec.
Incomplete: RSB morphology with QRS complex ≤0.12 sec.
Complete: QRS complex >0.12 sec., wide, notched R-waves in V1-V2, S-waves in V5-V6

1.13. Hemiblock* ○ LAH ○ LPH ○ none ○ unknown ○ not assessed

Hilfe: Left anterior hemiblock: over-rotated left type in chest wall leads, deep S-wave in V5-V6, QRS is not widened.
Left posterior hemiblock: right type to over-rotated right type.
In cases of atrial fibrillation or irregular rhythm on the ECG, the intervals are measured three times in total, each time during a different cycle. The mean value is entered.

1.14.	**Discordant negative T-waves***	○ yes ○ no ○ unknown ○ not assessed
1.14.1	**At least two of leads I, aVL, V6***	○ yes ○ no ○ unknown ○ not assessed
1.14.2	**At least two of leads II, III, aVF***	○ yes ○ no ○ unknown ○ not assessed
1.14.3	**At least two of leads V2, V3, V4, V5***	○ yes ○ no ○ unknown ○ not assessed
1.15.	**ST-segment pathological***	○ yes ○ no ○ unknown ○ not assessed
1.15.1	**At least two of leads I, aVL, V6***	○ yes ○ no ○ unknown ○ not assessed
1.15.2	**At least two of leads II, III, aVF***	○ yes ○ no ○ unknown ○ not assessed
1.15.3	**At least two of leads V2, V3, V4, V5***	○ yes ○ no ○ unknown ○ not assessed
1.15.4	**Others; please specify***	

Hilfe: Infarct typical (Measured at the J point in at least 2 adjacent leads ≥ 0.25 mV in men ≤ 40 years, ≥ 0.2 mV in men > 40 years, or ≥ 0.15 mV in women in leads v2-v3 or ≥ 0.1 in other leads in the absence of left bundle branch block).

1.16.	**Q waves as an indication of expired infarction***	○ yes ○ no ○ unknown ○ not assessed
1.16.1	**Q-wave in leads v2-v3 ≥ 0.02 sec or QS complex in leads v2 and v3***	○ yes ○ no ○ unknown ○ not assessed
1.16.2	**Q-wave ≥ 0.03 sec and ≥ 0.1 mV deep or QS complex in leads I, II, aVL, aVF or v4-v6 in at least 2 neighbouring leads (I, aVL; v1-v6; II, III, aVF)***	○ yes ○ no ○ unknown ○ not assessed

2. *Long-term ECG*

2.1. Date of examination* [ ] tt.mm.jjjj
○ unknown ○ not assessed

2.2. Recording duration* [ ] hh:mm
○ unknown ○ not assessed

2.3.	**Average heart rate***	☐ per minute ○ unknown ○ not assessed
2.4.	**Minimum heart rate***	☐ per minute ○ unknown ○ not assessed
2.5.	**Maximum heart rate***	☐ per minute ○ unknown ○ not assessed
2.6.	**Number of VES***	☐ ○ unknown ○ not assessed
2.7.	**Number of SVES***	☐ ○ unknown ○ not assessed

Hilfe: **VES:** Ventricular extrasystoles during the recording period
SVES: Supraventricular extrasystoles during the recording period

2.8.	**Duration of longest ventricular tachycardia***	☐ seconds ○ unknown ○ not assessed
2.9.	**Frequency of longest ventricular tachycardia***	☐ per minute ○ unknown ○ not assessed
2.10.	**Duration of fastest ventricular tachycardia***	☐ seconds ○ unknown ○ not assessed
2.11.	**Frequency of fastest ventricular tachycardia***	☐ per minute ○ unknown ○ not assessed
2.12.	**SDNN***	☐ ms ○ unknown ○ not assessed

Hilfe: Standard deviation of the NN intervals (to help RR intervals)

2.13.	**Pauses >3 seconds***	○ yes ○ no ○ unknown ○ not assessed
2.13.1	**Number of pauses >3 seconds***	☐ ○ unknown ○ not assessed
2.13.2	**Duration of longest pause >3 seconds***	☐ seconds ○ unknown ○ not assessed
2.13.3	**Time of the longest pause >3 seconds***	☐ hh:mm ○ unknown ○ not assessed

Mögliche Angaben

Bitte wählen Sie bei den oben mit Anmerkungen versehenen Feldern eine der hier aufgelisteten Angaben.

1)

1
2
3

7.3 FACT-SHEET DZHK-ECG-POSTPROCESSOR

The DZHK ECG postprocessor is based on the C#-ECG Toolkit by M.J.B. van Ettinger (https://sourceforge.net/projects/ecgtoolkit-cs/). The toolkit can convert various ECG formats (GE-MUSE-XML, ISHNE, OmronECG, SCP-ECG, DICOM-ECG, HL7-aECG) into the DICOM waveform ECG and is used in the DZHK ECG postprocessor.

Installation

The use of a Windows 64 bit system is required.

1. download the DZHK ECG postprocessor as a ZIP file from the service4studies page.

2. unpack into a directory of your choice

Performing the conversion/annotation

1. export the data from the ECG device to the input directory (in_Data - **Figure 11** top right).

Note: If necessary, rename the file name it that it consists only of letters and numbers and hyphens and underscores. (e.g. sema-221312332.dcm).

2. start the conversion/annotation process with the script run.bat (**Figure 11**- marked with A).

3. transfer of the annotated data (surname_first_name_date_time_original_filename.dcm) from the directory (ex_DICOM_sorted - Figure 11 bottom right) to the BDMS (DZHK-SOP-P-02).

4. emptying the input directory (in_Data - Figure 11 top right)

5. deletion of the export directories via the deletion script Reset.bat (**Figure 11** – marked with B)

Important: UNC paths (like \dataserver.MusterCenter.de\FolderXY) are not supported, please run the batch file Run and Reset from a drive folder (like C:\FolderXY).

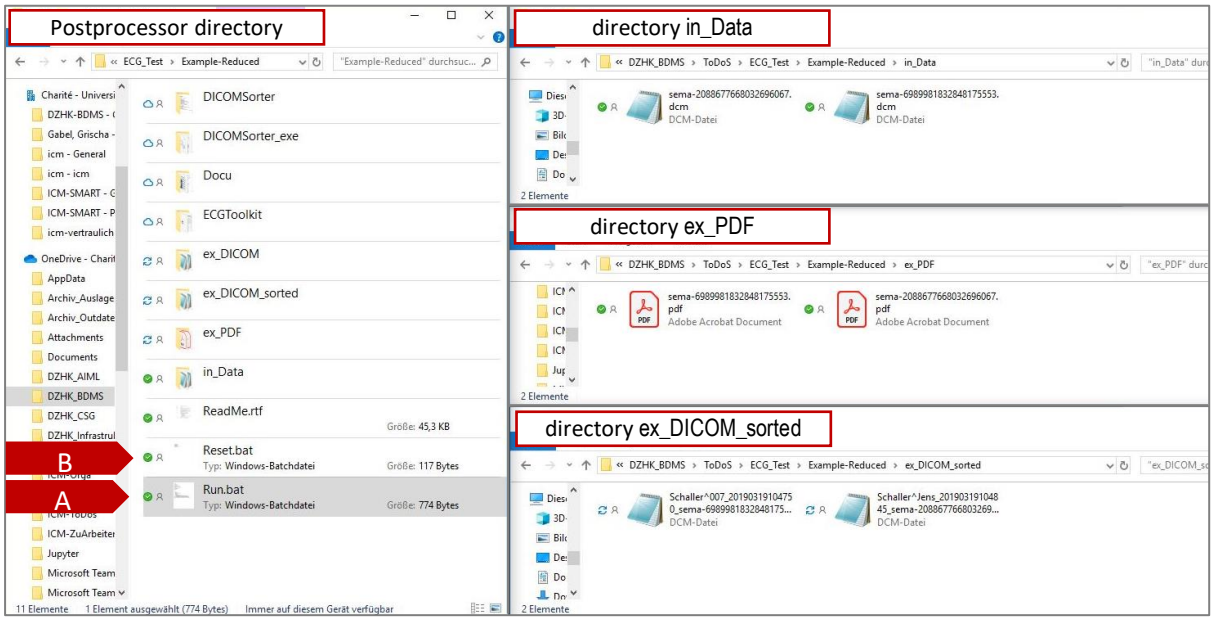

Figure 11: Directory structure of the DZHK ECG postprocessor with start script A for starting the conversion process and script B for deleting the files in all export directories (ex_XXXXXXX). The data to be converted are copied to the Input directory in_Data before the start and after the conversion process PDFs are generated to display the curves and DICOM files are generated with prefixed annotations (structure: lastname^firstname_recordingdatetime_originalfilename.dcm).